Ward, Theatre and Department
Controlled Drugs
Standard Operating Procedure

V13

August 2020
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**Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 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.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the [Information Use Framework Policy](#) or contact the Information Governance Team [rch-tr.infogov@nhs.net](mailto:rch-tr.infogov@nhs.net)
1. Introduction

1.1. This document details all aspects of the management of schedule 2 controlled drugs (CDs) and other CDs where special storage or ordering requirements are needed, in clinical areas at RCHT.

1.2. It sets out the process for appropriate action when a patient is found to have illicit substances in their possession.

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

2. Purpose of this Policy/Procedure

By adhering to this procedure, Royal Cornwall Hospitals Trust will achieve the following:

- Safe, legal ordering, receipt, storage, administration, disposal and recording of CDs.
- Safe, legal use of patient’s own CDs.
- Safe, legal use of CDs from other wards.

3. Ownership and Responsibilities

3.1. The overriding responsibility concerning the use of controlled drugs at RCHT lies with the Controlled Drug Accountable Officer (CDAO). At the time of writing, the CDAO is the Deputy Medical Director.

3.2. Any recurring issues will be discussed at the Medication Safety Group and fed back to the Medicines Practice Committee.

3.3. Role of the Managers

Line managers are responsible for:

- Ensuring that staff working in their clinical area have read and understood this procedure and follow the correct processes in their daily practice.
- Assessing and signing off assistant practitioners and student nurses in their clinical areas to undertake the specific roles outlined in the procedure.
- Raise issues and non-adherence to the procedure with the CD accountable officer and chief pharmacist for action and review.

3.4. Role of Individual Staff

All staff members are responsible for:

- Ensuring they have read and understood the procedure and adhere to its requirements.
4. Standards and Practice

4.1. Ordering of Controlled Drugs (CDs)

Are you an approved signatory for CDs?

Y

Order drug in the requisition book, or on the “Pharmacy Ordering Portal” - POP.
For wards using the Omnicell cabinets, the cabinets will automatically place an order with pharmacy when a set minimum level is reached.

N

Seek permission from ward/theatre manager and ensure pharmacy has a copy of your signature

Has the CD prescription already been screened by a pharmacist?

N

Add the patient name and number to the requisition

Y

Send the Order to Pharmacy via:
- HCA, student nurse, AP, ODP, registered nurse or delegated member of the ward team.
- Pharmacy locked box
- Pharmacy Green Bag.
- Electronic transmission with POP and Omnicell

Y

Request ward pharmacist to screen the drug, or send the order to the dispensary

N

Pharmacist to add the patient name and number to the requisition

4.2. Details of Ordering Process

4.2.1 Each unit/ward that keeps CDs must have a “CD stock list” of all regularly used items. Any changes to the list must be discussed with and agreed by a pharmacist (see section 11).
4.2.2 Each unit/ward that keeps CDs must have a “CD stock list” of all regularly used items. Any changes to the list must be discussed with and agreed by a pharmacist (see section 11).

4.2.3 Each unit/ward must supply the Pharmacy Department with an up to date list of signatures of all registered medical and nursing staff approved to order CDs. It is the responsibility of the department manager to keep this list up to date. The Pharmacy cannot supply CDs if they do not have in the pharmacy department a copy of the signature of the person ordering.

4.2.4 All orders for ward stock must be ordered using the CD order book (Department of Health book reference 90-500) supplied by the Pharmacy Department or using the Pharmacy Ordering Portal (POP) For wards that use Omnicell electronic drug cabinets, the cabinet will automatically send an order to pharmacy when a set minimum level is reached.

4.2.5 A new CD order book will automatically be issued by the Pharmacy Department when the book in use has 5 or fewer pages left.

4.2.6 To place an order complete the CD order book
   - Use a separate page for each item ordered
   - Make sure the carbon paper is in situ and the correct way up
   - Add the name of ward or theatre
   - Add the required Drug, Strength, Form, Ampoule/Vial size (if appropriate) and Quantity required (only order complete packs – check your CD stock list which can be found in the yellow “CD file”)
   - If the CD required is not on the CD stock list, then order the medicine as above but also add the patient name and number to the order. The pharmacist will review the drug chart on EPMA for non-stock CDs. Either contact the ward pharmacist or send the CD order to the dispensary.
   - Date, sign and print the name of the registered nurse or registered operating department practitioner (ODP) ordering.

4.2.7 Send the completed CD order book to the Pharmacy Department either in a locked Pharmacy box, a pharmacy green bag, an HCA, student nurse, Assistant Practitioner (AP), ODP, registered nurse or delegated member of the ward team may deliver the order by hand.

4.2.8 For POP and Omnicell orders, these are electronically transmitted to the pharmacy department and printed out within pharmacy.

4.2.9 Accessing Controlled Drugs Out of Hours
   4.2.9.1 When wards/ clinical areas require a supply of controlled drugs outside of pharmacy opening hours (8.30am to 5pm 7 days a week) wards should in the first instance try and obtain the dose from another ward following the process set out in section 10 of this document.
4.2.9.2 For urgent advice, or instances where the Controlled Drug is not available from another clinical area, the on-call pharmacist should be contacted via RCHT switchboard on 01872 250000.

4.3. **Receipt of CDs**

- A registered nurse, ODP, or midwife collects and takes it back to the ward or department.
- Another member of the ward/ theatre team may also collect a CD order but they must first be nominated by a registered nurse, ODP, or midwife to the pharmacy by telephone.

**Porter collects the controlled drug bag on his/her round**

- Porter arrives on the ward with controlled drug bag
- Registered nurse, midwife or ODP signs for receipt of the bag

**A member of pharmacy staff will check the member of staff’s ID card and ask them to sign for collection of a sealed bag containing the completed CD order. **

**CDs will not be released without ID**

**Confirm the Order**

A Registered nurse, midwife or ODP immediately checks the CDs against the requisitions and signs the ‘received by’ section of the pink copy.

**Contact pharmacy urgently if there is a discrepancy**

**Record of Receipt**

Registered nurse, midwife or ODP and a **witness** (can be a pharmacist, pharmacy technician, student nurse or suitably trained AP)
- enter details of the receipt in the CD register.
- update the running balance
- check that the balance tallies with the quantity that is physically present in the ward/department.

Note: for Omnicell wards, the register and checks are electronic but the same principles apply.

**Lock the Controlled Drugs in the CD cupboard**
4.3.1 **Details of Receipting Process**

There are two ways in which CDs will be delivered to a ward or department.

4.3.1.1 Pharmacy porters or other pharmacy staff will deliver CDs in number-sealed green bags. On receipt a registered nurse, midwife or ODP must sign the delivery record presented by the messenger. The delivery record is confirmation that a bag has been received and that the numbered seal is intact. **It is not necessary to check the contents of the bag at this stage.** If no appropriate member of staff is available to receive CDs, they will be returned to the pharmacy and must then be collected by ward staff.

4.3.1.2 The receiving member of staff must make their Trust identification available to the messenger to confirm that they are entitled to receive the CDs.

4.3.1.3 A registered nurse, ODP, or midwife may collect a completed order and take it back to the ward or department when orders are urgent or there are no suitable delivery rounds. Another member of the ward/ theatre/ clinic team may also collect a CD order but they must first be nominated by a registered nurse, ODP, or midwife to the pharmacy by telephone.

4.3.1.4 A member of pharmacy staff will check the member of staff’s ID card and ask them to sign for collection of a sealed bag containing the completed CD order. The signature is confirmation that a bag has been received and that the numbered seal is intact. **It is not necessary to check the contents of the bag at this stage.**

4.3.2 CDs should not be transported using the pneumatic tube system.

4.3.3 When a CD order arrives on the ward or department a registered nurse, midwife or ODP should immediately:

4.3.3.1 Check the drug, strength, form and quantity of the CDs delivered against the requisition – including comparing the number ordered and received. It is not necessary to break tamper evident seals to check the contents of an intact pack.

4.3.3.2 If the order is correct, sign the ‘Received by’ box on the pink copy of the order in the order book.

4.3.3.3 Notify pharmacy immediately of any discrepancy by telephoning the appropriate dispensary during normal working hours or the on-call pharmacist at other times.

4.3.3.4 Enter details of the receipt in the CD record book, update the running balance and check that the balance tallies with the quantity that is physically present in the ward or department (see section 5 below).
4.3.3.5 The person making the entry and the witness must be a registered nurse, midwife, ODP or pharmacist. Both must sign the record. Where a second registered member of staff is not available a student nurse, pharmacist, pharmacy technician or suitably trained AP, who has been assessed as competent, may witness the process.

4.3.3.6 Place the CDs in the appropriate CD cupboard.

4.3.3.7 For Omnicell wards, the register is electronic and the CD cupboard integral to the Omnicell unit. However, the same principles apply of confirming the balances are correct and putting stock away.
4.4. Administration of a CD to a patient

Patient requires a controlled drug

Obtain the CD keys from nurse/midwife/ODP in charge

Request one of the following to act as a witness:
- registered nurse, midwife or ODP
- doctor
- in exceptional circumstances, a pharmacist, pharmacy technician student nurse or suitably trained AP

Note: For injectable medicines it must be two registered practitioners

Prepare the dose

Is there any excess before administration?

Y

Destroy excess on ward and enter in the register.
e.g. 5mg given, 5mg destroyed. Signed by both practitioners.

N

Both practitioners sign the register/ Omnicell register and EPMA. REMEMBER- you are signing as witness for the preparation and administration of the drug.

Is there any excess after administration?

Y

Destroy excess on ward and enter in the register.
e.g. 5mg given, 5mg destroyed. Signed by both practitioners.

N

Lock the register away in the CD cupboard or other lockable cupboard

Return the key to nurse/midwife/ODP in charge

REMEMBER- THE WHOLE ADMINISTRATION PROCESS MUST BE WITNESSED
(with the exception of administration during anaesthesia- see section 4.4.4)
4.4.1 Details of the Administration Process

4.4.1.1 Administration of a CD must be carried out in accordance with RCHT Medicines Policy.

4.4.1.2 A registered nurse, midwife, appropriately trained ODP or doctor may administer a CD.

4.4.1.3 The **whole process** of administration of any CD (with the exception of administration during anaesthesia, see section 3.4) must be witnessed by a doctor, registered nurse, midwife or ODP. If these are not available, in exceptional circumstances, a pharmacist, pharmacy technician, student nurse or suitably trained AP may witness the process. This does not apply to injectable medicines, where the witness must be a registered practitioner.

4.4.1.4 The process starts from obtaining the Controlled Drugs from the CD cupboard and includes each subsequent process, all the way through to the witnessing of the disposal of any surplus controlled drug (see section 7).

4.4.1.5 Both practitioners must enter and sign for the transaction in the CD Record Book or on the Omnicell electronic CD register.

4.4.1.6 The following information must be recorded on the correct page of the ward CD record book.

- Date
- Time of administration,
- Name of patient,
- Amount given
- Amount disposed of (if relevant)
- Signature of registered nurse/ midwife/ ODP/ Dr administering CD
- Signature of witness
- Balance in stock.

4.4.1.7 When doses of CDs are prepared on the ward but not administered, or where only part of an ampoule is given to the patient, the remainder must be immediately destroyed by the registered nurse, midwife, ODP or doctor. This destruction must be witnessed and appropriately signed for in the CD Record Book (e.g. 5mg given, 5mg destroyed).

4.4.1.8 The drug must be disposed of in the blue-lidded sharps bin (for hazardous/cytotoxic waste). Volumes not exceeding 10ml on each occasion may be disposed of in this way, larger volumes must be disposed of in a denaturing kit available of each ward (see section 4.8.4).
4.4.1.9 Following administration of the CD, both the administering and witnessing practitioner must sign the prescription chart at the specified time/complete the entry on the EPMA system.

4.4.2 Self Administration of CDs

4.4.2.1 It is acceptable to allow self-administration of CDs once an assessment of the patient’s ability to self-administer medicines has been made in accordance with “Guidelines For Patient Self-Administration Of Medication (SAM) Within The Royal Cornwall Hospitals NHS Trust”

4.4.2.2 Except where the paragraphs below do not allow, follow the procedures given in the Trust Medicines Policy.

4.4.2.3 The medicine must be fully labelled and dispensed as for discharge.

4.4.2.4 For supplies labelled with full directions the CD may be kept in the patient’s bedside lockable cupboard (state in the CD record book where the CD is stored), otherwise the medicine must be stored in the ward CD cupboard.

4.4.2.5 Record receipt of the CD in the Patient’s Own CD Record Book and use this record book to record administration.

4.4.2.6 A daily count of the quantity of medicine should be made and recorded in the CD record book. This record should indicate that the number remaining reconciled with the quantity self-administered.

4.4.2.7 When returning patient’s own CDs to a patient at discharge, please ensure these are correctly signed out of the Patient’s Own CD Record Book.

4.4.2.8 Nursing staff should be alert to the possibility that patients with opioid seeking behaviour may covertly self-administer their own controlled drugs without informing the ward staff. Such patients are at high risk of overdose and should be monitored closely.

4.4.3 Application of Opioid Patches

4.4.3.1 When a patch is applied to a patient (e.g. fentanyl and buprenorphine) ensure that the previous patch has been removed before applying the new patch.

4.4.3.2 On application of a new patch, record the relevant information on the ‘Opioi patch sticker’ (see Appendix 6) and stick this in the patient’s nursing notes. Information to record: patient details (can attach an addressograph), which patch – fentanyl or buprenorphine, indicate removal of old patch and application of new patch including area of the body. Sign and date the sticker.
This information should be clearly communicated to the patient, carer and/or community hospital to reduce the risk of inadvertent overdose.

4.4.3.3 These stickers will be automatically supplied by pharmacy with the supply of opioid patches. Please contact pharmacy if further supplies are needed.

4.4.4 Administration of Controlled Drugs for the Purpose of Anaesthesia

4.4.4.1 It is acknowledged that during anaesthesia it is not practical for the whole administration process to be witnessed.

4.4.4.2 The theatre Controlled Drug Register allows for the amount issued, administered and destroyed to be recorded.

4.4.4.3 A witness signature is required for the issued and destroyed elements of this process.

4.4.4.4 The witness for these two steps may be different registered practitioners.

4.5. Recording of CDs in Ward CD Record Books

4.5.1 Operating theatres and Recovery must use a Theatre Controlled Drugs Record Book (Department of Health book reference 0900502) and all other wards and departments must use a Ward Controlled Drugs Record Book (Department of Health book reference 90-501). The exception to this is those wards with Omnicell drug cabinets, where the CD register is electronic.

4.5.2 Within the book, a separate page must be used for each preparation. [e.g. separate pages for “morphine sulphate injection 15mg in 1ml, morphine sulphate injection 30mg in 1ml, morphine sulphate injection 30mg in 2ml]

4.5.3 Entries must be made in ink or otherwise so as to be indelible.

4.5.4 Entries must be made in chronological order and include the date the entry was made.

4.5.5 The person making the entry must be a registered nurse, midwife, ODP or doctor. The witness must be a registered nurse, doctor, midwife, ODP, pharmacist, pharmacy technician, student nurse or a competent and suitably trained AP. Both must sign the record.

4.5.6 Ensure the full name, strength and correct preparation (e.g. tablets or capsules, slow release etc) of the drug are entered accurately into the register.

4.5.7 On reaching the end of a page or transferring the balance into a new CD Record Book, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page.
and the index updated. The person making the transfer must be a registered nurse, doctor, midwife or ODP. The witness must be a registered nurse, doctor, midwife, ODP, pharmacist, pharmacy technician, student nurse or a competent and suitably trained AP. Both must sign the record.

4.5.8 For the purposes of returning CDs to pharmacy, a pharmacist or registered pharmacy technician must sign the record book as a witness.

4.5.9 If a mistake is made it should be marked as a mistake in such a way that the original entry is still clearly legible i.e. a single line strike-through. Both the person making the amendment and the witness must initial the error.

4.5.10 Under no circumstances should a CD record book be tampered with or pages removed.

4.5.11 For the recording arrangements for patient’s own controlled drugs please refer to section 8 of this SOP.

4.6. **CD Stock checks**

4.6.1 Stock checks should be carried out by a registered nurse, midwife or ODP during each shift on the wards and at least every 24 hours for operating departments and clinic areas (when open). Omnicell wards are exempted from this stock check but must undertake a monthly stock reconciliation process.

4.6.2 The stock check witness must be a registered nurse, doctor, midwife, ODP, pharmacist, pharmacy technician, student nurse or a competent and suitably trained AP or physician/ nursing associate.

4.6.3 Wards using the Ward Controlled Drugs Record Book (Department of Health book reference 90-501) should use the form in Appendix 4 to record these stock checks. These forms should be filed in the yellow CD ward folder.

4.6.4 Staff must check the balances in the register against the stock in the cupboard and not the other way round. By just checking the present stock in the cupboard against the register you will not identify missing boxes of controlled drugs because it won’t be there to count.

4.6.5 Theatres & recovery areas using the Theatre Controlled Drugs Record Book (Department of Health book reference 0900502) should record the stock checks in the section at the back of the register.

4.6.6 It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.

4.6.7 Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle.
4.6.8 Any discrepancies must be reported to the senior nurse/ODP on duty and reported on datix immediately and in accordance with the Trust’s incident reporting policies. The exception to this is liquids medicines e.g. morphine sulphate 10mg in 5 ml liquid, where only discrepancies of >10% volume need be reported. This is to take account for the natural wastage with multiple administrations.

4.6.9 Both checkers must sign the stock check to indicate it has been completed.

4.6.10 If expired stock is discovered whilst carrying out a stock check it must still be locked in the CD cupboard and must be included in the running balance for that particular item. See section 6.1 for further details.

4.7. **Returning Unwanted Controlled Drug Stock**

Controlled drugs that need to be returned include:
- Expired CDs
- CDs for a patient that has been discharged
- Excessive stock
- Stock that is no longer routinely used on the ward

Place a ‘RETURN TO PHARMACY’ sticker on the Controlled Drug and store it in the controlled drug cupboard in a segregated area from the ‘in use’ stock.

Inform the ward pharmacist +/- the ward pharmacy technician that there are Controlled drugs to be returned to pharmacy. Continue to count the stock in the daily stock checks until the drug is removed.

Sign the controlled drugs out of the register with the ward pharmacist/ technician

Ward pharmacist/ technician will take the CD to pharmacy for destruction or return into main stock.
4.7.1 Expired stock, CDs that are not on the CD stock list and are no longer required for a current patient, unwanted patient’s own CDs or excess stock must be returned to the pharmacy department.

4.7.2 **Place a ‘RETURN TO PHARMACY’ sticker on the unwanted CD** (provided by pharmacy). The drug must be stored in the CD cupboard, **segregated** from ‘in use’ stock, awaiting collection by the pharmacy team. The sticker acts as a barrier to the inadvertent use of an expired medicine. The product must still be counted as part of the daily/shift end controlled drug stock checks.

4.7.3 Replacement stickers will be sent up to the wards by pharmacy on a regular basis. Please contact pharmacy if you require more.

4.7.4 **Controlled drugs must not be sent in the ward box/green bags.** Approved pharmacy staff (such as the ward pharmacist or pharmacy medicines management technician) must be contacted to collect these returns.

4.7.5 If the patient has died all medicines including CDs should be kept for 7 days to ensure they are not required by the coroner. After the 7 days, these medicines should be returned to pharmacy. Controlled drugs of a deceased patient should not be returned to the family.

4.7.6 The pharmacist or pharmacy technician responsible for the area will come and collect any unwanted CDs from the ward. If the drugs have not been removed within 2 working days of the pharmacy department being made aware of the need for removal the Chief Pharmacist should be contacted.

4.7.7 For expired stock and unwanted Patient’s Own CDs the approved pharmacy staff member and a registered nurse, midwife or ODP will together count the expired stock, the stock remaining in the cupboard and then record in the Ward CD Record Book or the ‘Return, Transfer or Disposal’ section of the Patient’s Own CD record book, the following information:

- Date,
- Quantity taken by the member of pharmacy staff
- “Returned to Pharmacy for Destruction”
- Signatures of registered nurse/midwife and member of pharmacy staff
- Balance remaining in the cupboard

4.7.8 Excess stock or items not kept on the ward CD stock list should be returned to pharmacy. This reduces the risk of selection error.

4.7.9 For excess stock the approved pharmacy staff member and a registered nurse, midwife or ODP will together count the stock to be returned and check the balance remaining. They will record in the Ward CD record book the following information:

- Date
• Quantity taken by the member of pharmacy staff
• “Returned to Pharmacy, no longer required”
• Signatures of registered nurse/midwife and member of pharmacy staff
• Balance remaining in the cupboard

4.7.10 Once returned to the Pharmacy Department the CDs will be dealt with according to the pharmacy department Standard Operating Procedures.

4.8. **Disposal of surplus CD material**

4.8.1 Disposal of waste or of surplus material must be in accordance with the requirements of chapter 5 of the Trust Medicines Policy.

4.8.2 Only part-doses of CDs should be destroyed on wards, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up but not used.

4.8.3 The residual volume in the ampoule or vial should be drawn into a syringe and expelled into a blue-lidded yellow sharps bin. Volumes not exceeding 10ml on each occasion may be disposed of in this way.

4.8.4 Large quantities of CDs, (for example, discontinued infusions, epidural bags or PCA syringes) need to be disposed of using the denaturing kits available on the wards. (which can be ordered from EROS). For further advice on larger volume disposal contact the Pharmacy Department.

4.8.5 Disposal of waste or of surplus material must be witnessed by a second appropriate member of staff and documented as set out in section 3.

4.8.6 Disposal of complete doses of CDs should be done via the pharmacy department as set out in section 6.

4.9. **Patient’s Own Controlled Drugs**

4.9.1 **Receipt of Patient’s Own CDs**

4.9.1.1 Patients may bring their own medication into hospital, including CDs when they are admitted from home or transferred from another hospital.

4.9.1.2 On admitting a patient to the ward check all medication received with the patient and identify any CDs that require safe storage.

4.9.1.3 Inform the patient that the CDs will need to be stored and recorded separately. If the patient refuses then the CDs must be given to a member of the patient’s family to take home.

4.9.1.4 If in exceptional cases the patient refuses to allow either of these scenarios to happen despite repeated prompting, and insists on holding onto their own legally obtained CDs, a bespoke patient’s own medicines locker for the patient can be provided from
pharmacy on request. The controlled drugs must be recorded in the patient’s own CD register and counted twice a day by the ward staff as part of the routine CD checks to confirm that the patient is not inappropriately self-administering medicines and thus increasing the risk of overdose.

4.9.1.5 Follow the procedure for assessing patients own medication as set out in RCH Trust Medicines Policy.

4.9.1.6 Check:
- Patient name
- Date of dispensing: ensure dispensed within the last 6 months
- Directions on dispensing label
- Expiry date and batch number.

4.9.1.7 Make an entry for the patient on the index page of the Patients Own CD record book and then record each patient’s own CD as a separate entry in the record book.

4.9.1.8 If a TTO containing CDs is received on the ward and the patient is not being discharged immediately the CDs should be entered into the Patient’s Own CD record book and signed out on discharge.

4.9.1.9 If a patient dies, the CDs should be retained by the hospital rather than returned to the patient's family. These should be returned to pharmacy for destruction. Where the death is unexpected the CDs should be quarantined in pharmacy pending the inquest.

4.9.2 Transfer of Patient’s Own CDs between Wards or Departments

4.9.2.1 If a patient is transferred to another ward or department and they have brought their own CDs in with them the medicines should be transferred to the new ward or department.

4.9.2.2 Both the supplying and receiving wards patient’s own CD record books will be required.

4.9.2.3 A registered nurse, midwife or ODP from each of the receiving and supplying wards should:
- Check the quantity against the supplying CD record book.
- Write the quantity and the ward/hospital transferring to in the appropriate box, complete the balance box (which should be “nil”). The registered practitioners must sign the ‘actioned by’ and ‘witnessed by’ boxes.
- Complete the receiving Patient’s Own CD record book (in accordance with Section 8.1 above).
- Immediately store the CDs in the receiving ward’s CD cupboard.
4.9.3 Administration of Patient's Own CDs

4.9.3.1 Ensure that the patient’s own drugs have been assessed for suitability to use.

4.9.3.2 The Patient’s own CDs must be prescribed before they can be administered.

4.9.3.3 Obtain the patient’s permission to use their own CDs. N.B. Patients own CDs must never be used to treat other patients.

4.9.3.4 Record the same information in the Patient's Own CD record book as for administration of ward stock.

4.9.4 Returning Patient’s own CDs & TTO CDs to patient on Discharge

4.9.4.1 On discharge the patient should only be given back their ‘patients own’ CDs if it is prescribed on their discharge prescription. However, patients own drugs are patient property and they can therefore insist the CDs are returned to them.

4.9.4.2 Consent should be obtained for disposal.

4.9.4.3 Unwanted medicines must be dealt with according to Section 6.

4.9.4.4 On discharge, check the CD against the entry in the Patients Own CD record book and check the directions and strength of the medicine against the discharge prescription. Ensure the patient is clear if there has been any change in dosing and encourage them not to take the CD home if there has been a change.

4.9.4.5 A Registered Nurse/ODP/midwife/doctor should record in the 'Return, Transfer or Disposal' section of Patients Own CD record book, the quantity returned to the patient, the balance remaining in the cupboard (which should be “Nil”) and the appropriate practitioners must sign the ‘actioned by’ and ‘witnessed by’ boxes.

4.9.4.6 The index page of the record book should be annotated to indicate the patient has now been discharged.

4.10 Safe Storage

4.10.1 CD Cupboards

4.10.1.1 All CD cupboards must conform to British Standard 2881 and meet "The Misuse of Drugs (Safe Custody) Regulations 1973". Specifically:
  - CD Cupboards must be made of metal and have internal hinges
  - CD Cupboards must be fitted with internal pick and drill resistant lock(s)
  - CD Cupboards do not need to be a cupboard inside of another cupboard
- CD Cupboards must be securely fixed to a solid wall which, ideally, would be an internal wall.

4.10.1.2 A minimum size specification for CD cupboards is 500mm wide x 300mm deep x 550mm tall. However, wards and departments should purchase bigger CD cupboards if space allows to ensure that all stock CDs, Patient’s Own CDs and CD stationery can be easily stored within it.

4.10.1.3 Only CDs and CD stationery must be stored in a CD cupboard.

4.10.1.4 Specifically, patient’s valuables must not be stored in CD Cupboards – they should be dealt with in accordance with the Trust’s “Patient’s Property Policy”.

4.10.1.5 In exceptional circumstances, if the CD Record Book cannot fit into the CD cupboard, it may be stored in another lockable cupboard.

4.10.1.6 For best practice there should be designated sections of the CD cupboard used for storing Patient’s own CDs, CD TTOs, Ward Stock and any out of date CDs all separate from each other.

4.10.1.7 Cupboards must be locked when not in use and the keys must in the possession of the Ward or Department Manager or of an appropriately registered healthcare professional nominated by them.

4.10.1.8 Any spare keys for the CD cupboard must be held by pharmacy. It is the wards responsibility to provide pharmacy with a spare set of keys.

4.10.1.9 Should the CD key go missing and cannot be found, the CD cupboard locks must be changed as soon as possible and a replacement spare key provided to pharmacy.

4.10.1.10 Omnicell cabinets comply with the British Standard. Access to these cabinets is via fingerprint technology rather than using keys. Wards managers must ensure that access control to the cabinets is kept up to date and staff leavers are taken off the database in a timely fashion.

4.10.2 Ensuring Safe Practice with High Dose Ampoules of Diamorphine and Morphine

4.10.2.1 To minimise the risk of simple selection error causing a potentially fatal incident, high dose preparations should only be stocked on specific wards and their use kept to a minimum.

4.10.2.2 Where there is a need to store high and low dose ampoules, use separate storage locations such as shelves, bags or boxes for low strength products used for bolus administration in acute care, and high strength products used to prepare infusions.
4.10.2.3 In areas that use high dose infrequently, ensure high dose ampoules are returned to pharmacy when no longer needed, to reduce the risk of selection error.

4.10.3 CD Key holding

4.10.3.1 The nurse, ODP, doctor or midwife in charge of the ward or department is responsible for the CD key and should know its whereabouts at all times.

4.10.3.2 Key-holding may be delegated to other suitably trained registered members of staff but the legal responsibility rests with the nurse, ODP or midwife in charge of the ward or department.

4.10.3.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff.

4.10.3.4 CD keys must be on a separate key-ring to the other drug keys. This ensures that only staff that require access to the CD cupboard have access to the keys.

4.10.3.5 No more than one set of CD keys should be in use on the ward. A spare set can be kept and arrangements for their secure storage must be in place and is the responsibility of the ward or department manager. Pharmacy is the recommended place for the storage of spare keys.

4.10.3.6 If the CD keys go missing every attempt must be made to find them, including phoning nursing staff that are off shift. If they cannot be located an incident form must be completed and the issue escalated to the deputy CDAO or CDAO Accountable Officer informed. If the key is not found, estates must be contacted urgently to change the locks (even when a spare exists).

4.11. Using CDs from another Ward or Department

4.11.1 It is not permissible to borrow or transfer CDs from one ward or department to another. This does not apply to patient’s own CDs (see section 8.2)

4.11.2 Should a ward or department need to administer a CD and not have the required stock the stock should be ordered from Pharmacy urgently.

4.11.3 Out of hours or if ordering the CDs from pharmacy has the potential to unacceptably delay treatment and lead to patient harm, the dose of the controlled drug may be obtained from another ward or department that has sufficient stock.

4.11.4 The CD must be administered directly from the supplying ward’s stock as follows:
- A registered nurse, ODP, Doctor or midwife should take the patient's drug chart or prescription to the supplying ward.
- The required dose should be recorded in the supplying ward or departments CD record book in accordance with section 3 above and taken out of the CD cupboard. This process must be witnessed by a registered nurse, ODP, doctor or midwife working on that ward or department.
- The dose should then be taken directly back to the ward where it is required and administered to the patient immediately.

4.12. **CD Stock Lists**

4.12.1 All ward, theatre or clinic locations must have a CD stock list which is stored in the yellow CD folder.

4.12.2 Only CDs on the stock list can be ordered and kept as stock, other CDs must be ordered only when there is a current patient requiring that item (see section 1).

4.12.3 Any CDs not on the stock list must be returned to the pharmacy (see section 7) immediately as soon as the patient that they were required for is no longer prescribed them or has been discharged.

4.12.4 The CD stock list can be updated at any time if necessary due to changing requirements. This should be authorised by the pharmacist responsible for the area who will confirm that the addition is appropriate and ensure the stock list is changed and reprinted.

4.13. **CD stationery**

4.13.1 Each Ward, department or theatre must have their own CD order and Record Books, with the exception of Omnicell wards who do not require a record book.

4.13.2 Wards using the Pharmacy Ordering Portal to order their controlled drugs should still have a CD order book for business continuity reasons.

4.13.3 There is a specific CD record book for theatres that allows for easy recording of the quantity supplied, administered and discarded. These books should only be used in the theatre and recovery environment.

4.13.4 All CD Order Books and CD Record Books must be stored in the CD Cupboard when not in use.

4.13.5 Where the CD cupboard is not large enough to store the Record Book, this may be stored in another lockable cupboard or drawer.

4.13.6 A ward or department must have only one CD Record Book in use at any one time and one Patient's Own CD Record Book.

4.13.7 To order a new CD Record Book (including patients own), complete a page in the CD order book and send to the Pharmacy Department.
4.13.8 Pharmacy will automatically issue a new CD order book when only five order pages are left. In an emergency a Ward or Department Manager may order a new book using a standard ward requisition.

4.13.9 Loss of any CD stationery must be dealt with an incident, as described in section 4.15.

4.13.10 Completed requisition books and record books must be retained for a minimum of 2 years from the date of the last entry in the book. Wards and clinical areas can send their completed requisition books and record books for archiving.

4.13.11 Wards that use the Pharmacy Ordering Portal to order their CDs are not required to keep records of receipt as these are available electronically on the POP system and receipt is recorded in the CD register.

4.13.12 Wards that stock FP10 pads for occasional prescribing out of hours must follow the guidance set out in the Controlled Drugs Policy (section 6.1.2) regards safe storage and maintain a full audit trail of usage.


4.14.1 If a patient has illicit drugs in their possession when they are admitted to hospital:

- Inform the patient that the illicit drugs must handed over for safe storage and destruction.
- Advise the patient that confidentiality will be maintained but that if the patient requires the drugs to be handed back at any stage this can only be undertaken by the Police via the Controlled drug Accountable Officer.
- If the patient declines to hand the illicit drug over, the Ward or Department Manager must inform the police via the Trust’s Accountable Officer for CDs (the Medical Director) for the substance to be seized.
- The Trust’s accountable officer for controlled drugs must be notified (either verbally or via email).

4.14.2 The receiving nurse and a witness must allocate a page in the CD record book to record receipt of the drug.

4.14.3 The drug must be placed in a plastic bag clearly marked with the name of the patient, the name, description and quantity (e.g. two tablets, joints, wraps, blocks etc) of the suspected substance (if known), and ‘To be sent to pharmacy for disposal’.

4.14.4 If the quantity of substance is not easily defined (e.g. it is a powder, or a bag of hemp) efforts should be made to weigh the substance and for this to be recorded.
4.14.5 The bag must be placed in the CD cupboard, in a sealed signed envelope so that it is tamper evident, with the intention to transfer it to the pharmacy department as soon as possible for destruction i.e. when pharmacy is next open.

4.14.6 Under no circumstances should a member of staff return any illicit substance to a patient or their carer. This can only be undertaken by involvement of the police.

4.14.7 For removal and disposal of the illicit substances from the ward- a nurse and pharmacist must sign it out of the ward register. The pharmacist will bring the substance to the pharmacy department. The drug will then be taken to Pharmacy for witnessed disposal by a senior member of the pharmacy team and the police. If the police are unable to attend in a timely manner, authority will be given for 2 members of senior pharmacy team and/or the CD accountable officer to destroy the drugs.

4.14.8 New Psychoactive Substances (aka NPS or ‘legal highs’) are illegal as of the 26th May 2016 and should be treated in the same way as illicit drugs. NPS can cause significant health issues to patients and interact with treatment and must therefore be handed over by the patient on admission. Although it is not illegal to be in possession of NPS’s, it is illegal to supply them and therefore healthcare staff cannot legally return these substances to the patient. Similarly, there is no chemical analysis of these substances, and some might in fact contain illicit drugs.

4.14.9 The drug liaison Police can be contacted through the 101 (as an external) telephone number.

4.14.10 CBD (Cannabidiol) as an isolated substance in its pure form is not controlled, but products containing CBD may contain other controlled cannabinoids such as THC. As such these products would need to be dealt with in a similar way to other illicit drugs unless they have been prescribed by a specialist doctor. Further information and guidance on CBD please refer to Guideline on Use of Cannabidiol (CBD) products in RCHT.

### 4.15. Incident reporting and Misappropriation Concerns

4.15.1 On discovering a medication error or a near miss involving a Schedule 2 or 3 CD or drug of abuse the incident should be reported to the senior nurse on duty and reported on Datix immediately and in accordance with the Trust’s incident reporting policies.

4.15.2 If the incident may compromise patient care the duty medical practitioner must also be informed.

4.15.3 If a stock discrepancy is discovered it must be reported immediately to the senior nurse on duty and the ward pharmacist, or, during out of hours, the on-call pharmacist. The incident should also be reported as soon as is reasonably possible on Datix.
4.15.4 If keys to a CD Cupboard or any CD stationery are lost the ward pharmacist (or on-call pharmacist out of hours) and duty nurse manager should be contacted and attempts made to locate the missing items. This loss should also be reported on Datix as soon as is reasonably possible and in accordance with Trust’s incident reporting policies.

4.15.5 The Trust’s Accountable Officer (AO) for Controlled Drugs will be made aware of all CD incidents through the Datix system. However, for serious CD incidents please contact the CDAO by phone or email within 24 hours of the incident.

4.15.6 Any concerns relating to suspected or known misappropriation of controlled drugs by staff or patients should be reported to the AO immediately. Any concerns raised will be treated confidentially.

4.15.7 In situations where staff misappropriation is suspected, - e.g. acute loss of a drug of a particular degree of concern the following process should be followed:

- Immediate escalation to the most senior person of that area who is available and not involved in the incident. This would be e.g. matron in hours, site coordinator out of hours.
- Appropriate members of the senior leadership team, the chief pharmacist and the CD Accountable Officer should also be notified as soon as possible.
- In hours where there is strong suspicion that misappropriation occurred within a recent time frame (e.g. one hour), the senior lead, in consultation with the CDAO/ deputy, should also contact the counter fraud team (Gareth Cottrell at time of writing) via switchboard and log the suspected theft with the police on the 101 number. If there is no response on the 101 number, it may be necessary to complete an online form. If the police are required to assist with a search, they should be contacted on 999.
- Out of hours the Counter Fraud Officer is willing to be notified via switch if there is strong suspicion of misappropriation.
- Out of hours the police may or may not wish to attend site but ensure the crime number is entered into the subsequent datix
- When possible, the area should be put into ‘lock down’, with staff being asked not to leave until the initial investigation is completed. Staff cannot be detained against their will (unless police present)
- A list of names of all staff that may have had access to the controlled drugs during the shift should be taken.
- Statements from those directly involved in raising the concerns and/or the last known staff to handle those controlled drugs should be taken.
- The Trust does not have the powers to search staff, however the Trust can ask staff to voluntarily empty their pockets and go through their locker contents etc. Importantly, it should be the member of staff who opens their own locker and extracts the
A record should be made of those staff that have agreed and not agreed to be voluntarily searched.

If searches do occur they should be in a separate room providing privacy.

Members of the senior team not connected to the incident should also undertake a search of the communal areas, such as the toilets and changing rooms and check bins and other areas where the drug could have been discarded/hidden.

A datix incident should be completed detailing the incident and the investigation to date.

A primary concern in these instances is the welfare of staff and patients. Section leads need to be aware of the risk of the misappropriated drug being used in a suicide attempt and there needs to be heightened vigilance and surveillance of staff and patients following such instances. Such steps might include urgently following up any member of staff that unexpectedly does not report into work the following day or speaking to a staff member who you know is going through a difficult time.

All investigations must be kept confidential throughout the process. Names of staff under suspicion must only be shared on a need to know basis.

4.16. **Arrangements for West of Cornwall (WCH) and St Michaels Hospital (SMH)**

Arrangements for WCH and SMH are as outlined in the above procedure with the following differences in process for when ordering CDs from the Treliske site.

4.16.1 **Ordering of Controlled Drugs (CDs)**

4.16.1.1 Both hospitals are live with POP and can therefore send ward orders through electronically.

4.16.1.2 For same day delivery ensure the order to pharmacy is sent before 10.00am

4.16.2 **Receipt of CDs**

4.16.2.1 All CDs will be transported and delivered by the regular NHS Courier Service unless the CDs are needed in an emergency when it is acceptable for a taxi to be used. The taxi should be organised by the ward after discussion with the on-call pharmacist or pharmacy department.

4.16.2.2 The CDs will be transported in either the ward’s locked pharmacy drug box or in a tamper-proof, sealed pharmacy bag. The box or bag will be marked “Special Storage Conditions”-open as soon as possible.
4.16.2.3 When the ward box or sealed pharmacy bag arrives on the ward a registered member of staff must be made aware of its arrival and sign the appropriate courier paperwork to confirm delivery.

4.16.2.4 When a CD order arrives on the ward or department a registered nurse, midwife or ODP must immediately:

- Check the drug, strength, form and quantity of the CDs delivered against the requisition – including comparing the number ordered and received. It is not necessary to break tamper evident seals to check the contents of an intact pack.
- If the order is correct sign the ‘Received by’ box on the pink copy of the order in the order book.
- Notify pharmacy immediately of any discrepancy by telephoning the appropriate dispensary during normal working hours or the on-call pharmacist at other times.
- Enter details of the receipt in the CD record book, update the running balance and check that the balance tallies with the quantity that is physically present in the ward or department (see section 5).
- The person making the entry and the witness must be a registered nurse, midwife, ODP, or pharmacist. Both must sign the record. Where a second registered member of staff is not available a 3rd year student nurse or a competent and suitably trained AP may witness the process.
- Place the CDs in the appropriate CD cupboard.

4.16.2.5 Each CD order will be accompanied by the Fax Back Special Delivery Confirmation Form that must be completed and faxed back to the pharmacy department at RCHT stating that the correct order has arrived safely. This must be signed and faxed back within 2 hours of receipt of the CDs. This form details the relevant CD requisition number and the number of packs supplied.

4.16.2.6 If the CD order was faxed to the pharmacy department, attach the original white copy of the order from the CD order book to the receipt form sent from pharmacy. Sign and date this and return to the pharmacy department in the sealed pharmacy box on the next available transport.

4.17. The Role of Student Nurses, Assistant Practitioners, Physician and Nursing Associates

4.17.1 Only registered practitioners can hold keys, order, receive or administer controlled drugs as described in this procedure.

4.17.2 Where a second check is required, ideally this should be undertaken by a registered practitioner, however when this is not possible this second check may be undertaken by a student nurse or a suitably...
trained assistant practitioner (AP), Nursing Associate (NA) or Physician Associate (PA). Healthcare assistants are not permitted to undertake these checks.

4.17.3 The ward manager must use their discretion in deciding which members of staff they select to take on this important role.

4.17.4 APs, NAs and PAs, must complete the accreditation pack to demonstrate and evidence competence in this area (see appendix 5). Student nurses have undertaken CD training as part of their undergraduate training and are therefore not required to complete the accreditation, however the ward manager must assure themselves that the student nurse understands this SOP.

4.17.5 This accreditation is valid if the member of staff moves to another ward, however, it remains the discretion of the new ward manager whether the member of staff undertakes this role on their ward.

4.17.6 Student nurses and APs must be reminded of the importance of reporting any concerns to the ward manager or the Controlled Drug Accountable Officer as appropriate.

4.17.7 A record of the individual’s accreditation must be kept at ward level.

4.18. Morphine sulphate (Oramorph) solution 10mg in 5ml, and Schedule 3 drugs including buprenorphine, midazolam, temazepam, tramadol, gabapentin and pregabalin

4.18.1 Although not Schedule 2 CDs, Schedule 3 controlled drugs, for example buprenorphine, midazolam, tramadol, gabapentin and pregabalin and the schedule 5 drug morphine sulphate 10mg in 5ml solution, must be ordered in the CD order book according to the relevant CD SOP for ordering CDs.

4.18.2 They must be stored, when not in use, in the CD cupboard. If storage capacity is limited in the ward controlled drugs cupboard tramadol, gabapentin and pregabalin only may be stored in a designated space in the ward top-up drug cupboard.

4.18.3 They must be recorded (for receipt, administration) in the CD register book. However, unlike other CDs it has been agreed that one nurse’s signature will suffice for recording purposes, unless the ward manager decides for their ward/unit that two signatures are required.

4.18.4 For some wards where there is frequent use of tramadol, gabapentin, pregabalin and morphine sulphate 10mg in 5ml solution it may, with the agreement of the CDAO/deputy, be stored in the individual bay drug cabinet under lock and key. In this instance stock is ordered from Pharmacy in the CD order book and is recorded as received onto the ward in the normal way. A bottle or box is then booked out of the CD register to the “bay drug cabinet” and individual administrations to patients on each bay are then recorded in a designated specific record book.
4.18.5  Tramadol, gabapentin, pregabalin and morphine sulphate 10mg in 5ml solution may, when being given as part of a medication round, be stored in the medicines trolley together with the CD register as long as it is not left unattended. They must be returned to the CD cupboard on completion of the drug round.

4.19.  **Parenteral intravenous potassium solution**

4.19.1  Parenteral intravenous concentrated potassium is not a controlled drug but to ensure safe use, the drug must be ordered in the CD order book according to the relevant CD SOP for ordering CDs.

4.19.2  Potassium additions to infusion bags should be avoided and wherever possible potassium must be prescribed in concentrations which are available commercially in ready diluted bags.

4.19.3  Concentrated potassium should only be administered in areas designated as “stockholding” areas.

4.19.4  Only Clinical areas approved by MPC may store concentrated potassium.

4.19.5  The Designated areas at RCHT are:

- Coronary Care Unit
- Critical Care Unit
- Emergency Department
- Lowen Ward
- Neonatal Unit
- Renal Unit

4.19.6  Patients should not be transferred to non stockholding areas whilst receiving concentrated potassium.

4.19.7  Potassium chloride concentrated solutions should not be transferred between clinical areas. All supplies should be made directly from the pharmacy department.

4.19.8  The transfer of stock between clinical areas is not permitted under any circumstances, even between two authorised stockholding areas.

4.19.9  Out of ours supply must be obtained through “oncall” pharmacist

5.  **Dissemination and Implementation**

5.1.  This document will be held on the document library and will be available on the Clinical Shelf.

5.2.  Previous versions (V1.0 to V7.0) of this document have been held within the pharmacy document management system, with hard copies present on the
ward. These hard copies will now be taken off the wards and this version will become a Trustwide SOP.

5.3. Training for this SOP will be provided as part of Trust medicines management induction session and as part of the local medicines management induction at ward level.

6. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>All elements of this SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>The accountable officer for controlled drugs and the chief pharmacist</td>
</tr>
<tr>
<td>Tool</td>
<td>A number of different tools will be used to monitor this policy.</td>
</tr>
<tr>
<td></td>
<td>1. Ward CD audits undertaken by pharmacy</td>
</tr>
<tr>
<td></td>
<td>2. Daily checks at ward level.</td>
</tr>
<tr>
<td></td>
<td>3. Review of all datix incidents by the CD accountable officer and a quarterly report for the Trust and to the CDLIN.</td>
</tr>
<tr>
<td></td>
<td>4. Pharmacy safe and secure audits of all ward and clinical areas.</td>
</tr>
<tr>
<td></td>
<td>5. Ward level audits and matron walk rounds.</td>
</tr>
<tr>
<td>Frequency</td>
<td>Monitoring is on an on-going rolling basis. The ward audits aim to be carried out on a quarterly basis and the safe storage audits on a 6-12 monthly basis.</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Compliance will be reported within the Trust through to the medication practice committee. Outside of the Trust, incidents and compliance to good practice will be reported through to the Devon and Cornwall Local Intelligence Network (CDLIN)</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>The medication safety committee will review themes to incidents and the senior nursing and midwifery forum will also receive briefings regards compliance with the SOP. The Medication Practice Committee will lead on the recommendations and policy/ SOP changes</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Lessons and changes in practice will be communicated through the Pharmacy newsletter to the Trust and the internal pharmacy newsletter. There will also be feedback via the medicines management trust induction sessions and briefings to appropriate meetings</td>
</tr>
</tbody>
</table>

7. Updating and Review

To be reviewed every 3 years by the Medication Practice Committee

8. Equality and Diversity

8.1. 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.

8.2. The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th><strong>Document Title</strong></th>
<th>Ward, Theatre and Department Controlled Drugs Standard Operating Procedure V13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>This document replaces (exact title of previous version):</strong></td>
<td>Ward and Department Standard Operating Procedure for Controlled Drugs V12.1</td>
</tr>
<tr>
<td><strong>Date Issued/Approved:</strong></td>
<td>June 2020</td>
</tr>
<tr>
<td><strong>Date Valid From:</strong></td>
<td>August 2020</td>
</tr>
<tr>
<td><strong>Date Valid To:</strong></td>
<td>August 2023</td>
</tr>
<tr>
<td><strong>Directorate / Department responsible (author/owner):</strong></td>
<td>Iain Davidson, Chief Pharmacist</td>
</tr>
<tr>
<td><strong>Contact details:</strong></td>
<td>01872 252593</td>
</tr>
<tr>
<td><strong>Brief summary of contents</strong></td>
<td>This document details all aspects of the management of schedule 2 controlled drugs (CDs) and other CDs where special storage or ordering requirements are needed, in clinical areas at RCHT. It sets out the process for appropriate action when a patient is found to have illicit substances in their possession.</td>
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<tr>
<td><strong>Suggested Keywords:</strong></td>
<td>Use this section to suggest keywords to be added by the Uploader to aid document retrieval.</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td>RCHT</td>
</tr>
<tr>
<td><strong>Executive Director responsible for Policy:</strong></td>
<td>Medical Director</td>
</tr>
<tr>
<td><strong>Approval route for consultation and ratification:</strong></td>
<td>Controlled Drug Assurance Group Medication Practice Committee Clinical Support Care Group Meeting</td>
</tr>
<tr>
<td><strong>General Manager confirming approval processes</strong></td>
<td>Richard Andrezjuk</td>
</tr>
<tr>
<td><strong>Name of Governance Lead confirming approval by specialty and care group management meetings</strong></td>
<td>Kevin Wright, Governance Lead</td>
</tr>
<tr>
<td><strong>Links to key external standards</strong></td>
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<td><strong>Related Documents:</strong></td>
<td>RCHT Controlled Drug Policy</td>
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<tr>
<td><strong>Training Need Identified?</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Publication Location (refer to Policy on Policies – Approvals and Ratification):</strong></td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td><strong>Document Library Folder/Sub Folder</strong></td>
<td>Clinical / Pharmacy</td>
</tr>
<tr>
<td>Date</td>
<td>Version No</td>
</tr>
<tr>
<td>------------</td>
<td>------------</td>
</tr>
</tbody>
</table>
| Oct 2015   | V8.0       | • Pharmacist technician included as witness for receipt and stock checks.  
• Assistant practitioner and student nurses included for stock check witness  
• Stock check to be during shift, not at limited to handover  
• Changes to reflect move to EPMA  
• Addition of appendix for Patch Stickers when applying an opioid patch  
• Illicit drugs. Changed due to there no longer being on-site police. Contact the CDAO and send to pharmacy for disposal.  
• Reformatted to comply with template for publication on Documents Library | Chief Pharmacist                       |
| May 2016   | V9.0       | Illicit drugs section updated to include more thorough instructions on what to do if a patient had illicit medicines in their possession. Section expanded to include New Psychoactive Substance/ Legal Highs guidance. | Chief Pharmacist                       |
| July 2017  | V10        | Included a more comprehensive section on returning controlled drugs and the introduction of a ‘return to pharmacy’ quarantine sticker. Amendments to reflect changes in storage arrangements on Trauma Unit and other surgical areas. | Chief Pharmacist                       |
| Dec 18     | V11        | - CDAO changed to the Medical Director  
- Added in that Nursing and Physician Associates can undertake second checks if signed off as competent  
- Added in section about Tramadol  
- Added in ordering details through the pharmacy ordering portal and Omnicell cabinets  
- Borrowing from wards out of hours put above calling out the on call pharmacist  
- Cannabis oil addition | Iain Davidson  
Chief Pharmacist |
<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Changes</th>
<th>Author</th>
</tr>
</thead>
</table>
| Mar 19   | V12     | - Added in changes to reflect reclassification of gabapentin and pregabalin  
           |         | - Added in section on potassium injection  
           |         | - Reformatted in line with the PRG requests.  
           |         | - Learning from SI regards potential overdose due to convert self-administration of opioids  
           |         | - Change in CDAO to deputy medical director                                  | Iain Davidson  
           |         | Chief Pharmacist                                                            |
| August 19| V12.1   | - Added in index table                                                   | Iain Davidson  
           |         | - Amend gabapentin/ pregabalin section 14.17 for other schedule 3 drugs      | Chief Pharmacist |
|          |         | - Added in section (within section 14.14) expanding what to do in situations of suspected misappropriation regards investigation and escalation.  
          |         | - Added in section explaining what to do if patients insist on holding their own legal CDs (within section 4.9)                      | |
| July 20  | V13     | - Learning from Serious incidents in the Trust- adding in more specific detail regards not tampering with CD record books in section 4.5.  
           |         | - Section 4.13 Retention of records when ordering through the pharmacy ordering portal.  
           |         | - 4.13.12 FP10s- reference to 6.1.2 cross references the CD policy  
           |         | - 4.13.10- pharmacy to archive ward records for 2 years. Learning from SI where disposed of by ward and needed for investigation.  
           |         |                                                                           | 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 for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). 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 Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Directorate and service area: Pharmacy</th>
<th>Is this a new or existing Policy? Existing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward, Theatre and Department Controlled Drugs Standard Operating Procedure V13</td>
<td></td>
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</tr>
</tbody>
</table>

| Name of individual/group completing EIA | Contact details: 01872 252593 |
| Iain Davidson |  |

1. **Policy Aim**
   - **Who is the strategy / policy / proposal / service function aimed at?**
   - Appropriate and safe use of controlled drugs in clinical areas. For all relevant staff and to ensure good patient outcomes.

2. **Policy Objectives**
   - Safe use of controlled drugs.

3. **Policy Intended Outcomes**
   - Safe use of controlled drugs.

4. **How will you measure the outcome?**
   - As described in the compliance section of the policy.

5. **Who is intended to benefit from the policy?**
   - Staff and patients.

6a). **Who did you consult with?**
   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other
   - X

   **Please record specific names of groups:**
   - Medication Practice Committee

6b). **Please list any groups who have been consulted about this procedure.**

6c). **What was the outcome of the consultation?**
   - Agreed
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 a positive/negative impact on:

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female non-binary, asexual etc.)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Gender reassignment</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Race/ethnic communities /groups</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Disability (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Religion/other beliefs</td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td>Marriage and civil partnership</td>
<td>X</td>
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<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Sexual orientation (bisexual, gay, heterosexual, lesbian)</td>
<td>X</td>
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</tbody>
</table>

If all characteristics are ticked ‘no’, and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

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: Iain Davidson, Chief Pharmacist

If you have ticked ‘yes’ to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here: Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net
Appendix 3. SOP sign-off

Ward and Department Standard Operating Procedure for Controlled Drugs – Royal Cornwall Hospital, Treliske

Ward or Department Name……………………

Name of Ward or Department manager……………………………….

I have read and understood the following Standard Operating Procedure for CDs and agree to comply with them.

<table>
<thead>
<tr>
<th>Date Read</th>
<th>Name (please print)</th>
<th>Designation</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
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### Appendix 4. Controlled Drugs – Daily Stock Check Record

**Daily Stock Check Log for the Month of …………… 20…… Clinical Area …………………………………………………**

Stock checks must be carried out at shift change over and a minimum of once in every 24 hours. Stock checks must include both ward stock drugs and patient’s own controlled drugs. It is the Ward Manager’s responsibility to ensure that checks are done and that this log is completed. Any errors found must be reported to the ward manager, ward pharmacist and logged on DATIX as soon as possible.

<table>
<thead>
<tr>
<th>Time</th>
<th>Nurse 1 or ODP3 Signature</th>
<th>Nurse 1 or ODP3 Print Name</th>
<th>Nurse 2 or ODP3 Signature</th>
<th>Nurse 2 or ODP3 Print Name</th>
<th>Stocks checked &amp; correct</th>
<th>Discrepancies found</th>
<th>DATIX completed &amp; pharmacy notified</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
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</table>
Assistant Practitioner/ Physician and Nurse Associate Accreditation for Witnessing the Administration of Controlled Drugs

The following accreditation must be completed before a practitioner is deemed competent to act as a witness to the receipt or administration of controlled drugs.

Guidance:
- Only staff deemed suitable by the ward manager should be put forward for this accreditation.
- The accreditation is for witnessing of simple administration only and does not cover injectable medicines.
- Ward managers’ signing off competence must stress the importance to accredited staff of challenging poor practice and escalating as appropriate.

<table>
<thead>
<tr>
<th>Policy/ Procedure Title</th>
<th>Location</th>
<th>Date</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rules Relating to all activities involving controlled drugs</td>
<td>Doc Library</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ward and Department Standard Operating Procedure for Controlled Drugs – Royal Cornwall Hospital, Treliske</td>
<td>Ward CD file</td>
<td></td>
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<tr>
<td>Guidance on Governance Arrangements to Medicines</td>
<td>Doc Library</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Medicines Policy</td>
<td>Doc Library</td>
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</tbody>
</table>

Remember to also sign off the ward SOP training record: □
Assistant Practitioner/ Physician and Nurse Associate Accreditation for Witnessing of Controlled Drugs Activities

Observation

Observe 5 occurrences of two nurses/ midwifes/ ODPs/ suitably trained AP *administering / witnessing the administration* of controlled drugs to a patient.

<table>
<thead>
<tr>
<th>Date</th>
<th>Pt Initials</th>
<th>Drug Involved</th>
<th>Signature of trainee</th>
<th>Name and Signature of registered nurse/ midwife/ ODP</th>
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<tbody>
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</table>

Observe 5 occurrences of two nurses/ midwifes/ ODPs/ suitably trained AP *receiving / witnessing receipt* of controlled drugs into the register.

<table>
<thead>
<tr>
<th>Date</th>
<th>Pt Initials</th>
<th>Drug Involved</th>
<th>Signature of trainee</th>
<th>Name and Signature of registered nurse</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Comments by trainee:

Comments by trainers/ supervisors:

Sign Off of Competence:

AP:  
Date: 

Ward Manager:  
Date: 
Appendix 6. Patch sticker

![Fentanyl or Buprenorphine Patch Sticker](image)

<table>
<thead>
<tr>
<th>Patch: (Please tick)</th>
<th>Fentanyl</th>
<th>Buprenorphine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old patch removed</td>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>New patch applied</td>
<td>Location:</td>
<td></td>
</tr>
<tr>
<td>Area of the body new patch applied to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign:</td>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Print:</td>
<td>Time:</td>
<td></td>
</tr>
</tbody>
</table>