Royal Cornwall Hospitals
NHS Trust

Ward, Theatre and Department Controlled Drugs Standard Operating Procedure

V14.2

July 2024

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

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

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

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

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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.
- Suggested considerations in process changes for covid-19 scenarios (Appendix 7).

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 Controlled Drug Assurance Group and 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.

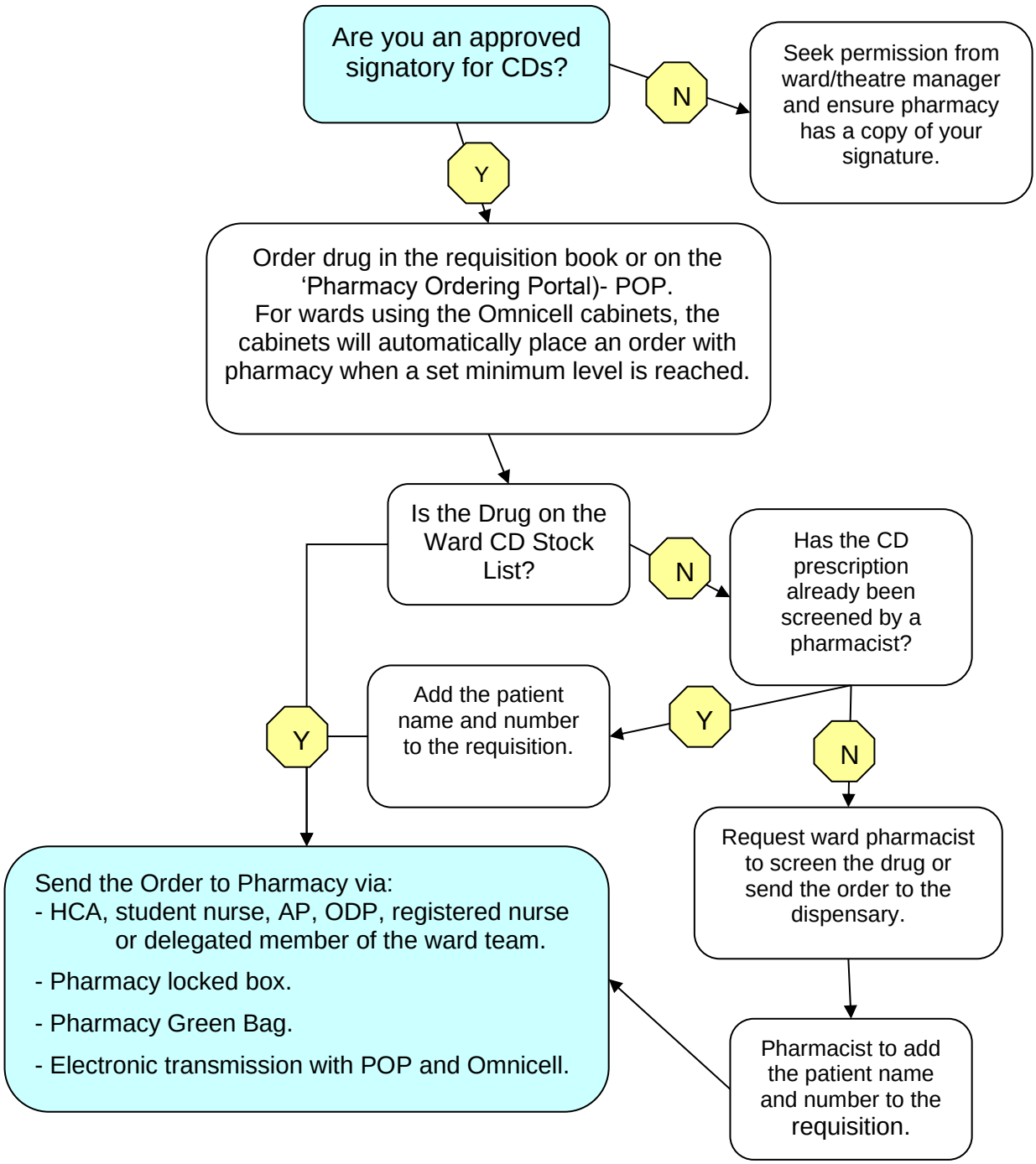
3.4. Role of Individual Staff

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)



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 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.

4.2.3. 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.

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

4.2.5. 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.

4.2.6. 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.

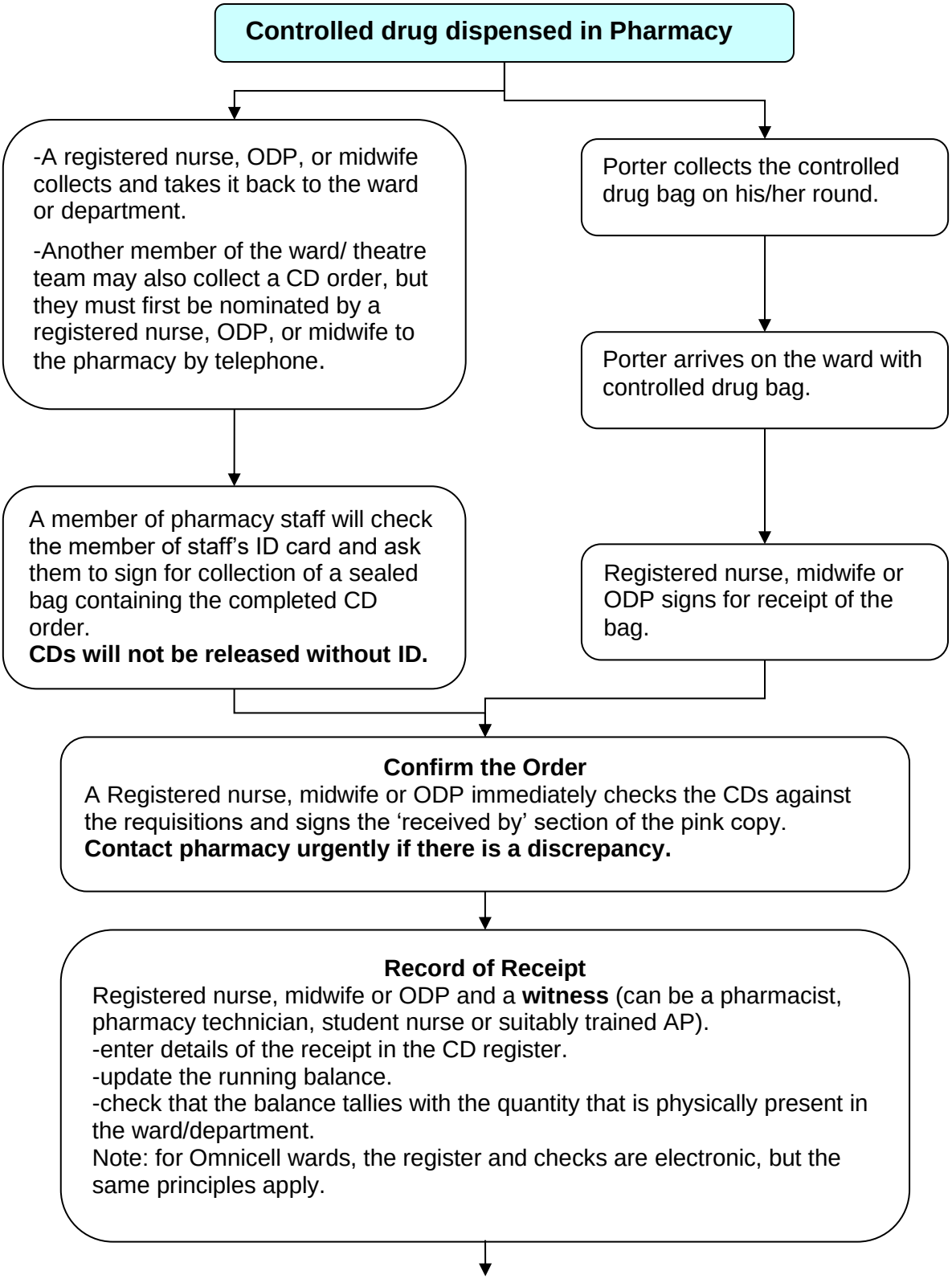
4.2.7. For POP and Omnicell orders, these are electronically transmitted to the pharmacy department and printed out/processed within pharmacy.

4.2.8. **Accessing Controlled Drugs Out of Hours**

4.2.8.1. 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.

4.2.8.2. 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**



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.

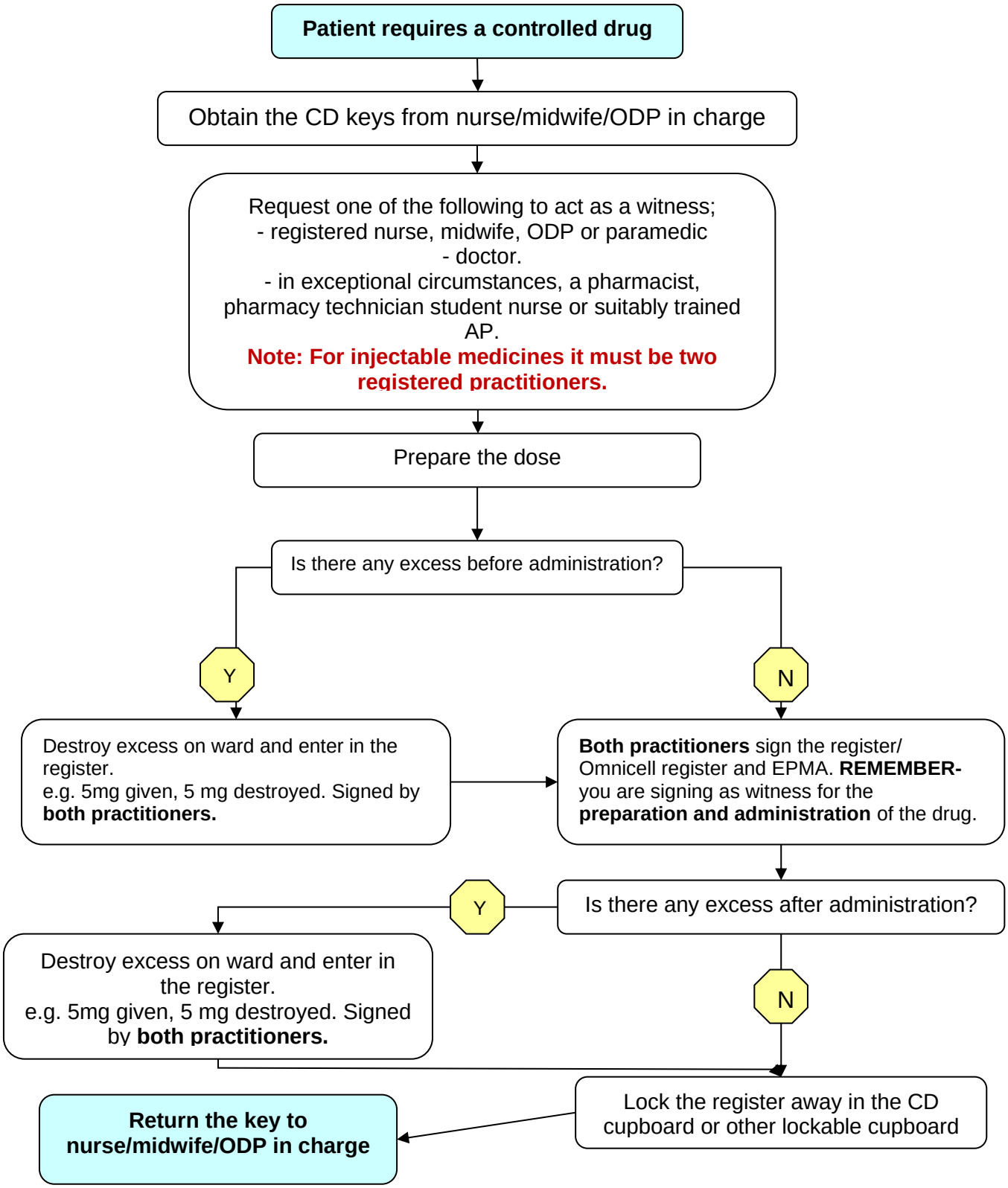
4.3.3.4. Enter details of the receipt in the CD record book, update the running balance and check that the balance tallies with the quantity that is physically present in the ward or department (see section 5 below).

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**



REMEMBER- THE WHOLE ADMINISTRATION PROCESS MUST BE WITNESSED (with the exception of administration during anaesthesia- see section 4.4.3)

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. Paramedic independent prescribers are allowed to prescribe and administer, and direct others to administer, the following five controlled drugs: morphine sulfate (oral, injection), diazepam (oral, injection), midazolam (oralmucosal, injection), lorazepam (injection) and codeine phosphate (oral).

4.4.1.4. 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, paramedic 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.

4.4.1.5. 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).

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

4.4.1.7. 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.

4.4.1.8. 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).

4.4.1.9. 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).

4.4.1.10. 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 "Self-Administration of Medicines (SAM)- Assessment and Consent form"

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.

4.4.2.9. Application of Opioid Patches

4.4.2.10. 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.

4.4.2.11. If the previous patch cannot initially be found on the patient's skin, it is important that this is investigated before a new patch is applied. The patient's skin must be searched thoroughly. The

patient would be at risk of opioid toxicity if a new patch is applied with the previous patch in situ. The administering and witnessing practitioners must both make the decision that it is safe to proceed with the application of the new patch.

4.4.2.12. On application of a new patch, record the relevant information on the 'Opioid 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.

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

4.4.3. **Administration of Controlled Drugs for the Purpose of Anaesthesia**

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

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

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

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

4.4.3.5. Timings of administration for purposes of anaesthesia is not required.

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 registered.

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 Standard Operating Procedure (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 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 and 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.

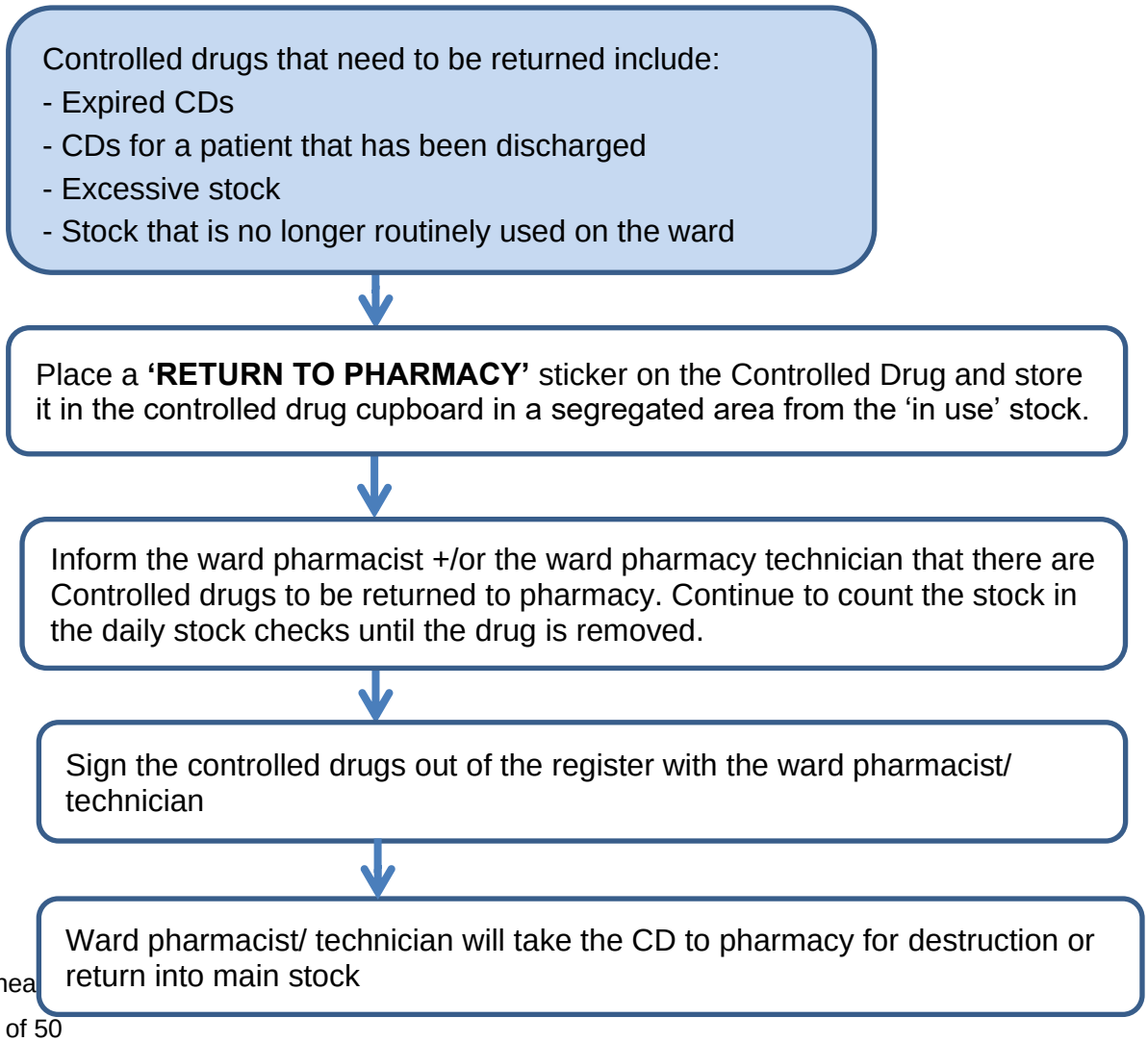
4.6.7. Stock balances of liquid medicines may be checked by visual inspection, but the balance must be confirmed to be correct on completion of a bottle.

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



4.7.1. Unwanted stock or unwanted patients own CDs of Schedule 4 drugs zaleplon, zolpidem and zopiclone and the schedule 5 drug morphine sulphate 10mg in 5ml solution can be destroyed on the ward with pharmacy involvement and do not need returning to pharmacy. Disposal must be witnessed by a pharmacist or pharmacy technician and documented in the CD register with Date of destruction, Quantity being destroyed, Name and signature of the authorised person who witnesses the destruction, Name and signature of the pharmacist or pharmacy technician destroying the drug. Disposal must be in accordance with the requirements of chapter 5 of the Trust Medicines Policy using DOOP kits. For patients own CDs see also section 4.9.1.10

4.7.2. For schedule 2 and schedule 3 CDs, 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.

4.7.3. **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.

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

4.7.5. **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.

4.7.6. 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.

4.7.7. 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.

4.7.8. 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.

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

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 4.4.

4.8.6. Disposal of complete doses of CDs should be done via the pharmacy department as set out in section 4.7.10.

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. For patients with known substance misuse/ dependency issues who are regularly prescribed medicines that might be harmful in overdose (e.g., opioids or benzodiazepines), satisfy yourself that the patient in not concealing a personal supply of these medicines which may be used 'on top' of medicines prescribed by the hospital during their admission.

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

4.9.1.7. Check:

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

4.9.1.8. 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.

4.9.1.9. 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.

4.9.1.10. 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 and 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 4.7

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 kits (e.g., RSI kits) and blister packs containing 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 keyring 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) which refers to the Security of FP10HNC Prescription Forms Policy regards safe storage and must maintain a full audit trail of usage.

4.14. Illicit Drugs (and New Psychoactive Substances)

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 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 or if is a small quantity of illicit substance for personal use, authority will be given for 2 members of senior pharmacy team and/or the CD accountable officer to destroy the drugs.

4.14.8. The Trust has a responsibility to maintain patient confidentiality unless disclosure of an individual patient's information would be in the greater public interest. As a result, suspected illicit substances handed over by the patient should be handed to the Police at the earliest convenience (normal working hours). This would normally be as an ANONYMOUS supply, giving no patient specific information. Hence name of the patient as in section 4.14.3 should be removed prior to the Police attendance.

4.14.9. New Psychoactive Substances (aka NPS or 'legal highs') are illegal as of the 26 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.

4.14.10. The drug liaison Police can be contacted through the 101 (as an external) telephone number. As in 4.14.8 Patient details should not be provided to the Police unless felt to be in the public interest e.g. if it appears the person may be involved in supply then it is good practice to report to police. Pointers to supply may include large quantity of the illicit substance, having lots of cash, scales, or multiple mobile phones.

4.14.11. 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 via switchboard.

- 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.

- 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 content and not the person conducting the search who will be present to monitor and observe.

- 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.

- The police only wish to get involved if there is an absolute crime with a suspect established through the internal investigation process.

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 scanned and emailed back to the pharmacy department at RCHT stating that the correct order has arrived safely. **This must be signed and returned 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/scanned and emailed 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, Schedule 3 drugs including buprenorphine, midazolam, temazepam, tramadol, gabapentin and pregabalin, and the Schedule 4 drugs zaleplon, zolpidem tartrate, and zopiclone

4.18.1. Although not Schedule 2 CDs, Schedule 3 controlled drugs, for example buprenorphine, midazolam, tramadol, gabapentin and pregabalin, Schedule 4 drugs zaleplon, zolpidem and zopiclone, and the schedule 5 drug morphine sulphate 10mg in 5ml solution, must be ordered in the CD order book or on POP 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 or on POP 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, morphine sulphate 10mg in 5ml solution and zaleplon, zolpidem and zopiclone 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 hours 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

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	All elements of this SOP.
Lead	The accountable officer for controlled drugs and the chief pharmacist.
Tool	A number of different tools will be used to monitor this policy. 1. Ward CD audits undertaken by pharmacy. 2. Daily checks at ward level. 3. Review of all Datix incidents by the CD accountable officer and a quarterly report for the Trust and to the CDLIN. 4. Pharmacy safe and secure audits of all ward and clinical areas. 5. Ward level audits and matron walk rounds.
Frequency	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.
Reporting arrangements	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).
Acting on recommendations and Lead(s)	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.
Change in practice and lessons to be shared	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.

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 And Inclusion Policy or the Equality and Diversity website.

8.2. Equality Impact Assessment

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

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Ward, Theatre and Department Controlled Drugs Standard Operating Procedure V14.2
This document replaces (exact title of previous version):	Ward and Department Standard Operating Procedure for Controlled Drugs V14.1
Date Issued/Approved:	May 2024
Date Valid From:	July 2024
Date Valid To:	10 May 2025
Directorate / Department responsible (author/owner):	Iain Davidson, Chief Pharmacist
Contact details:	01872 252593
Brief summary of contents:	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.
Suggested Keywords:	Use this section to suggest keywords to be added by the Uploader to aid document retrieval.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Controlled Drug Assurance Group. Medication Practice Committee. Clinical Support Care Group Meeting.
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright, Governance Lead
Links to key external standards:	None required

Information Category	Detailed Information
Related Documents:	RCHT Controlled Drug Policy
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
	V1.0-7.0	Local procedural documents, not published on Documents Library	Chief Pharmacist
October 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	Chief Pharmacist

Date	Version Number	Summary of Changes	Changes Made by
		surgical areas.	
December 2018	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
March 2019	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 2019	V12.1	- Added in index table. - Amend gabapentin/ pregabalin section 14.17 for other schedule 3 drugs. - 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).	Iain Davidson, Chief Pharmacist
July 2020	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	Iain Davidson Chief Pharmacist

Date	Version Number	Summary of Changes	Changes Made by
		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.	
May 2021	V13.1	- 4.4.3.2 Addition of information regarding escalation, if previous opioid patch cannot be located for removal. Learning from Serious incident where previous patch was not removed.	Ann Cardell, Medication Safety Pharmacist
July 2021	V13.2	- Addition of 4.4.4.5 regarding timing of administration in anaesthesia (not required). New patch sticker at Appendix 6.	Mike Wilcock, Head of Prescribing Support Unit
April 2022	V14.0	- Addition of text at 4.10.1.3. - Addition of text to 4.14.8 and 4.14.10 regarding Police contact and patient confidentiality. - Addition of text 14.13.12 regarding new FP10HNC policy. Changes to process due to covid-19- appendix 7.	Mike Wilcock, Head of Prescribing Support Unit
June 2023	V14.1	- Inclusion of stricter controls for Z drugs at 4.18. - Inclusion of pharmacy involvement in destroying certain CDs on the ward at 4.7.1.	Mike Wilcock, Head of Prescribing Support Unit
May 2024	V14.2	- Inclusion of text relating to paramedics and CDs at 4.4.1.3. - Change in information when to involve the police 4.15.7.	Mike Wilcock, Head of Prescribing Support Unit and Ann Cardell, Pharmacy

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

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

This document is only valid on the day of printing.

Controlled Document.

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

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

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

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

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Ward, Theatre and Department Controlled Drugs Standard Operating Procedure V14.2
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Iain Davidson, Chief Pharmacist
Contact details:	01872 252593

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	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 each 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? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No

Information Category	Detailed Information
	• Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Medication Practice Committee.
6c. What was the outcome of the consultation?	Agreed
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

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

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

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

Protected Characteristic	(Yes or No)	Rationale
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

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

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

Name of person confirming result of initial impact assessment:
Iain Davidson, Chief Pharmacist

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

Appendix 3. SOP sign-off

To be printed (not available separately).

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.

Date Read	Name (please print)	Designation	Signature

Appendix 4. Controlled Drugs – Daily Stock Check Record

To be printed (not available separately).

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.

	Time	Nurse 1 or ODP3 Signature	Nurse 1 or ODP3 Print Name	Nurse 2 or ODP3 Signature	Nurse 2 or ODP3 Print Name	Stocks checked and correct	Discrepancies found	Datix completed and pharmacy notified
1st	__:__							
	__:__							
2nd	__:__							
	__:__							
3rd	__:__							
	__:__							
4th	__:__							
	__:__							
5th	__:__							
	__:__							
6th	__:__							
	__:__							
7th	__:__							
	__:__							
8th	__:__							
	__:__							

	Time	Nurse 1 or ODP3 Signature	Nurse 1 or ODP3 Print Name	Nurse 2 or ODP3 Signature	Nurse 2 or ODP3 Print Name	Stocks checked and correct	Discrepancies found	Datix completed and pharmacy notified
9th	__:__							
	__:__							
10th	__:__							
	__:__							
11th	__:__							
	__:__							
12th	__:__							
	__:__							
13th	__:__							
	__:__							
14th	__:__							
	__:__							
15th	__:__							
16th	__:__							
	__:__							
17th	__:__							
	__:__							
18th	__:__							
	__:__							
19th	__:__							
	__:__							
20th	__:__							

	Time	Nurse 1 or ODP3 Signature	Nurse 1 or ODP3 Print Name	Nurse 2 or ODP3 Signature	Nurse 2 or ODP3 Print Name	Stocks checked and correct	Discrepancies found	Datix completed and pharmacy notified
	__:__							
21st	__:__							
	__:__							
22nd	__:__							
	__:__							
23rd	__:__							
	__:__							
24th	__:__							
	__:__							
25th	__:__							
	__:__							
26th	__:__							
	__:__							
27th	__:__							
	__:__							
28th	__:__							
	__:__							
29th	__:__							
	__:__							
30th	__:__							
	__:__							
31st	__:__							

Appendix 5. Practitioner Accreditation Records

To be printed (not available separately).

Royal Cornwall Hospitals NHS Trust

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.

NAME: JOB TITLE: CLINICAL AREA:

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.

Policy/ Procedure Title	Location	Date	Signature
Rules Relating to all activities involving controlled drugs	Document Library		
Ward and Department Standard Operating Procedure for Controlled Drugs – Royal Cornwall Hospital, Treliske	Ward CD file		

Policy/ Procedure Title	Location	Date	Signature
Guidance on Governance Arrangements to Medicines	Document Library		
The Medicines Policy	Document Library		

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.

Date	Pt Initials	Drug Involved	Signature of trainee	Name and Signature of registered nurse/ midwife/ ODP

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

Date	Pt Initials	Drug Involved	Signature of trainee	Name and Signature of registered nurse

Comments by trainee:

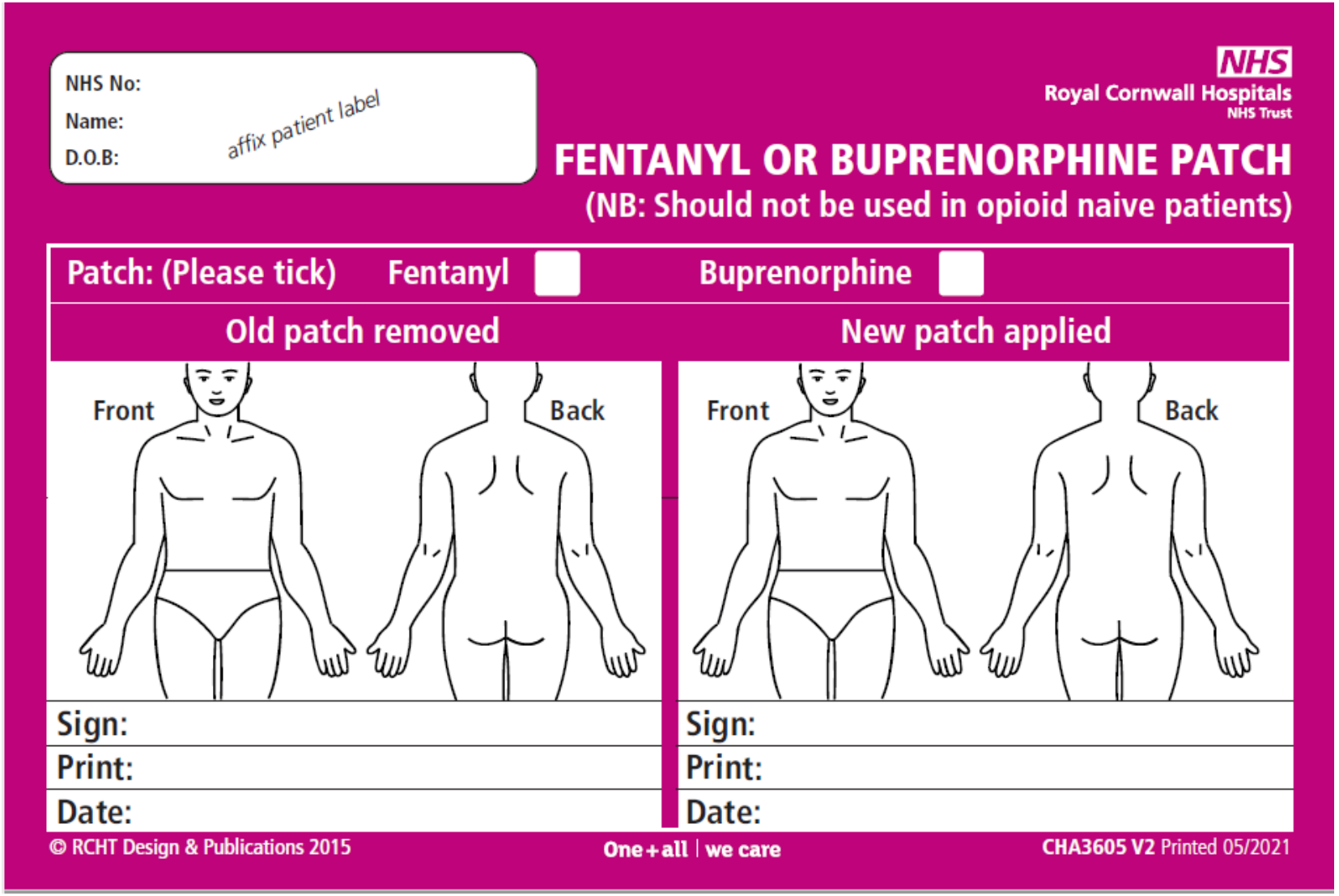
Comments by trainers/ supervisors:

Sign Off of Competence:

AP: Date:

Ward Manager: Date:

Appendix 6. Patch sticker



These stickers will be automatically supplied by pharmacy with the supply of opioid patches.

Appendix 7. Amendments to the Controlled Drugs Policy and Procedures During the COVID-19 Pandemic

- Summary of changes to CD policy are set out below.
- These changes should only be considered for adoption in clinical areas impacted by COVID pandemic e.g. due to infection control strategies, use of PPE and availability of staff.
- When implementing these changes staff should remain alert to the possibility of drugs are going missing and report in the usual way.

	Potential Policy Change	Details of Change
1.	Storage and register arrangements for; • Oramorph liquid 10mg/5ml. • Tramadol. • Gabapentin. • Pregabalin. • Diazepam.	Clinical areas can make a local decision regards relaxing the controls on these medicines. These relaxations include: • Not having to store them in a CD cupboard. • Not having to record them in a CD register. • No requirement for double signature witnessing on administration. • Porters will transport them as per normal drugs.
2.	Double signature requirements for all controlled drugs in CD registers.	There is no legal requirement for a double signature for controlled drug administrations. Where this is operationally difficult this could be relaxed.
3.	Wet signatures on discharge and outpatient prescriptions for Schedule 2 and 3 controlled drugs **for RCHT** prescriptions. For example; • Morphine inj and tabs. • Fentanyl. • Oxycodone. • Alfentanyl. • Buprenorphine. • Tramadol. • Gabapentin. • Pregabalin.	It remains a legal requirement to have a wet signature (or formal electronic signature) on the prescriptions for Sch 2and3 controlled drugs. To reduce the infection risk of paper being sent from Covid areas to the dispensary, an independent prescribing pharmacist will countersign the prescription on receipt, allowing the prescriptions to be printed off in the dispensary. The pharmacist will first check that the dose is safe and reasonable as part of the routine clinical pharmacist check of the prescription. This applies even for IPs whose usual scope of practice might be different to the clinical specialty of the prescription. The signature is to meet legal requirements. The clinical responsibility for the prescription rests with the original prescriber. The CD register entry should record the name of the signatory IP pharmacist and the original prescriber.
4.	Dispensing from scanned	In an emergency situation, pharmacy can dispense

	Potential Policy Change	Details of Change
	copies of prescriptions and requisitions from outside hospitals and other external bodies e.g. GP practices	controlled drugs from a scanned prescription or requisition on the proviso that the original is provided within 24 hours. To facilitate the rapid distribution of medicines around the county, the COVID pandemic is viewed as an 'emergency situation'. Failure to provide an original is an offence on the part of the prescriber. Through intelligent anticipatory ordering it should be possible to provide an original order ahead of a supply but where this has not occurred and there is an immediate then it can be dispensed. **A request has been submitted to review the law requiring wet signatures on CD requests but as things stand- this remains the legal requirement.**
5.	Dispensing a stock requisition for a different legal entity with no prescriber signature.	It remains a legal requirement for a requisition to be signed by a healthcare professional that is legally allowed to requisition medicines e.g. a Dr, pharmacist, paramedic etc. This only applies when dealing with separate legal entities. If, for example, a community hospital requires stock controlled drugs and has no access to a prescriber, the requisition should be signed by two nurses and can be dispensed by RCHT against a scanned copy. The requisition should be signed retrospectively by an appropriate healthcare professional and provided to RCHT within 24 hours of the request.
6.	Destruction of CDs on wards- DUPE kits	Schedule 3,4 and 5 and patients' own controlled drugs can be destroyed on the ward by the ward or pharmacy staff. DUPE kits will be provided and once full, placed with the other pharmaceutical waste for destruction. The appropriate CD register, and patients own CD register records should be made. Schedule 2 stock controlled drugs must be destroyed by a Home Office authorised witness- the chief pharmacist. For non-covid areas, these medicines can be returned to pharmacy for destruction at a later date. For Covid areas, the chief pharmacist will attend the area to complete the destruction on the ward.
7.	CD checks end of shift- moving to once a day	Some areas, at the discretion of the leadership team for the area, can move to once a day rather than end of each shift controlled drug checks.