

Controlled Drug Policy

V5.0

February 2019

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1. Introduction

1.1 The legislation for controlled drugs as outlined in the Misuse of Drugs Act, and through the Controlled drugs regulations (Misuse of Drugs Regulations 2001). This policy is written to comply with the requirements of the Royal Cornwall Hospitals Trust Guidance on Governance Arrangements Relating to Medicines¹, the Department of Health publication: Safer management of controlled drugs: a guide to good practice in secondary care (England) October 2007², The Controlled Drugs (Supervision of Management and Use) Regulations 2013 and NHS Protect security requirements.

1.2 This version supersedes any previous versions of this document.

2. Purpose of this Policy/Procedure

To provide all staff within RCHT, medical and non-medical, with clear rules governing all aspects of the use of substances listed in the various orders made under the Misuse of Drugs Act.

3. Scope

3.1 This policy applies to all staff that are involved with controlled drugs within the Royal Cornwall Hospitals NHS Trust.

3.2 The Department of Pharmacy at the Royal Cornwall Hospital maintains separate procedures relating to Controlled Drugs which apply to the activities carried out within the pharmacy department

3.3 Wards, theatres and departments have specific Controlled Drug Standard Operating Procedure held within the departments which must be followed at all times

4. Definitions / Glossary

The definitions given below shall apply within this policy and to all activities governed by this policy notwithstanding any other definition found in another policy of the Trust or elsewhere.

4.1 Controlled Drug Accountable Officer for the Trust

The Medical Director is the Controlled Drug Accountable Officer (CDAO) for the Royal Cornwall Hospitals Trust. The nominated deputy CDAOs are the chief pharmacist and the Principal Pharmacist for Prescribing Support.

4.2 Controlled Drug (CD)

Any substance listed as a controlled drug in a schedule (1-5) to the Controlled drugs regulations (Misuse of Drugs Regulations 2001). The more harmful the drug, the higher the schedule.

4.3 Ward or Department

A physical location within the Trust which is clearly distinguishable from other locations and which holds a single stock of medicines.

¹ See the document library

² http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618

4.4 Ward Or Department Manager

A nurse or midwife who is registered with the Nursing and Midwifery Council or a registered Operating Department Practitioner, who has been appointed to manage a ward or department within the Trust.

In exceptional circumstances where management of a ward or department must be by a person not registered as described above, the CDAO may agree to the nomination of a person who is so registered to be responsible – as if they were the Ward or Department Manager – for controlled drugs.

A Ward or Department Manager may manage more than one ward or department. For example, in sets of operating theatres, anaesthetic and recovery rooms commonly hold separate stocks of CDs and thus are separate departments for the purposes of this policy, and each must hold its own order and record books (see below). For operational reasons it may be better for these “departments” to be managed in groups.

5. Ownership and Responsibilities

5.1 Accountable Officer for Controlled Drugs is responsible for:

- Ensuring that Trust policy is updated and reflects current guidance and legislation
- Giving assurance through audit and monitoring that the policy is being followed across the Trust
- Ensure the policy and subsequent updates are implemented across the Trust
- Monitors CD usage across the Trust.
- Ensure the policy and subsequent updates are implemented across the Trust
- Instigating investigations where necessary into unexplained variances or concerns raised by staff.
- Share learning across the Trust and with the CD Local Intelligence Network (CDLIN)
- Attend the CDLIN
- Provide an annual report to the Trust Board
- Report any concerns to the CDAO for NHS England
- Appoint a deputy(ies) to ensure suitable cover arrangements when off site and absent.
- The CDAO deputies are the chief pharmacist and the Lead Prescribing Support Pharmacist.

5.2 Chief Pharmacist & Deputy Controlled Drug Accountable Officer(s)

- Assist the AO with audit programme.
- Assist the AO with policy and local guideline and procedure update
- Provide usage data to the AO for review
- Assist the AO with investigations into CD incidents
- Maintain the necessary standards for storage and license requirements for the supply of controlled drugs.

- Raise any concerns with the CDAO.
- Attend the CDLIN on behalf of the CDAO

5.3 The Ward or Department Manager shall be responsible for:

- The safe and appropriate management of CDs in the area which they manage. They may delegate control of access (i.e. key holding) to the CD cupboard or any other task to another from time to time but legal responsibility remains with the Ward or Department Manager. Whilst a task can be delegated, responsibility cannot.
- Ensuring staff they manage have read and been trained on the policy before carrying out duties involving controlled drug.

5.4 The Medication Practice Committee is responsible for:

- Ratifying proposed changes to the policy
- Reviewing relevant audit data and other feedback from the CDAO
- Signing off the CDAO quarterly CDLIN occurrence report

5.5 Line Managers are responsible for:

- Training the staff on the policy and local guideline and ensuring the duties are undertaken in line with them.
- Completing an incident form where the policy has not been adhered to.
- Notifying the CDAO where a serious breach has occurred or where there are concerns about a member of staff, the public, or patient relating to controlled drugs.

5.6 Role of Individual Staff

All staffs are responsible for:

- Reading and understanding the policy.
- Attending training and update sessions.
- Completing an incident form where the policy has not been adhered to and notifying the Trust Accountable Officer when serious breaches occur.
- Ensure they carry out the responsibilities and duties outlined in this policy.

5.7 NHS England CDAO

- Co-ordinating the CDLIN for Devon and Cornwall
- Reviewing the RCHT quarterly CD occurrence report
- Cascading information around the network
- Providing advice and support to the RCHT AO

6. Standards and Practice

Throughout, the convention is used that the words “shall” or “must” indicate actions which are mandatory – either because they are legal requirements or because the Trust, through the Medication Practice Committee, has decided that they will be mandatory. All other statements may be interpreted as guidance (or as explanation).

6.1. Controlled Drug Stationery

6.1.1 The following stationary is used for all transactions of controlled drugs in all areas within the Trust with the exception of the pharmacy department:

- Controlled Drug Order Book - Department of Health book reference 90-500
- Ward Controlled Drug Record Book - Department of Health book reference 90-501
- Theatre Controlled Drugs Record Book - Department of Health book reference 0900502
- These books must be used in accordance with the instructions given in the theatre based Controlled Drug SOPs to record all controlled drugs transactions in theatres.
- The CD order book and register must be stored in the CD cupboard. If the CD register cannot fit into the CD cupboard it may be stored in another locked cupboard in the treatment room.
- This stationary is not required for wards and departments using the electronic Pharmacy Ordering Portal or with Omnicell electronic drug cabinets.

6.1.2 **FP10** prescriptions must also be handled as controlled stationary in compliance with NHS Protect requirements of **Security of Prescription Forms Guidance (August 2013)**

6.1.2.1. Wards and departments must ensure that a full audit trail exists for the receipt and use of FP10 prescriptions used in their areas and that these are stock checked on a regular basis (i.e. daily).

6.1.2.2. A full audit trail requires that when prescription(s) are issued to a clinician by a designated member of staff from a locked cupboard at the start of a clinic, a record must be made of:

- Date of supply
- The codes for the prescription(s) (RK number) that were used
- Name of the hospital doctor who received the prescription(s)

6.1.2.3. Wards and departments will be issued with a reconciliation list with their FP10s. This reconciliation list must be completed. If it is not completed then replacement FP10s will not be issued to that ward or department.

6.2 Controlled Drug Cupboards

- 6.2.1 Ward CD cupboards should meet the standard BS2881 standards. If there are any queries, liaise with the Accountable Officer
- 6.2.2 When purchasing a new or replacement cabinet please ensure the cupboard is large enough for the stock holding and allows room for the storage of the Controlled drug register and order book. The preferred supplier is Bristol Maid Via Supplies with whom the Trust has a contract
- 6.2.3 It is the ward or department manager's responsibility to ensure that the controlled drug cupboard enables ward based controlled drug procedures to be complied with. If it does not, the ward or department manager should procure a new controlled drug cupboard.

6.3 Ordering Controlled Drugs

All Controlled Drugs must be ordered in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.4 Supply of Controlled Drugs

- 6.4.1. The RCHT pharmacy department can supply controlled drugs on both a named patient and stock basis.
- 6.4.2. The pharmacy department holds a wholesale dealer and Home Office license, enabling it to supply other legal entities with controlled drugs. For queries relating to supplies of controlled drugs please liaise with the Chief Pharmacist.
- 6.4.3. Wards and departments should not supply other areas with CDs, unless for single doses as set out in section 10 of the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.5 Receipt of Controlled Drugs

Receipt of all Controlled Drugs must be carried out in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.6 Stock Checks

Stock check must be carried out in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs'. These stock checks must include the reconciliation of FP10s stored in that area.

6.7 Recording of Controlled Drug transactions

Controlled Drug transactions must be carried out in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.8 Management of Patient's Own CDs

Patient's own controlled drugs must be dealt with in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.9 Incident Reporting

- 6.9.1 All incidents involving controlled drugs should be dealt with in accordance with the ward/department based CD procedures.
- 6.9.2 If a patient or member of staff have any concerns about unusual, excessive or inappropriate prescribing of CDs this should be reported to the Trust's Accountable Officer who will undertake an investigation. The member of staff should not feel that they need to prove any concerns, they only need reasonable belief that something untoward may be happening.
- 6.9.3 The Trust's CDAO (or nominated deputy) will investigate all significant incidents involving Controlled Drugs, Controlled Drug Storage and Controlled Drug stationary
- 6.9.4 The Trust's CDAO will report all CD incidents to the Controlled Drug Local Intelligence on a quarterly and ad hoc basis should any serious incidents involving Controlled Drugs, Controlled Drug Storage or Controlled Drug stationary occur. The CDAO will also report into the RCHT Medication Practice Committee.
- 6.9.5 The Trust's Accountable Officer will escalate any serious untoward incidents involving Controlled Drugs, Controlled Drug Storage or Controlled Drug stationary via the Datix report. Where necessary the Police, NHSE South CDAO and counter-fraud will be notified to assist.

6.10 Illicit Drugs

When a patient is found to be in possession of an illicit drug, the 'Ward and Department Standard Operating Procedure for Controlled Drugs' must be followed.

6.11 Key Holding and Access to CD Keys

The Ward or Department Manager is responsible for the keys to all controlled drug cupboards as set out in the 'Ward and Department Standard Operating Procedure for Controlled Drugs'.

6.12 Unwanted Controlled Drug Stock

If a ward or department's Controlled Drug cupboard contains any unwanted Controlled Drugs the 'Ward and Department Standard Operating Procedure for Controlled Drugs' must be followed.

6.13 Disposal of surplus Controlled Drug material

Disposal of waste or of surplus material must be in accordance with the 'Ward and Department Standard Operating Procedure for Controlled Drugs' and/or the pharmacy SOPCD02- Destruction of Controlled Drugs.

6.14 Supplementary Prescribers

6.14.1 A supplementary prescriber, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP), can prescribe and administer

and/or supply or direct any person to administer any CD provided that the CD is included in the CMP.

6.14.2 A special prescription form FP10SS is needed for prescribing a CD required to be dispensed by a community pharmacy. Access to these forms is by special arrangement and a formal request will need to be made to the Chief Pharmacist (RCHT).

6.14.3 For further information please refer to the trust Non-Medical Prescribing policy.

6.15 Nurse & Pharmacist Independent Prescribers

6.15.1 The agreed changes to the Misuse of Drugs Regulations 2001 relating to nurse and pharmacist independent prescribing of controlled drugs (*Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2012 (Statutory Instrument 2012/973)*) came into force on 23 April 2012 .

6.15.2 The changes to legislation allow nurse and pharmacist independent prescribers to prescribe any controlled drug listed in Schedules 2-5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction.

6.15.3 Nurse and pharmacist independent prescribers are able to requisition controlled drugs and are authorised to possess, supply, offer to supply and administer the drugs they are able to prescribe. Persons acting in accordance with the directions of a nurse or pharmacist independent prescriber are authorised to administer any Schedule 2-5 drugs that the nurse or pharmacist can prescribe.

6.16 Patient Group Directions (PGDs)

6.16.1 Patient Group Directions (PGD) are not a form of prescribing, but the agreed changes to the Misuse of Drugs Regulations 2001 amendments also made changes to the authorities that nurses and pharmacists possess when acting in accordance with a PGD.

6.16.2 Nurses and pharmacists working under a PGD are now authorised to supply, or offer to supply, diamorphine and morphine where administration of such drugs is required for the immediate and necessary treatment of sick or injured persons (excluding the treatment of addiction). This removes the restrictions whereby a nurse could only supply diamorphine under a PGD for the treatment of cardiac pain in patients admitted to a coronary care unit or an accident and emergency department of a hospital.

6.16.3 Registered nurses, pharmacists, paramedics, midwives ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists, orthotists, prosthetists and speech and language therapists can supply or administer any Schedule 4 or 5 CD in accordance with a PGD, except:

- The anabolic steroids in Schedule 4, part 2
- Injectable formulations for the purpose of treating a person who is addicted.

6.16.4 Individual professionals who are to work within a PGD must be named on it and have signed it.

6.17 Mixing of medicines that include controlled drugs

- 6.17.1 Pharmacists have authority to mix any drugs in Schedules 2-5. Nurse and pharmacist independent prescribers, as well as supplementary prescribers acting in accordance with the terms of a clinical management plan for an individual patient, are authorised to mix any drugs listed in Schedules 2-5 prior to administration.
- 6.17.2 Persons acting in accordance with the written directions of a nurse or pharmacist independent prescriber or, a supplementary prescriber when acting in accordance with the terms of a clinical management plan, are authorised to mix drugs listed in Schedules 2-5.

6.18 Ward Closures or Location Changes

- 6.18.1 In the majority of ward closure situations the stock should be returned to the pharmacy. The pharmacist will stock check and sign appropriate sections of the CD record book and these will be countersigned by the nurse in charge or authorised person. The stock will be removed by the pharmacist and returned for secure storage in the pharmacy.
- 6.18.2 In exceptional circumstances and only with the authorisation of the Accountable Officer, stocks may be retained in a ward or department. In such a situation the final decision will only be taken following a full and documented security risk assessment.
- 6.18.3 Depending on the length of closure, new stock may be issued or the original stock returned.
- 6.18.4 For a ward location transfer the pharmacist will take responsibility for amending records and transferring stock to the new location.
- 6.18.5 For permanent ward closures the CD record book and order book should be sent to Pharmacy for safe keeping for the required two-year period.
- 6.18.6 For temporary closure the CD record book may be retained securely on the ward if for less than seven days. For longer periods the order and record book should be sent to Pharmacy until the ward is ready to open.
- 6.18.7 CD keys must be clearly labelled and sent to the pharmacy at Treliiskefor safe keeping.

7. Dissemination and Implementation

- 7.1 The policy is available on the document library. Significant updates will be communicated via Trust-wide email.
- 7.2 Implementation of the policy will be via Trust-wide communication and supported by appropriate training for the relevant staff members.
- 7.3 Training for this policy will be set out in the medicines management section of the core training matrix of the Trust Core Training Policy

8. Monitoring compliance and effectiveness

Element to be monitored	Elements 6.1 to 6.7, 6.10 and 6.11 of the policy will be monitored by 3 monthly audits carried out by pharmacy. All other elements of the policy will be monitored by the senior staff nurse/ ward manger and the Accountable Officer in response to reported incidents and observations in practice.
Lead	The pharmacy department will lead on the regular monitoring of adherence to policy. The AO will lead on the review of the reported incidents and subsequent investigations.
Tool	The controlled drug audit: Implementation of 'wards and department SOP for controlled drugs in RCHT' form will be used for monitoring sections 6.1-6.7, 6.10 and 6.11. (available from pharmacy) Datix will be used to record drug incidents
Frequency	Ward and department audits will be carried out on a 3 monthly basis. A full report will be sent to those areas where compliance has not been met. Drug usage review is undertaken across the Trust on a monthly basis. The monitoring of incident reports will be reviewed when reported as part of the AO monthly review and quarterly reports submitted to the MPC and CDLIN.
Reporting arrangements	The ward and department audits are reported to the nurse in charge, the matron for that area and the AO. These can then be raised at their individual governance meetings as deemed appropriate. Drug incidents are compiled into an occurrence report by the AO that is sent to the MPC. A version of that report is also sent to the CDLIN. The AO will liaise with clinical staff to ensure learning is passed on.
Acting on recommendations and Lead(s)	The lead for acting on recommendations will depend on the recommendation. Broadly speaking the MPC, TMC Governance (of which MPC is a sub-group) and the CDLIN will make recommendations. These will be carried out by: Pharmacy: Chief Pharmacist Nursing: Director of nursing Prescribers: Medical director Non medical prescribers: Trust lead for NMP
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 4 weeks or as otherwise stated 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

This policy will be reviewed every 3 years or sooner in the light of changes in legislation or practice. The policy review will be ratified by the Medication Practice Committee when changes are substantial. For minor changes, the chair of the Medication Practice Committee can approve and re-publish

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 & Human Rights 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

Document Title	Controlled Drug Policy V5.0		
Date Issued/Approved:	December 2018		
Date Valid From:	February 2019		
Date Valid To:	February 2022		
Directorate / Department responsible (author/owner):	Iain Davidson Chief Pharmacist		
Contact details:	01872-252593		
Brief summary of contents	Details of rules and responsibilities for controlled drugs at RCHT		
Suggested Keywords:	Controlled drug Controlled drugs FP10s FP10 CD CDs Non medical prescribing NMP		
Target Audience	RCHT ✓	CFT	KCCG
Executive Director responsible for Policy:	Medical Director		
Date revised:	20/9/18		
This document replaces (exact title of previous version):	Controlled Drug Policy V4.0		
Approval route (names of committees)/consultation:	Medication Practice Committee		
Divisional Manager confirming approval processes	Iain Davidson- interim CD for Clinical Support Care Group.		
Name and Post Title of additional signatories	'Not Required'		
Signature of Executive Director giving approval			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only

Document Library Folder/Sub Folder	Clinical / Pharmacy
Links to key external standards	CQC Regulation 12
Related Documents:	Medicines Policy Ward and Department SOP for Controlled Drugs
Training Need Identified?	Yes Learning and Development department have been informed.

Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
01/04/08	V1.1	Amendments to be in line with Department of Health Guidance on Controlled Drugs	John Pickup- Trust Audit & Incident Lead
28/02/11	V2	Full review & reformat to bring into line with the Policy on Policies	Iain Davidson- Chief Pharmacist and Accountable Officer
10/06/11	V2.1	Additional reformat in line with new template in the policy of policies	Iain Davidson- Chief Pharmacist and Accountable Officer
07/03/14	V3.0	Due for review. Updated in reference to changes in legislation. In particular for non medical prescribers and patient group directives. Changed accountable officer to the Director of Nursing Change of name from Rules relating to the use of controlled drugs, to controlled drug policy	Iain Davidson- Chief Pharmacist
20/2/17	V4.0	Minor changes made to the document.	Iain Davidson- Chief Pharmacist
20/9/18	V5.0	<ul style="list-style-type: none"> - Change of CDAO to Medical Director - Inclusion of reference to Omnicell - New wording regards reconciliation of FP10s. 	Iain Davidson- Chief Pharmacist

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

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.

<i>Name of Name of the strategy / policy /proposal / service function to be assessed</i> Controlled Drug Policy V5.0						
Directorate and service area: Pharmacy			Is this a new or existing <i>Policy</i>? Existing			
Name of individual completing assessment: Iain Davidson			Telephone: 01872 252593			
1. <i>Policy Aim*</i> <i>Who is the strategy / policy / proposal / service function aimed at?</i>		All staff using controlled drugs in their practice.				
2. <i>Policy Objectives*</i>		Use of controlled drugs is standardised and meets legislative and regulatory requirements.				
3. <i>Policy – intended Outcomes*</i>		Safe use of controlled drugs.				
4. <i>*How will you measure the outcome?</i>		Audit.				
5. Who is intended to benefit from the <i>policy</i> ?		Staff, Trust and patients				
6a Who did you consult with		Workforce	Patients	Local groups	External organisations	Other
		X			X	
b). Please identify the groups who have been consulted about this procedure.		Please record specific names of groups Medication Practice Committee. CQC				
What was the outcome of the consultation?		Changes made as per the version control table.				

7. The Impact				
Please complete the following table. If you are unsure/don't know if there is a negative impact you need to repeat the consultation step.				
Are there concerns that the policy could have differential impact on:				
Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		X		
Sex (male, female, trans-gender / gender reassignment)		X		
Race / Ethnic communities /groups		X		
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		X		
Religion / other beliefs		X		
Marriage and Civil partnership		X		
Pregnancy and maternity		X		
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		X		
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> You have ticked "Yes" in any column above and No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or Major this relates to service redesign or development 				
8. Please indicate if a full equality analysis is recommended.			Yes	No
				X
9. If you are not recommending a Full Impact assessment please explain why.				
Because there is no impact as per the table in section 7.				

Signature of policy developer / lead manager / director 		Date of completion and submission 20/09/2018
Names and signatures of members carrying out the Screening Assessment	1. Iain Davidson 2. Human Rights, Equality & Inclusion Lead	

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead
c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa,
Truro, Cornwall, TR1 3HD

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust's web site.

Signed:  (Iain Davidson, Chief Pharmacist)

Date: 20/09/2018

Appendix 3. Example Form for recording clinic issues of FP10HNC

The example below illustrates the details that should be recorded in clinics where FP10HNCs are utilised. These details will help with the audit trail described in this policy at 6.1.2

11. A full audit trail requires that when prescription(s) are issued to a clinician by a designated member of staff from a locked cupboard at the start of a clinic, a record must be made of: Date of supply; The codes for the prescription(s) (RK number) that were used; Name of the hospital doctor who received the prescription(s)

Record of issues of FP10HNCs					
Date of issue	Unique (RK) number of FP10HNC prescription	Name of Doctor receiving the prescription	Specialty	Location (if relevant)	Dr Signature