Royal Cornwall Hospitals
NHS Trust

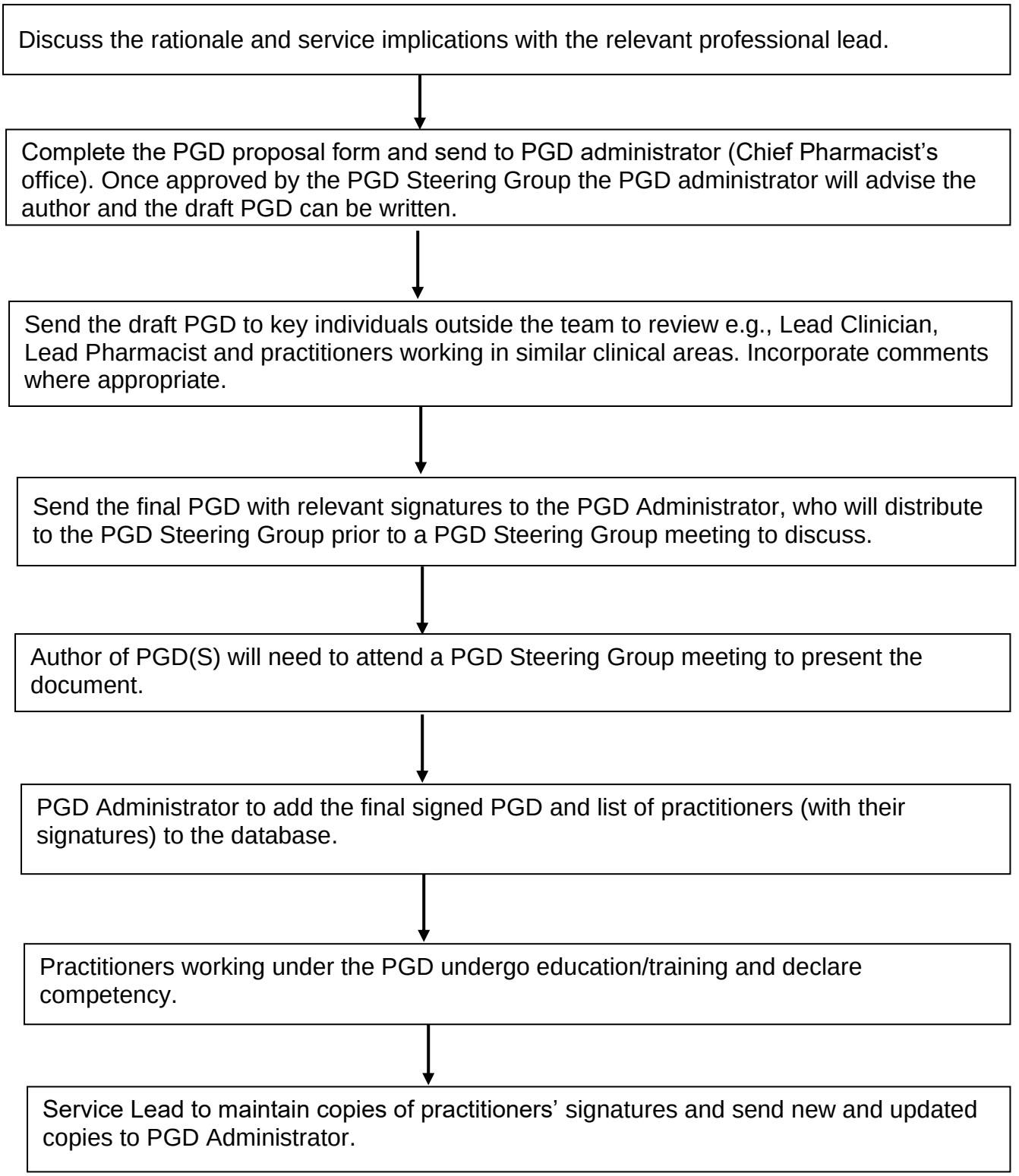
Developing, Implementing and Reviewing Patient Group Directions (PGDs) Policy

V6.0

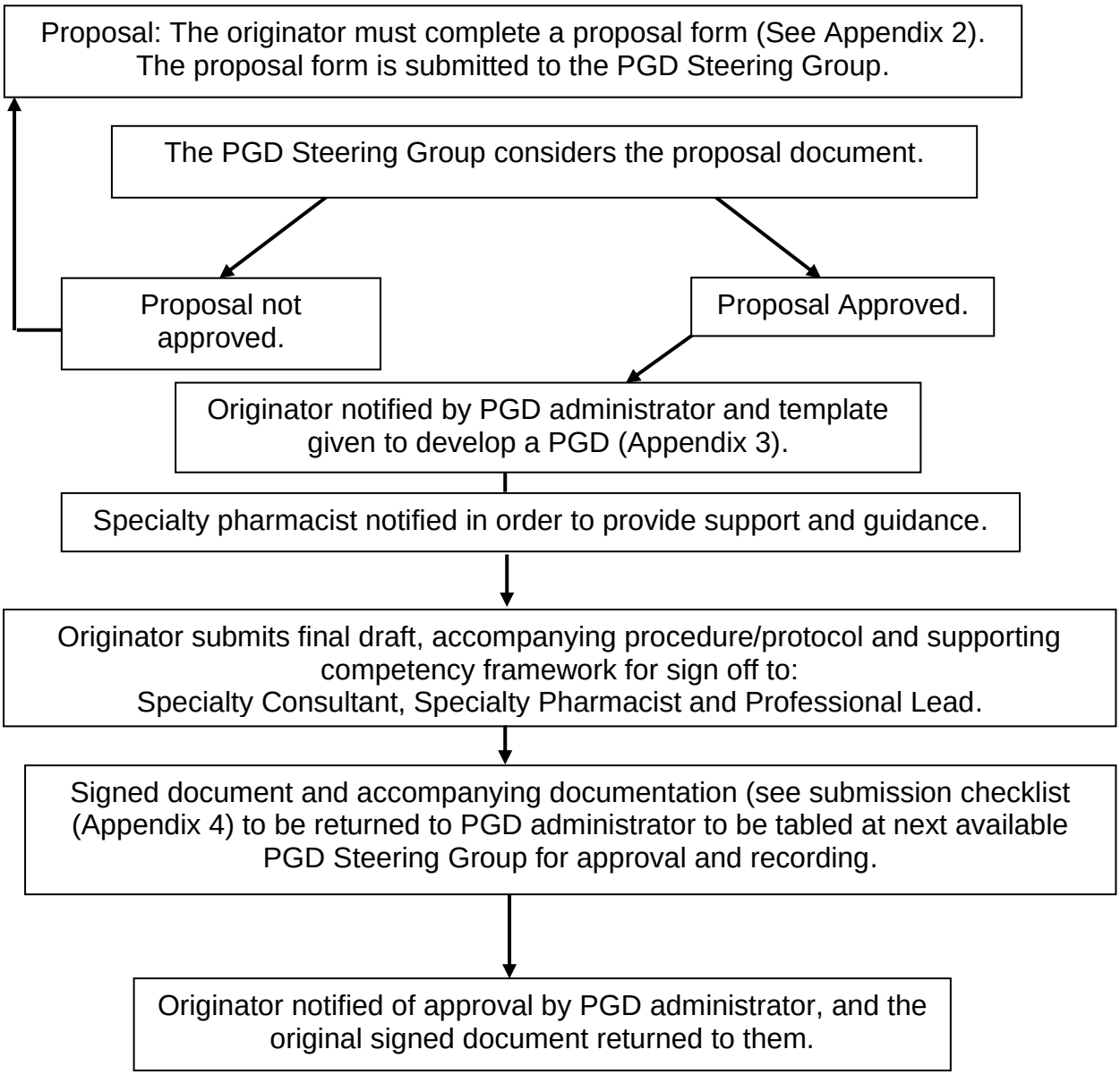
June 2025

Summary

Flowchart summarising PGD development:

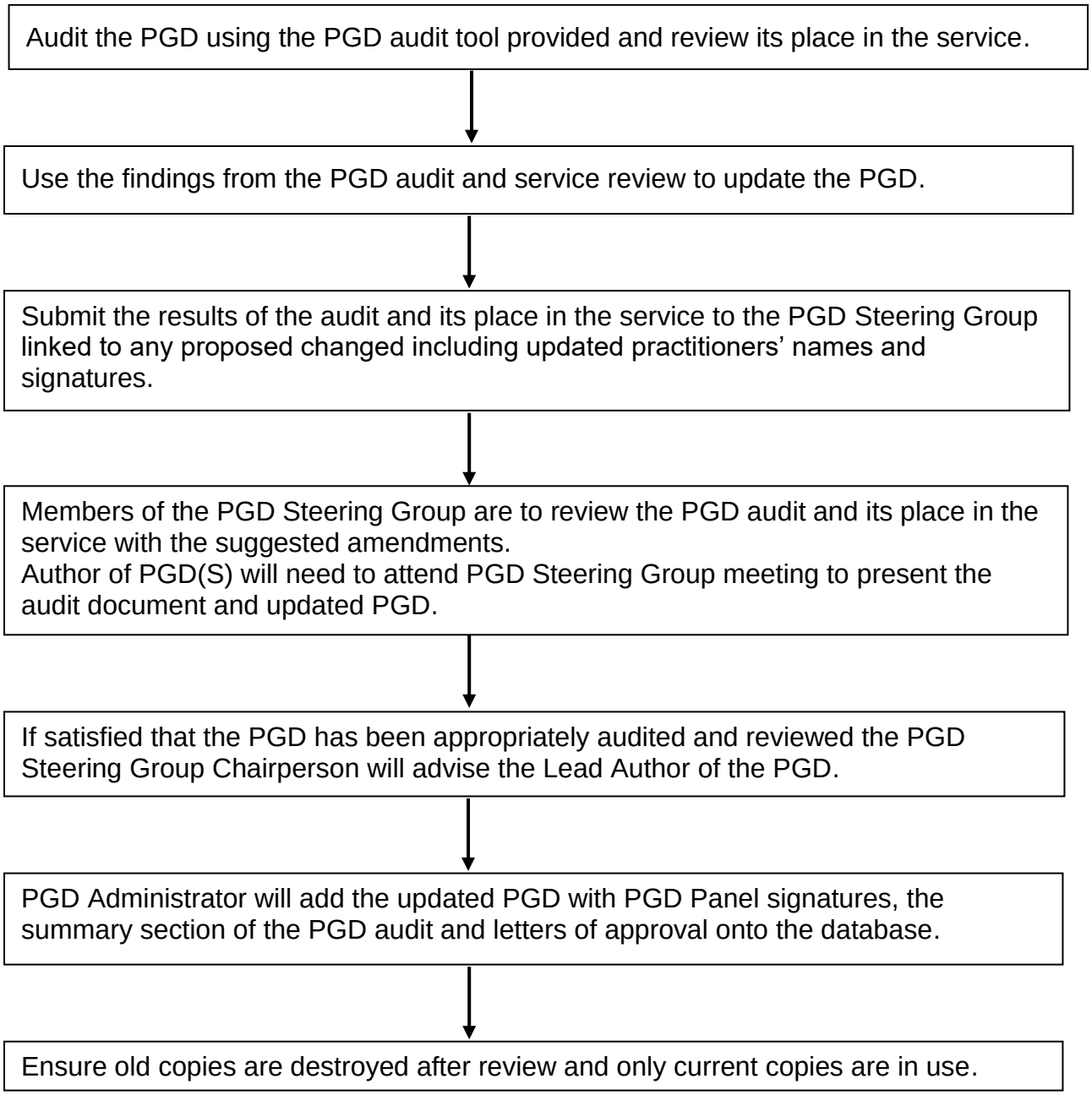


Ratification Process for PGDs



Flowchart summarising PGD review:

PGDs should be reviewed in in advance of their expiry date or sooner if problems are identified.



Flowchart summarising PGD Escalation:

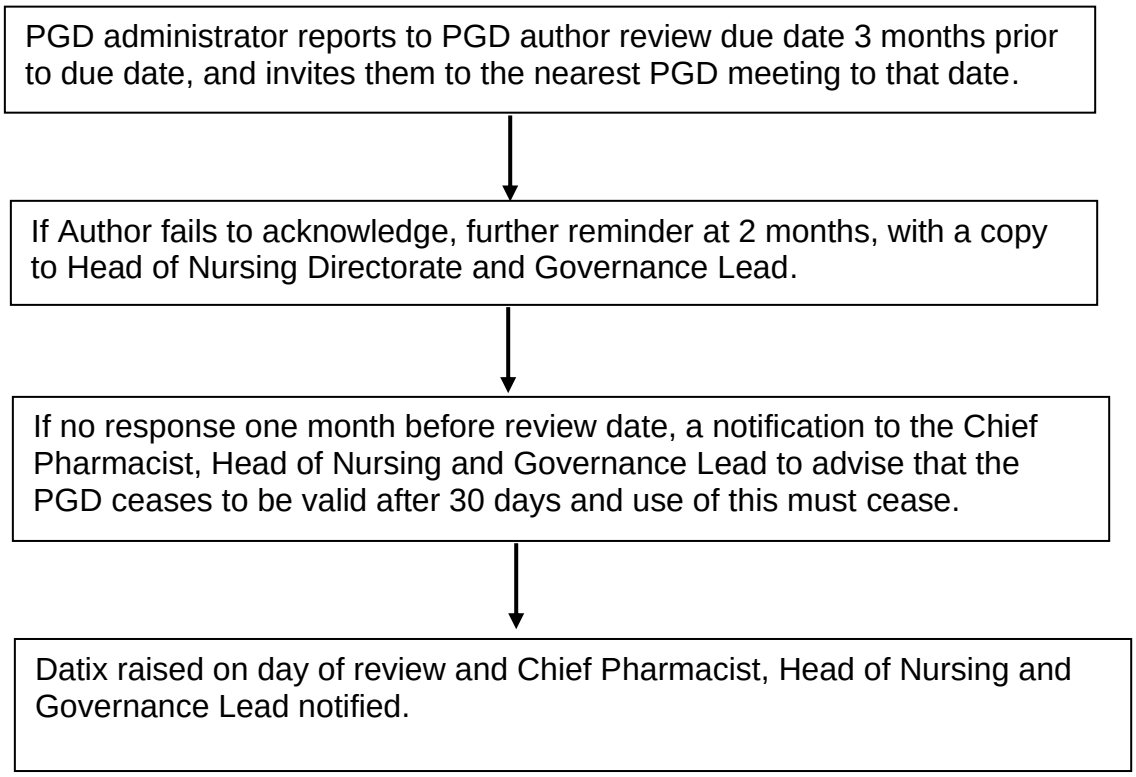


Table of Contents

Summary 2
1. Introduction 8
2. Purpose of this Policy/Procedure 8
3. Scope 8
4. Definitions / Glossary 11
5. Ownership and Responsibilities 11
5.1. Role of the PGD Steering Group 11
5.2. The Specialty Governance Groups are responsible for: 12
5.3. The Nominated/Professional Lead 12
5.4. Role of Line Managers 12
5.5. Role of Individual Staff 12
5.6. Role of the Chief Pharmacist 12
6. Standards and Practice 13
6.1. Guidance on the Appropriateness of a PGD 13
6.2. PGD Content 13
6.3. Expiry Date 14
6.4. Reviewing PGDs 14
6.5. Supply of Medicines 14
6.6. Documentation of Supply 15
6.7. Antimicrobials 15
6.8. Training, Competency and Sign-off 15
7. Dissemination and Implementation 16
8. Monitoring compliance and effectiveness 16
9. Updating and Review 17
10. Equality and Diversity 17
Appendix 1. Governance Information 18
Appendix 2. Equality Impact Assessment 21
Appendix 3. Patient Group Direction Proposal Form 24
Appendix 4. PGD template 25
Appendix 5. PGD Checklist 31
Appendix 6. Competency Assessment for Patient Group Directions 32
Appendix 7. PGD Audit Tool 36

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Patient Group Directions (PGDs) provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a prescriber.

1.2. A Patient Specific Directive (PSD) remains the preferred option for the majority of care. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without compromising patient safety, and there are clear governance arrangements and accountability.

1.3. This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

The purpose of this policy is to set out the arrangements for approval, implementation and review of PGDs and to outline the competencies, training and audit required within RCHT.

3. Scope

This document applies to all PGDs developed for use by registered healthcare practitioners under the jurisdiction of the Royal Cornwall Hospitals NHS Trust (RCHT). This document outlines the process to be followed within RCHT. It must be noted that a PGD is not an authorisation to prescribe. All activities within RCHT, which includes the supply and administration of medicines to patients under a Patient Group Direction must comply with the criteria as set out in this policy. The current legislation for PGDs is included in The Human Medicines Regulations 2012. Failure to comply with the criteria falls outside the law and could result in criminal prosecution. The PGD must be signed by a senior doctor (or if appropriate a dentist) and a senior pharmacist, both of whom should have been involved in developing the direction. The PGD must be authorised by the chairperson of the PGD Steering Group (Deputy Chief Nurse) or the Chief Medical Officer (in their capacity of Chair of the Medication Practice Committee).

3.1. **Medicines and healthcare products excluded from PGDs**

Legislation requires that the following must not be included in a PGD:

- Unlicensed medicines, including:
  - The mixing of 2 licensed medicines to form 1 new (unlicensed) product, unless 1 is a vehicle for administration, such as water for injection.
  - Special manufactured medicines.
- Dressings, appliances and devices.
- Radiopharmaceuticals.
- Abortifacients, such as mifepristone.

3.2. **Off Licence Use**

Medicines can be used outside the terms of their Summary of Products Characteristics (SPC) known as 'off licence' use (as opposed to unlicenced), provided such use is supported by best clinical practice, and the PGD must state when the product is being used outside the terms of the SPC and why this is necessary (DoH 2006). Patients should be informed that the product is being used outside of its licence and the reasons for this.

3.3. **Controlled drugs**

Only certain controlled drugs are legally eligible to be included in a PGD, in accordance with The Misuse of Drugs Regulations (2001); see table 1.

Table 1 Controlled drugs that may be considered for inclusion in a PGD

Schedule	**Controlled drugs that may be considered for inclusion in a PGD**	**Additional comments**
Schedule 2	Morphine. Diamorphine. Ketamine.	Use by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person (except for treating addiction).
Schedule 3	Midazolam.	Since reclassification to Schedule 3 CDs, tramadol, gabapentin and pregabalin may not be supplied under PGD.
Schedule 4	All drugs, including benzodiazepines.	Anabolic steroids and any injectable preparation used for treating addiction **must not** be included in a PGD.
Schedule 5	All drugs.	

3.4. **Existing Exemptions for the Supply of Medicines**

3.4.1. There are a number of distinct exemptions for the supply of medicines. A full list of exemptions is included in The Human Medicines Regulations 2012.

- A range of exemptions enable certain groups of health professionals, such as chiropodists and podiatrists, midwives, paramedics and optometrists, to sell, supply and administer particular medicines directly to patients.
- Occupational health schemes.
- Pandemic disease.

3.4.2. Other legal options for prescribing, supplying and/ or administering medicines are:

- The prescriber (a doctor, dentist or non-medical independent prescriber) takes responsibility for the clinical assessment of the patient, establishing a diagnosis, the clinical management needed and prescribing.
- Supplementary prescribing – a voluntary partnership between a doctor or dentist and a supplementary prescriber, to prescribe within an agreed patient-specific clinical management plan with the patient's agreement.
- Patient Specific Directions (PSDs) – written instructions, signed by a doctor, dentist, or nonmedical prescriber for a medicine to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. Writing a PSD is a form of prescribing.
- Parenteral medicines that can be administered in an emergency without the directions of a prescriber.
- Emergency supplies – in an emergency and under certain conditions, a pharmacist working in a registered pharmacy can supply a previously prescribed prescription-only medicine (POM) to a patient without a prescription, if requested by a prescriber or the patient.

3.4.3. These options provide RCHT with a range of alternatives to consider when making decisions about the safest and most appropriate way for patients to get the medicines they need.

3.5. **Permitted Professional Groups**

3.5.1. Legislation requires that PGDs must only be used by the following registered health professionals:

- Chiropodists and podiatrists.
- Dental hygienists.
- Dental therapists.
- Dietitians.
- Midwives.
- Nurses.
- Occupational therapists.
- Optometrists.
- Orthoptists.
- Orthotists and prosthetists.

- Paramedics.
- Pharmacists.
- Pharmacy technicians.
- Physiotherapists.
- Radiographers.
- Speech and language therapists.

3.5.2. Individual health professionals must be named and authorised to practice under a PGD.

3.5.3. The registered healthcare professional cannot delegate the administration/ supply of a medicine via a PGD to another member of staff e.g., a nurse cannot delegate the administration of a vaccine to a healthcare assistant when the instruction to supply is via a PGD.

4. Definitions / Glossary

4.1. **Patient Group Direction (PGD)**

A PGD is defined in Health Service Circular (HSC 2000/026) as:

'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.' This definition should not be interpreted as indicating that the patient should not be identified. Patients may or may not be known to the service. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.

4.2. **Patient Specific Directive (PSD)**

This is a prescription written by a prescriber for a named patient.

5. Ownership and Responsibilities

All professional practitioners have a duty of care which cannot be delegated at any time.

5.1. Role of the PGD Steering Group

All proposals for PGDs must be submitted to the PGD Steering Group for approval. The approval of the final document (represented by a signature from the chairperson) demonstrates the process has been followed and Trust Board level agreement (which supplements the senior clinician approval within the speciality) for the document to be used in clinical practice.

5.2. **The Specialty Governance Groups are responsible for:**

- Ensuring PGDs are used appropriately in their speciality.
- Assurance that staff are appropriately trained and signed off.
- Ensuring that PGDs are in date and that expired PGDs are no longer in use.

5.3. **The Nominated/Professional Lead**

- Is responsible for managing the PGD process from development to audit and review, this includes ensuring the PGD process outlined within this document is adhered to at all times. Those involved in the developmental stages of the PGD must ensure it is appropriate and safe clinical use.
- Is responsible for ensuring all staff operating under the PGD understands their responsibilities and that appropriate training is available. Each practitioner who is operating under the PGD must ensure they have received sufficient training and are competent to do so.

5.4. **Role of Line Managers**

Line managers are responsible for:

- Ensuring that all PGDs used in their clinical area have been appropriately signed off by the Trust and are in date.
- Ensuring appropriate training is available and provided.
- Ensuring that only competent registered healthcare professionals provide care under a PGD.

5.5. **Role of Individual Staff**

- Each practitioner who is operating under the PGD must ensure they have received sufficient training and are competent to do so.

5.6. **Role of the Chief Pharmacist**

- The chief pharmacist is responsible for ensuring a log of all PGDs in use within the Trust is maintained, including their review dates and a copy of the original signed PGD.
- The chief pharmacist ensures reminders are sent to specialities regarding the review of PGD’s and will communicate when a PGD has expired and needs to be withdrawn from use.

6. Standards and Practice

6.1. Guidance on the Appropriateness of a PGD

6.1.1. The PGD Steering Group will base its approval process on the NICE Guidance Development Group (GDG) recommendations stated below.

6.1.2. PGDs may be appropriate when:

- Medicine use follows a predictable pattern, such as for people attending for contraception.
- Patients seek unscheduled care, such as for a minor ailment in a community pharmacy or walk-in centre.
- Supplying or administering a medicine for a discrete treatment episode, such as emergency contraception.
- There is a homogenous patient group, such as at-risk groups of patients needing immunisation.

6.1.3. Alternatives to PGDs should be used when:

- Managing long-term conditions, such as hypertension or diabetes.
- Uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example erectile dysfunction.
- The medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example anticoagulants or insulin.

6.2. PGD Content

Legislation requires that each PGD must contain the following information:

- The period during which the direction is to have effect.
- The description or class of medicinal product to which the direction relates.
- The clinical situations which medicinal products of that description or class may be used to treat or manage in any form.
- Whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions.
- The clinical criteria under which a person is to be eligible for treatment.
- Whether any class of person is excluded from treatment under the direction and, if so, what class of person.
- Whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances.

- The pharmaceutical form or forms in which medicinal products of that description or class are to be administered.
- The strength, or maximum strength, at which medicinal products of that description or class are to be administered.
- The applicable dosage or maximum dosage.
- The route of administration.
- The frequency of administration.
- Any minimum or maximum period of administration applicable to medicinal products of that description or class.
- Whether there are any relevant warnings to note and, if so, what warnings.
- Whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances.
- Arrangements for referral for medical advice.
- Details of the records to be kept of the supply, or the administration, of products under the direction.

RCHT uses a template to ensure all this information is captured (see appendix 3)

6.3. **Expiry Date**

- The expiry date on a PGD must be no longer than 3 years after the approval date. If it is still required following that date, the PGD must be reviewed and re-approved for use before it expires.
- **After the expiry date the PGD is not valid and medicines must not be supplied or administered on the authority of an expired PGD.**

6.4. **Reviewing PGDs**

- Should there be any changes in practice during the life of an approved PGD, the PGD must be amended accordingly and submitted for re-approval.
- The responsibility for initiating this process rests with the Speciality using the PGD.
- Reviewed documents undergo the same ratification process.

6.5. **Supply of Medicines**

- All medicines supplied via a PGD must be labelled.
- Ensure that the patient receives a manufacturer's patient information leaflet with each medicine.

- Wherever possible medicines should be supplied in pre-packs.

- Identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription charges. The appropriate prescription charge(s) should be collected from patients who are not exempt.

- There should be a system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and outgoing stock on a patient-by-patient basis. Names of the healthcare professionals providing treatment, patient identifiers and medicines provided should all be recorded.

6.6. **Documentation of Supply**

Document the following information about the clinical assessment and supply and/or administration of the medicine(s):

- Date and time of supply and/or administration.

- Patient details, such as name, date of birth, allergies, previous adverse events and, how the patient met the criteria of the PGD.

- Details of medicine, such as name, strength, dose, frequency, quantity, route and, site (if by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance).

- A statement that supply or administration is by using a PGD.

- Name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine.

- Relevant information that was provided to the patient or their carer.

- Whether patient consent to treatment was obtained.

6.7. **Antimicrobials**

- An RCHT microbiologist must sign off any PGD involving antimicrobials to ensure the PGD reflects local policy.

6.8. **Training, Competency and Sign-off**

- Practitioners operating under a PGD are bound by their Professional Code of Conduct to act within their competence area of expertise.

- ‘PGDs (see definition) require the practitioner to self-declare their competency. For the practitioner to self-declare competence they must have:

    - Read and understood the Trust PGD policy.

    - Read and understood the PGD in question.

    - Had any queries resolved.

- Confirm the PGD is within their area of expertise.
- Completed their professional annual fitness to practice process or equivalent.
- Complete competency framework (appendix 6) including Patient Group Directions elearning package on ESR .

- Each clinical area must hold a record of those practitioners competent to practice under each PGD and a copy of the PGD for easy reference. The record must be reviewed and updated on an annual basis.

7. Dissemination and Implementation

7.1. The document will be available on the Document Library. Significant updates will be communicated via Trust-wide email.

7.2. Implementation of this policy will be via Trust-wide communication and supported by appropriate training for the relevant members of staff.

7.3. Training for this policy will relate directly to the approved PGDs and training will be provided locally by the Clinical Lead.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	1. In-date PGDs that are in use. 2. Competency sign-off. 3. Patient records.
Lead	1. Currency of PGDs- PGD Steering Group. 2. Competency sign off- Specialty/ clinical lead. 3. Patient records- specialty governance.
Tool	1. Currency of PGDs- PGD log held by the chief pharmacist. 2. Competency sign off- Specialty/ clinical lead records. 3. Patient records- specialty governance audit tool.
Frequency	1. Currency of PGDs- annual review. 2. Competency sign off- annual review. 3. Patient records- every 3 years.
Reporting arrangements	Audits of practice to be submitted to the PGD Steering Group.
Acting on recommendations and Lead(s)	The PGD Steering Group will lead on recommendations.

Information Category	Detail of process and methodology for monitoring compliance
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within the timeframe set out in the action plan. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all relevant stakeholders.

9. Updating and Review

9.1. This policy will be reviewed no less than every three years or sooner in the light of changes to legislation or practice.

9.2. The policy review will be ratified by the PGD Steering Group.

9.3. Any revision activity will be recorded on the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Developing, Implementing and Reviewing Patient Group Directions (PGDs) Policy V6.0
This document replaces (exact title of previous version):	Developing, Implementing and Reviewing Patient Group Directions (PGDs) Policy V5.0
Date Issued/Approved:	Friday 6 June
Date Valid From:	June 2025
Date Valid To:	June 2028
Directorate / Department responsible (author/owner):	Iain Davidson, Chief Pharmacist
Contact details:	01872-252593
Brief summary of contents:	Outlines the RCHT process for Developing, Implementing and Reviewing Patient Group Directions (PGDs).
Suggested Keywords:	Patient Group Directions, PGD, PGDs, Patient specific directive, PSD.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Director of Nursing, Midwifery and Allied Health Professionals
Approval route for consultation and ratification:	PGD Steering Group. Medication Practice Committee. Clinical Support Board.
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	CQC Medicines Management- Outcome 9.

Information Category	Detailed Information
Related Documents:	NICE Good Practice Guidance August 2013 (updated March 2017). NICE Competency framework: For health professionals using Patient Group Directions- January 2014. The Human Medicines Regulations 2012. NMC Code of Conduct, Performance and Ethics. HPC Standards of Performance, Conduct and Ethics. RCHT Patient Identification Policy. RCHT Consent to Treatment/Examination. RCHT Standards of Record Keeping. RCHT The Medicines Policy Reference and Associated documents.
Training Need Identified?	Yes- Learning and Development department have been informed.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
06.03.09	V1.0	Approved and document published	Sandra Arnold, Lead Nurse Practice Development
05.03.12	V2.0	Review with minor amendments	Iain Davidson, Chief Pharmacist
01.12.14	V3.0	Major review to incorporate NICE guidance changes	Iain Davidson, (Chief Pharmacist). Fraser Underwood, (Associate director of Nursing)
14.08.18	V4.0	Review with minor amendments to incorporate the new PGD Steering Group responsibilities.	Claire Martin (Deputy Chief Nurse)

Date	Version Number	Summary of Changes	Changes Made by
17.02.22	V5.0	Audit tool review and removal of stock recording requirement. Flowchart updated. Reminders now sent to Hon and governance Leads.	Helen McClay (Deputy Chief Pharmacist)
20.05.25	V6.0	Merged complex/simple PGD requirements (appendix 6) into one requirement. Update audit tool in line with NICE guidance. Updated CD list (table) to reflect current schedules. Updated training requirements. Included pharmacy technicians under professionals who can work under PGDs.	Helen McClay (Deputy Chief Pharmacist)

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity & Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Developing, Implementing and Reviewing Patient Group Directions (PGDs) Policy V6.0
Directorate and service area:	Applicable across the Trust, but written by pharmacy.
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Helen McClay, Deputy Chief Pharmacist
Contact details:	01872 255997

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Aimed at registered healthcare professionals and service leads.
2. Policy Objectives	To ensure patient group directions are developed and used in line with the law and best practice guidance.
3. Policy Intended Outcomes	Safe patient care and improved access to medicines.
4. How will you measure each outcome?	Audit and incident reporting.
5. Who is intended to benefit from the policy?	Patients.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** PGD Steering Group. Medication Practice Committee. Clinical Support Board.
6c. What was the outcome of the consultation?	Changes made as per the version control table.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** Staff.

7. The Impact
Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Helen McClay, Deputy Chief Pharmacist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Patient Group Direction Proposal Form

This form must be completed and submitted to the PGD Steering Group Committee for approval before a full Patient Group Direction (PGD) is developed.

Name of Medication to be supplied/administered under PGD		
Name of proposed originator/author		
Names of speciality leads:	**Lead Consultant**	
	Lead Professional	
	Lead Pharmacist	
Current service provision and case of needs for patient group direction:		
Benefits to patient care of this being delivered by a PGD:		
Name of Healthcare professional who will be contributing to the PGD		
Name	**Job Title**	
Statement of Support from Clinical Nurse Manager/ Professional Lead/ Divisional Nurse Manager:		
Printed Name: **Signature:** **Date:**		
Proposed Originator/ Author Signature: **Date:**		

PGD Steering Group Committee use Only		
Proposal approved	**YES**	**NO - Proposal needs further amendment:**

Chairperson	Job Title
Signed:	Date:

Appendix 4. PGD template

PATIENT GROUP DIRECTION (PGD)

REF NO:	Unique identification number allocated on approval	VERSION:	Number e.g., 01, 02
DATE OF FINAL VERSION	Date sent to PGD Steering Group	**SHEET:**	Page X of Y
ORGANISATION	Royal Cornwall Hospitals NHS NHS Trust	**REVIEW DATE**	**Date of final version plus 3 years**
AUTHOR:	**Name of author**		
NAME OF MEDICINE (S)	Name of drug to be supplied/administered		

1. Clinical condition	
Indication of situation/condition	A clear and unambiguous definition of the clinical condition/ situation where the drug is to be used.
Relevant National Guidance	Current BNF. Current edition of the Cornwall and isles of Scilly Joint Formulary. Any NICE or professional guidance.
Criteria for inclusion	Description of the clinical criteria under which a patient is eligible for treatment. E.g., Adults who have consented to treatment/ procedure.
Criteria for patient exclusion	Description of criteria for excluding patients from under treatment under a PGD e.g., Children under a certain age, those who do not consent, hypersensitivity.
Cautions/ Need for further advice	Details of where the practitioner may need to seek further clarification e.g., Renal impairments.
Action if patient excluded	What should the practitioner do if the patient cannot be cared for under PGD.
Action if patient declines	What action should be taken when patient does not provide consent.
Additional Action to be taken	For example, discussion with pharmacist, documentation.

2. Characteristics of Health Care Professionals	
Class of Healthcare professional for whom PGD is applicable and qualifications	The titles of professional groups and details of qualification required to administer under this PGD. E.g., Registered Radiographer or Nurse holding entry degree or diploma qualification.
Specialist competencies or qualifications considered relevant to the medicines used in the direction. **Competencies required:**	Specialist qualifications, training, experience and competence considered necessary and relevant to the clinical condition to be treated. Competences relevant to the PGD, e.g., Intravenous drug administration, IR (ME)R referrer. Able to provide evidence of education, competency and practice in the administration of drugs as evidence by successful completion of the RCHT drug administration training (modules 1 and 2) on ESR. Successful completion of RCHT PGD training package on ESR.
Continuing training and education	The responsibility for continuing education lies with the individual practitioner. It might be that the practitioner is requested to attend a yearly update.

3. Description of treatment	
Name and Form of Medicine **E.g., tablets**	Exact pharmaceutical name and form it is administered in i.e., Paracetamol 500mg Tablet
Legal status Prescription Only Medicine (POM) / General Sales List (GSL), Pharmacy Only (PO)	The legal status of the drug- check against the BNF as this may vary depending upon quantity.
Licensed / Unlicensed / Off-licensed **(State rationale for un/off-licensed use)**	Licensed for clinical use under the criteria of the PGD or off licensed.
Dose/s (where range is applicable include criteria for deciding on a dose)	Doses must be clearly stated and written for all patient groups i.e. If adults and children within inclusion criteria dose for each must be written.
Route/Method of Administration	Intravenous/ intramuscular/ oral / topical etc
Frequency of Administration	How often is the medication taken, One-off, four hourly, once per 24 hours
Total dose/number of times treatment can be administered over what time.	Check with pharmacy, this must be written clearly and in full e.g., 500mg taken every 4–6 hours to a maximum of 4.0grams daily- 32 tablets only

Maximum quantity that can be supplied (if applicable)	
Side Effects of drugs (to include potential adverse reactions) and any monitoring required	List the common side effects associated with the drug. Where there are side-effects which are only likely to occur outside of the criteria within this PGD, the speciality pharmacist must advise on appropriate content.
Procedure for reporting Adverse Drug Reactions (ADR)	Trust Procedure. The event is recorded on Datix and the yellow card completed before sending to pharmacy.
Special consideration for patients receiving concurrent medication	Is the dose modified? Warn of potential effects on other medications.
Information on follow-up treatment if needed	What should the patient be informed of? Make an appointment to see GP; you'll get the results via the GP in X number of days.
Written / verbal advice for patient / carer before / after treatment. Product information leaflet should be given to the patient / carer	Advice that must be given with the supply or administration of the drug, e.g., avoid other products containing paracetamol.
Method of recording supply / administration, names of HCP, patient identifiers, sufficient to enable audit trail.	Where will the episode and PGD be documented, this must include a clear audit trail. Document medication on EPMA system. Document the following in the patient's medical notes: Name of drug. Dose administered/supplied. Date of administration/supply. Time of administration. That the medicine was administered (or supplied as appropriate) under a PGD. Name (printed) and signature of nurse/practitioner. All administrations must be signed by the administering practitioner working under PGD.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by

4. Management and Monitoring	
Name of PGD owner	Name of originator/ author
Name of Clinical Nurse Manager/ Divisional Nurse Manager / Professional Lead who has authorised the PGD	Place name here
Names of individuals involved in drawing up the PGD	List all practitioners who have been consulted with in the development/ review of the PGD.
Date of PGD review	**As page 1**

The above document has my final approval	
Chairperson of PGD Steering Group	Name: Signature: Date:
Chairperson Medication Practice Committee	Name: Signature: Date:

The above document has my approval	
Lead Consultant	Name: Position: Signature: Date:
PGD Lead in Ward/Unit	Name: Position: Signature: Date:
Consultant Microbiologist (only if PGD antibiotics supply or administration of an antimicrobial)	Name: Position Signature: Date:
Speciality Pharmacist	Name: Position: Signature: Date:
The above document has my approval	
CD Accountable Officer **(only if PGD medication is a controlled drug)**	Name: Signature: Date:

REF NO:	Unique Identification number allocated on approval	**VERSION**	Version Number e.g., 01.02
DATE OF FINAL VERSION	Date sent to PGD Steering Group	**SHEET:**	Page X of Y
ORGANISATION	Royal Cornwall Hospitals NHS NHS Trust	**REVIEW DATE**	
AUTHOR:	Name of author	**DEPARTMENT**	

Notes to PGD owners: This is a list of all those who are competent and have agreed to act within the parameters of the above PGD. It does not remove inherent responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of professional Conduct.

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

NAME OF PROFESSIONAL	SIGNATURE	AUTHORISING MANAGER	DATE

Appendix 5. PGD Checklist

Submission Checklist.

Author, please complete and attach this document to each patient group direction being submitted to the PGD Steering Group.

Check your submission contains the following information.

	Tick
Original proposal form approved by the PGD Steering Group or previous PGD if review	
Completed PGD with reference and speciality signatures	
Supporting procedure/protocol included	
All relevant practitioners have been consulted with and all names are listed within PGD	
Competency framework which reflects Trust policy and clinical situation	

Please detail how the use of PGDs will be audited within clinical areas:

Who will be responsible for monitoring the use of this PGD?

Should this submission be successful, what is the proposed date of first audit?

Signed: Job Title: Date:

PGD Steering Group use Only	
Date submission received by committee:	
Has the PGD process for development or review been followed?	
Does the training plan meet national and local requirements?	
All speciality signatures present?	
Policy approved without further comment	
Policy needs further amendment (please give comments)	

Chairperson of PGD Steering Group (Deputy Chief Nurse):

Signed:

Date:

Appendix 6. Competency Assessment for Patient Group Directions

PDG Title:	**PGD Reference No:**		
Supply or Administration of Medicines under a Patient Group Direction (PGD)	**Initial Sign off Date:**	**Annual review Date:**	**Annual review Date:**
Professional Standards			
Understand the responsibilities and legal implications when working with PGDs.			
Understands the scope of PGDs in relation to clinical setting.			
Understand Trust policy related to medicines management and PGDs, and how this is met within clinical area.			
Understands current medicines legislation and professional code of practice, and how this applies to PGDs in clinical practice.			
Understands Trust policy for managing medicines, including unexpected reactions.			
Understands the consent process in relation to PGDs.			
Is aware of how to report necessary changes to PGDs.			
Understands method and standard of documentation when recording PGD activity.			
Clinical and Pharmaceutical Knowledge			
Understands the medical conditions being treated and assesses patient appropriately.			
Demonstrates knowledge of disease management and understands the role of the medicine stated within the PGD.			
Has an up-to-date knowledge of the drug, including:			
Indications, cautions and contraindications.			
Mode of action and the effect of the body on the drug (pharmacokinetics).			
Unwanted effects.			
Drug interaction.			
License, supply and monitoring.			
Public health issues (if antimicrobial).			

Supply or Administration of Medicines under a Patient Group Direction (PGD)	**Initial Sign off** **Date:**	**Annual review** **Date:**	**Annual review** **Date:**
Appreciates potential misuse of the drug.			
Is aware of own limitations and how to seek further advice regarding medications and patient group.			

Supply or Administration of Medicines under a Patient Group Direction (PGD)	**Initial Sign off Date:**	**Annual review Date:**	**Annual review Date:**
Consultation and Communication Skills			
Identifies patient in accordance to RCHT policy.			
Takes appropriate medical history, including physical examination where appropriate) to obtain an holistic assessment.			
Listens to and understands patients' beliefs and expectations, dealing sensitively with patients' emotions and concerns.			
Adapts the consultation to meet the needs of different patients (e.g., for age, level of understanding, religious/cultural needs).			
Requests and interprets relevant diagnostic tests to obtain a diagnosis.			
Explains the nature of the patient's condition and the rationale behind, and potential risks and benefits of treatment options (including no treatment, non-drug alternatives and drug treatment).			
Creates a relationship which does not encourage the expectation that a medicine will be supplied and / or administered.			
Undertakes a valid consent process, helping the patient to make informed choices about their options to reach an outcome both parties are satisfied with the outcome.			
Encourages patients to take responsibility for their own health and self-manage their conditions.			
Identifies opportunities to discuss health promotion with patients.			
Gives clear instructions to the patient about their medication (e.g., what it is for, how to take it, possible side effects and expected outcomes).			
Checks patients' understanding of, and commitment to, their treatment.			
A**dministration / Supply in Accordance with PGD**			
Checks expiry date and integrity of the product.			
Checks doses and calculations to ensure accuracy and safety.			
Checks the product is labelled with directions.			

Supply or Administration of Medicines under a Patient Group Direction (PGD)	**Initial Sign off Date:**	**Annual review Date:**	**Annual review Date:**
Practitioner must have documented evidence of ongoing clinical competence to prepare, administer and monitor via this route e.g., IV drug competency.			
Documentation and Record Keeping			
Completes and accurate record of care episode as per Trust Standards of Record Keeping.			
Completes Audit trail for PGD.			

Competency Sign-off for PGDs:		**Date**	**Initials**
1.	Read and understood the PGD policy.		
2.	Read and understood the PGD in question.		
3.	Had any queries resolved.		
4.	Completed the professional annual fitness to practice process or equivalent.		
5.	Confirm the PGD is within their area of expertise.		
6.	Completed the PGD eLearning package on Electronic staff record (ESR).		

The signed record of the PGD and the training record should be retained by the service lead as proof of training and competence. This sign-off should be reviewed annually.

I, the undersigned have read and understood this Patient Group Direction and agree to work within its confines. I have received the training needed to implement it effectively.

Name of professional ……..

Title of professional ……...

Signature of Professional …….

Date……

Appendix 7. PGD Audit Tool

RCHT Patient Group Directions (PGD) Audit Tool	
<Area or PGD(s)>	
In accordance with the RCHT Patient Group Direction (PGD) Procedure an audit must be carried out before revalidation of PGD(s). This is required to demonstrate compliance with the PGD(s) and to ensure that the requirements of the service are met. Use the audit tool to review if the PGD is being used appropriately and use the questions at the end to help review if the PGD is still the most appropriate method of delivering the service. The person responsible for authorising staff to work under the PGD is responsible for ensuring that the audit is undertaken. The Lead Author must review the audit data and if required amend the PGD as part of the review. The audit data must be submitted to the PGD for assurance.	
Name of practitioner responsible for authorising staff:	
Designation:	
Name of lead author:	
Designation:	
Date of audit:	

Question	Tick as appropriate		If 'no', state action required
	Yes	No	
Are all the people who approved the PGD(s) still in post?			
Do the managers listed on the PGD(s) hold a current list of authorised staff?			
Are you confident that all medicines supplied or administered under the PGD(s) are stored according to the PGD(s) where this is specified?			
Does the staff working under the PGD(s) have a copy available for reference at the time of consultation?			

Where the medicine requires refrigeration, is there a designated person responsible for ensuring that the cold chain is maintained?			

Audit of completion of Staff Records for (insert title of PGD)
The staff records of authorisation to work under the PGD must be checked using this form. Where more than 5 members of staff are authorised to work under the PGD, then a minimum of 5 and maximum of 10 records must be checked for each PGD. Otherwise, all staff records must be checked. For PGDs in use on multiple sites then an audit of each site must be undertaken.

Review date of PGD(s):	
Manager responsible for authorising staff, and for audit:	
Date of audit:	

NB: Answers to all questions except the first and last are 'Yes / No' i.e., no details are required.

Staff initials or identification number	Is their name on the master list of staff authorised to work under the PGD?	Is this authorisation dated?	Has the manager responsible for authorising staff signed the master list?	Is training specific to the PGD(s) up to date?	Comments

Staff initials or identification number	Is their name on the master list of staff authorised to work under the PGD?	Is this authorisation dated?	Has the manager responsible for authorising staff signed the master list?	Is training specific to the PGD(s) up to date?	Comments

Audit of completion of Patient Records for (insert title of PGD)
A sample of 10 sets of patient records for each PGD must be checked using this form. This sample must relate to at least 4 different dates on which the PGD was used, and if applicable where 3 or more members of staff are working under that PGD. For PGDs in use on multiple sites then an audit must be undertaken on each site.

Review date of PGD(s):	
Manager responsible for authorising staff, and for audit:	
Date of audit:	

NB: Answers to all questions except the first are Yes, No, not known (NK) or not applicable (NA) i.e., no details are required.

	1	2	3	4	5	6	7	8	9	10
Was the date of supply / administration recorded?										
Was patient consent obtained?										

Was allergy status recorded?										
Were the patient's concurrent medicines listed (if applicable)?										
Was the medicine given in accordance with the inclusion criteria?										
Where medication details documented – name, strength, dose, frequency, and quantity										
For injections, was the site, and route, recorded? **(batch number and expiry date must be recorded for vaccines, blood-derived products and other medicines if recommended by national guidance)**										
Has the practitioner included statement that administration/supply was under PGD?										
Has the practitioner signed the entry in the patient's notes?										
Was an up-to-date patient information leaflet supplied?										

PGD review
Is the PGD being used appropriately? Describe any areas of non-compliance found during the audit and detail the action required to remedy this. Include the person responsible for implementing the action and the proposed date for completion.
Is the PGD still the best way to provide for the patient group and pathway? Is the PGD still needed or has the delivery of the service changed e.g., introduction of non-medical prescribers.
Has the patient group and licensed indications for the medicine been reviewed? Consider if the patient group has been expanded. Has the SPC been updated to include new indications that could impact on the inclusion criteria?
Describe how the findings from the review link to the amendment of the PGD See example

Example

PGD (title)	Amendment(s)	Reason
Clotrimazole 500mg pessary and Clotrimazole 1% cream	1.1 Clinical condition expanded to include using cream to treat men. 1.2 References refer to the most up to date guideline. 1.3 Inclusion criteria have been amended to include: • Clinical features of genital candidiasis in men. • Removal of 'non offensive' discharge.	Service review has shown more men presenting with genital candidiasis. Review of SPC of clotrimazole 1% cream indicates it is licensed to treat genital candidiasis in men. Changes improve patient's direct access to treatment. As per SPC. Currently only symptomatic patients are treated.

Additional information:
Include any further details that are relevant to this review.

Submit the audit to the PGD Group for discussion and to obtain support. Once the information has been considered and the PGD supported for re-registration complete the following boxes and submit page 4 to the PGD Group Administrator.

Date audit reviewed by PGD Group	
Signature of PGD Chair	