Standard Operating Procedure

Title: Controlled Drugs in Community Services (including Community Hospitals, Community Nursing and Community Units)	
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Links to policies:	**Medicines Policy for Registered Professionals**

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1. Purpose of this SOP

To ensure all legal requirements of the Misuse of Drugs Act (1971) and the Controlled Drugs (Supervision of Management and Use) Regulations 2006 are met when Controlled Drugs are used within **Community hospital wards and Minor Injury Units (MIUs).**

2. Scope of this SOP

All registered nursing staff will work under professional codes of practice and within organisation polices and associated documents.

Registered Professionals who are trained, competent and authorised to prescribe, order, receive, storage, administration, recording keeping and destruction of controlled drugs.

3. Competencies Required

Registered professionals employed by the Torbay and Southern Devon Health Care and NHS trust in ward, unit and community settings with responsibility for handling controlled drugs.

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4. Patients Covered

All patients receiving Controlled Drug interventions (prescribing, administration, supply, disposal or destruction) when receiving care from registered TSDHCT staff**.**

5. Definitions

5.1 The Misuse of Drugs Act 1971 and its Regulations control the availability of drugs that are considered sufficiently 'dangerous or otherwise harmful', with the potential for diversion and misuse.

5.2 The drugs that are subject to the control of the Misuse of Drugs Act 1971 are listed within the Act and are termed 'Controlled Drugs' (or 'CDs').

5.3 The Misuse of Drugs Regulations 1985 and updated in 2006, divide CDs into five 'Schedules', which dictate the degree to which a CD's use is regulated. The Schedule in which a CD is placed depends upon its medicinal or therapeutic benefit balanced against its harm when misused. Schedule 1 CDs have the highest level of control, with Schedule 5 CDs having the lowest controls.

5.4 The schedule 1 controlled drugs have no recognised medicinal use although Sativex© (a cannabis-based product) is exempt from the requirements for a

specific licence to be held by the pharmacist or prescriber, and is currently being supplied on a named-patient basis.

5.5 This Standard Operating Procedure applies to:

- **All Schedule 2 CDs including more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.**
- **All Schedule 3 CDs include a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in schedule 2, or are less harmful if misused.**
- **Schedule 4 is split into Part 1 (CD Benzodiazepines and Ketamine) and Part 2 (CD anabolic and androgenic steroids such as testosterone, together with clenbuterol [adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).**
- **Schedule 5 CDs includes Morphine Sulphate 10 mg/5 mL oral solutions.**

5.6 A list of commonly prescribed Schedule 2 and 3 controlled drugs is included as **Appendix 1.**

5.7 A 'competent witness' is defined as any registered or unregistered staff member employed by, or working via a Service Level agreement for, Torbay and Southern Devon Health and Care Trust, who is authorised and competent to undertake the specified task.

5.8 An 'authorised person' is a person specified under the Misuse of Drugs Regulations 2001 Regulation 27, to witness the destruction of controlled drugs stock. The Department of Health has extended this list to include any person who is directly accountable to a director of an NHS Primary Care Trust, NHS Trust or NHS Foundation trust.

5.9 An 'authorised witness' is a suitably qualified person, specifically authorised by the organisation's Accountable Officer for controlled drugs to witness destruction of ward stock controlled drugs. An authorised witness should be subject to a professional code of ethics and/or have been subject of CRB checks and should have appropriate training. The Head of Medicines Optimisation is responsible for agreeing authorised witnesses with the Accountable Officer for controlled drugs, to ensure appropriate arrangements are in place for controlled drugs destruction.

5.10 High strength opiates: The term 'high strength opiates' applies to any single ampoule or vial of morphine or diamorphine injection that is equal to or greater than 30mg.

5.11 Within this document 'Community Hospitals and Units' refers to community hospital wards, outpatients, minor injury units, other trust units or buildings (e.g. trust dentistry) where stock controlled drugs are stored

5.12 Within this document 'Community Nursing Services' refers to district nurse, community nurses, community matrons, specialist nurses etc. who provide care in the patients home

6. Access to Controlled Drugs (CDs) in Community Hospitals and Units Only

6.1 The registered practitioner in charge will have overall responsibility for the safe and appropriate management of CDs within the Community Hospital and Units. In his / her absence another registered practitioner will take responsibility.

6.2 There must be two sets of keys for each Controlled Drug cupboard / cabinet. The ward/theatre keys must be stored separately from the duplicate set, which must be stored in a secure location on the premises.

6.3 Spare CD cupboard keys must be stored securely away from the clinical area where they may be used.

6.4 The registered practitioner in charge is accountable for the correct storage of all medicines in the hospital / unit, including any controlled drugs. The registered practioner can be a GP, doctor on ward, ward matron and sister or staff nurse in charge.

6.5 CD keys must be stored on a separate key ring from other medicine cupboards to ensure that only authorised staff can access controlled drugs.

6.6 The registered practitioner in charge is responsible for the CD key and must know its whereabouts at all times.

6.7 Key holding may be delegated to another suitably trained registered practitioner but the legal responsibility remains with the registered practitioner in charge.

6.8 The CD key must be returned to the registered practitioner in charge immediately when used by another registered member of staff.

6.9 On occasions, for the purpose of stock checking or audit, the CD key may be handed to other authorised staff e.g. pharmacist, pharmacy technician.

6.10 If the CD keys are missing, the registered practitioner in charge must ensure that the controlled drugs are secure and that medication is available for patients in a timely manner.

6.11 Urgent efforts must be made to retrieve the keys as speedily as possible, e.g. by contacting nursing staff that have just gone off duty.

6.12 If the CD keys cannot be found this must be reported immediately to line manager or matron. If none of these staff are available, then it should be reported to the on-call manager.

6.13 All incidents must be recorded on the Torbay and Southern Devon Health and Care NHS Trust via I-care website on the Datix Web Incident Reporting system. The Quality and Experience Team can be contacted by email on incidentreporting.t-sd@nhs.net for help and support.

7. Ordering Ward / Unit Stock Controlled Drugs (CDs) in Community Hospitals and Units

General Principles for ward / unit controlled drug stock lists:

7.1 The ward / unit controlled drugs stock list must be agreed with the supplying Trust Torbay pharmacy. The content of the stock list must reflect current patterns of controlled drugs usage by the ward or department. The CD stock list should be agreed between supplying Torbay Pharmacy and the medicines optimisation team, the registered practitioner in charge and, if appropriate, a member of the medical staff.

7.2 High strength opiates* must not be kept as stock, but ordered for specific patients where appropriate.

7.3 Only controlled drugs listed as stock will be routinely requisitioned via Controlled Drug requisition with authorised signatory.

7.4 The registered practitioner can delegate the task of preparing a requisition to another, such as another registered practitioner. However, a legal responsibility remains with the registered practitioner in charge.

When ordering controlled drugs:

7.5 Stock levels must be assessed prior to ordering to ensure excess stock is not held.

7.6 Orders for CDs must be made in the designated CD requisition book for the department, ward or unit, with each item being ordered on separate and successive pages.

7.7 CD requisition books must be stored securely when not in use. It is good practice to ensure that there are maximum two controlled drug order / requisition books per ward / unit. The need for spare CD requisition books should be risk managed and when not in use should be securely stored to prevent usage.

7.8 CD requisitions must be signed by an authorised registered practitioner and must be countersigned by a doctor, dentist or pharmacist. The doctor, dentist or pharmacist will be employed by the Trust. See **Appendices 2 and 3.**

7.9 A copy of the signature of each authorised signatory must be available in the supplying hospital pharmacy department for validation. A sample signature page should be kept in the inside cover of each requisition book. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition CDs.

7.10 Requisitions must contain the following information:

- Name of the community hospital
- Ward / department
- Drug name, form, strength, ampoule size if more than one available

- Brand name for fentanyl patches (e.g. Durogesic®), Morphine Sulphate M/R (e.g. MST and Zomorph)
- Total quantity
- Signature and printed name of registered nurse
- Countersigned signature by doctor, dentist or pharmacist
- Date
- Signature of person issuing the item from the pharmacy
- Signature of person checking the item from the pharmacy
- Each item must be ordered on separate and successive requisition pages.

7.11 The authorisation form for the ordering of CDs (Appendix 3), or supplying Torbay hospital pharmacy equivalent form, must be completed by each member of staff employed or contracted by Torbay and Southern Devon Health and Care NHS Trust who will be signing or countersigning CD requisitions. A copy of this form is to be retained by the ward or department by the matron and the original submitted to the supplying Trust pharmacy.

7.12 High strength opiates* must only be ordered when required to meet an individual patient's needs.

7.13 When ordering high strength opiates*, the requisition may need to be accompanied by a copy of the named patient Prescription and Medication Administration Record, according to the procedures of the supplying Trust pharmacy.

7.14 When ordering CDs during the out of hours period, liaise with the supplying trust's on-call pharmacist.

7.15 CDs must not be lent or borrowed between departments / wards and should only be removed from the controlled drugs cupboard for immediate administration to a patient for whom the medicine is prescribed, who maybe on another ward.

*** High strength opiates:** This term applies to any single ampoule or vial of **morphine or diamorphine injection, that is equal to or greater than 30mg**.

8. Collection of Controlled Drugs in Community Hospitals and Units and Community Nursing Services

In the community setting, the collection of CDs dispensed for a named patient is the responsibility of the patient or carer. In exceptional circumstances, a Torbay and Southern Devon Health and Care NHS Trust employee may collect a CD from the pharmacy or dispensing practice, where they will be asked to sign as the patient's representative and prove identity by the pharmacist or dispensing practice. Any CDs collected must be kept secure and out of sight within their vehicle and taken directly to the patient's home or inpatient setting from the pharmacy or dispensing practice.

9. Receipt of Controlled Drugs (CDs) in Community Hospitals and Units and Community Nursing Services

Hospital / Unit Stock

9.1 Controlled Drugs received by the ward / unit must be signed for on receipt, and the receipt returned / faxed to the supplying Trust pharmacy, according to local procedure, to complete the audit trail.

9.2 The registered practitioner is accountable to carry out receiving process as soon as they receive controlled drugs from Torbay hospital pharmacy.

9.3 The controlled drugs received must be checked against the requisition including the number ordered and received to ensure that the supply received reconciles with the order. If this is correct then the relevant (usually pink) sheet in the controlled drug requisition book should be signed in the 'received by' section

9.4 Where tamper proof seals on original controlled drug containers are unbroken it may be assumed that the stock contained within is as per pack quantity. There is no need to open original packs to count the contents.

9.5 On recording the receipt in the ward / unit controlled drugs record book, the serial number of the relevant requisition must be recorded and the running balance must be updated, and checked against the physical stock, to ensure they are the same. The entry must be signed by a registered practitioner and competent witness.

9.6 Store the Controlled Drugs in the CD cupboard straightaway.

9.7 If stock is received which is unfit for use, it must be signed for as received in the usual way and entered into the CD record book, including the running balance and reason why the stock is not fit for use. The supplying Trust pharmacy must be contacted, to inform them of the unfit stock received and arrangements for credit and replacement of stock made. The unfit CD stock must be destroyed in accordance with CD Disposal Policy, in the presence of a witness, as detailed in Section 11, and reported in accordance with Torbay and Southern Devon Incident Reporting Policy. The unfit stock must be clearly marked and stored separately from the in-date controlled drugs ward stock / patient's own CDs until destroyed.

Community Nursing Services

9.8 In the community, prescribed medicines remain the property of the patient they are prescribed for at all times.

9.9 After risk assessment and with prior agreement of the client, controlled drugs may be stored after receipt in the patient's home in a suitable locked storage container if this is considered appropriate to reduce risk.

9.10 In the community setting to support therapy offered by trust staff, i.e. syringe driver, all schedule 2 and 3 controlled drugs should be recorded and running stock balances maintained. The pharmacy label should be checked to ensure

that stocks are being kept for the intended client. Tamper evident seals should be left intact until contents are first used.

9.11 Discrepancies must be brought to the attention of the Accountable Officer and reported via the Trust's incident reporting system (see section 19).

9.12 Witnessing of administration by a competent witness should take place wherever possible but it is recognised that this is not always possible in a community setting.

10. Record Keeping: Community Hospitals and Units and Community Nursing Services

Hospital and Units

Organisational policies, associated standard operating procedures and Professional Codes of Practice provide up to date information on the completion of the records / ordering books.

10.1 Ward / unit controlled drugs record books must be ordered from Torbay hospital pharmacy, by completing a requisition within the CD order book.

10.2 Ward / unit controlled drugs record books must be stored within the medicines cupboard, or kept securely in the locked treatment room, where the CD cupboard is located.

10.3 Each area storing controlled drugs must keep separate controlled drugs record books for ward stock and patient's own controlled drugs.

10.4 A separate page must be used for each medicine. The name of the medicine is fully described, form and strength (including brand name if necessary) clearly distinguishing all controlled drugs.

10.5 Entries must be in chronological sequence, made on the day of the transaction.

10.6 All entries must be signed by a registered practitioner and competent witness.

10.7 When pages are complete the page where the next entry is made must be clearly indicated and the indices updated accordingly.

10.8 Entries in the controlled drugs record book must not have any cancellations, obliteration or alteration. Corrections must be made as a timed, dated and signed separate entry on a new line, in the margin or as a footnote at the bottom of the page or If a mistake is made, it should be crossed out with a single line or bracketed in such a way that the original entry is still clearly legible. This should be signed and dated, and witnessed by a second registered nurse

10.9 Ward / unit controlled drugs record and requisition books must be kept in their original form for two years from the last date of entry.

10.10 For administration of controlled drugs, see Section 14.

10.11 Any discrepancies found must be dealt with according to Section 19 of this document "Dealing with Discrepancies".

10.12 See Section 15 for stock balance / checking procedure.

Community Nursing Services

10.13 Use approved and standard documentation for record, receipt, stock and administration, stock adjustment and disposal.

10.14 Principles of recording are the same as on a ward setting except a competent witness is required only when available.

10.15 See Section 15 for stock balance / checking procedure.

11. Storage of Controlled Drugs (CDs)

11.1 Community Hospitals and Units

11.1.1 The Misuse of Drugs (Safe Custody) Regulations 1973 covers the safe custody of controlled drugs in certain specified premises. The regulations also set down certain standards for safes and cabinets used to store controlled drugs which are described in **Appendix 4.**

11.1.2 General measures for storage of CDs include the following:

- Cupboards must be kept locked when not in use.
- The lock must not be common to any other lock in the hospital.
- Keys must only be available to authorised members of staff and at any time the key holder should be readily identifiable.
- The cupboard should be dedicated to the storage of CDs.
- No other medicines or items should normally be stored in the CD cupboard.
- CDs must be locked away when not in use.
- For all CD cupboards follow standards set out in Appendix 4. Cupboards should be of a sufficient size and capacity to ensure safe management of controlled drugs.

High strength opiates* ordered for specific patients must be segregated from lower strength opiates. Appropriate care must be taken to prevent high strength opiates being given to opiate naïve patients. Reducing dosing errors with opioid medicines (NPSA/2008/RRR05)

*** High strength opiates:** This term applies to any single ampoule or vial of **Morphine Sulphate or Diamorphine injection, that is equal to or greater than 30mg**.

11.1.3 Wards / units must ensure that naloxone injection is stored and available in all clinical locations where Diamorphine and Morphine Sulphate injections are stored or administered.

11.1.4 High strength Midazolam (**5mg/ml in 2ml**) must only be stored in community hospital wards for the purpose of palliative care, in accordance with the NPSA Rapid Response Report "Reducing the risk of overdose with midazolam injection in adults (NPSA/2008/RRR011)"

11.1.5 Low strength Midazolam (**1mg/ml in 2mls or 5mls**) must only be stocked in clinical areas where it is used for conscious sedation, e.g. dentistry in accordance with the NPSA Rapid Response Report "Reducing risk of overdose with midazolam injection in adults".

11.1.6 Wards / units must ensure that flumazenil is stored and available for reversal of midazolam side effects in all clinical locations where midazolam injections are stored or administered[2].

11.1.7 Procedures for the storage of controlled drugs during community hospital / ward / unit deep cleaning or closure are detailed in **Appendix 5.**

11.2 Storage of Controlled Drugs (CDs) within Community Nursing Services and Patients Home Environment

11.2.1 The stock balance of all schedule 2 and 3 CDs used to support syringe driver care should be checked and reconciled on each visit.

11.2.2 The stock balance of Schedule 2 and 3 medicines supplied in respect of Just in Case / Anticipatory Prescribing will be in accordance with the relevant Trust Standard Operating Procedure.

11.2.3 Stock balances should be entered on approved Trust documentation for the purpose of recording CD stocks.

11.2.4 Patients own CDs remain the property of the patient. However, there should be a risk assessment undertaken if there are any concerned about storage / safeguarding. Alternative secure storage may be required. However, consent will be needed and recorded.

12. Prescribing of Controlled Drugs (CDs) in Community Hospitals and Units and Community Nursing Services

12.1 Prescribing of controlled drugs must only be undertaken by prescribers, according to their professional competence, expertise and in accordance with prescribing status as identified within their professional registration.

12.2 Wherever possible the prescribing and administration of medicines should be undertaken separately.

12.3 Medical doctors who have not achieved full registration with the GMC are not permitted to prescribe CDs for discharge prescriptions or outpatients.

12.4 Prescribing of controlled drugs should be in accordance with legislation and the Medicines Policy for Registered Professionals.

12.5 Prescribers must complete the Torbay and Southern Devon Health and Care NHS Trust Prescription and Medication Administration Record relevant to area of practice.

12.6 The prescriber must ensure that an accurate medication history (Medicines Reconciliation) has been taken prior to prescribing a controlled drug, to include previous / current medication, formulation and dosing. (This may be done, for example, through discussion with the patient or their representative, the prescriber or through medication records). This must include checking whether the patient is currently wearing any opioid analgesic patches.

12.7 Prescribing for opioid naïve patients: When an opioid medicine is prescribed for the first time, the prescriber must ensure that the appropriate starting dose is prescribed, according to local formulary prescribing recommendations, patient characteristics, the BNF or Summary of Product Characteristics (SPC), available at www.medicines.org.uk. **(See Appendix 6).**

12.8 When increasing the dose of any opioid medicine, the prescriber must ensure that the increased dose is safe for the patient (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose).

12.9 Prescribers must ensure they are familiar with the following characteristics of the active ingredient(s) and formulation: usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

12.10 When reviewing and or changing controlled drugs medication, the prescriber must check the previous doses and formulations that have been administered (including checking whether the patient is currently wearing any opioid analgesic patches).

12.11 If controlled drugs medication is reviewed and changed, the prescriber is accountable for checking and ensuring that any calculation of opiate equivalence is correct and documented in the patient's records.

12.12 The prescribing of midazolam for adult / child conscious sedation will only be undertaken by competent registered practitioners.

12.13 Verbal orders are not permitted for controlled drugs.

13. Prescribing of Controlled Drugs (CDs) on Discharge in Hospital and Units Only

13.1 Prescriptions for Schedule 2 and 3 CDs on discharge prescription, outpatient prescription, GP FP10** and FP10 (HNC)** prescriptions need to satisfy the legal prescription requirements for CDs. Prescriptions for CDs must be indelible, must be signed by the prescriber (their usual, handwritten signature),

be dated and include the prescriber's address. The prescription must always state:

- Patient's full name, address, NHS number or hospital number, and, where appropriate, age.
- Drug name, formulation and, where appropriate, the strength of the preparation.
- Dose to be taken and the frequency.
- Either the total quantity (in both words and figures) of the preparation, or the number (in both words and figures) of dosage units, as appropriate, to be supplied, or in any other case, the total quantity (in words and figures) of the CD to be supplied.
- The words 'for dental treatment only' if issued by a dentist.

** **Temazepam prescribed on FP10 script is exempt from the prescription requirements for controlled drugs.**

14. Administration of Controlled Drugs (CDs) in Community Hospitals and Units and Community Nursing Services

14.1 Administration of CDs should be carried out in accordance with professional codes of conduct and Torbay and Southern Devon Health and Care NHS Trust organisational policies and associated Standard Operating Procedures.

14.2 Staff administering a controlled drug must have access to the authorisation to administer from the signed Prescription and Medication Administration Record for the patient.

14.3 In specialist care units, the authority to administer will be documented and signed on the approved form.

14.4 When a registered practitioner is administering a controlled drug, they must have a clinical and pharmaceutical knowledge of the medication they are administering, including the therapeutic uses of the medicine to be administered, its normal dosage, including the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects, cautions and contra-indications.

14.5 Prior to administration, the registered practitioner must ensure that the medication to be administered meets the clinical needs of the patient.

14.6 Prior to administration, check the patient has no allergies, hypersensitivities or intolerance to the prescribed controlled drug or related compounds.

14.7 If administering the controlled drug via the injectable route, check that the medication has been risk assessed in accordance with the National Patient Safety Agency Alert 20 proforma within the Torbay and Southern Devon Health and Care NHS Trust Injectable Medicines Policy.

14.8 Check that the controlled drug is due to be administered within the time regime established within the Prescription and Medication Administration Record.

14.9 Where equipment is required to administer a controlled drug, staff must be familiar with and competent to use this equipment e.g. Syringe Driver Policy.

14.10 Check patient identity and that the patient is ready to receive the medication.

14.11 Administration process in Community Hospital and Units:

Follow points 14.2, 14.4 – 14.10 and:

14.11.1 The registered practitioner must have the up to date Prescription and Medication Administration Record and the ward controlled drug record book available.

14.11.2 The registered practitioner together with a competent witness will then:

- Select and remove the Controlled Drug (CD) from the CD cupboard.
- Check the name and strength of the selected CD against the Prescription and Medication Administration Record and the ward controlled drugs record book, the latter for stock balance.
- Check the expiry date of the medication.
- If a dose calculation is made, this will be documented by using a Controlled Drug calculation record (**Appendix 7**) that will be included in the patient's clinical records.
- If solid dose form, remove the correct quantity ready for administration.
- If oral liquid formulation, measure and check the correct volume to be administered.
- If injectable formulation, remove the required number of ampoules, and, where appropriate, using the appropriate diluent (which will either be prescribed or under Patient Group Direction), to reconstitute and draw up the dose required.
- Ensure that a record is made in the controlled drugs record book which includes the running stock balance and is checked against the physical amount of stock left (NB: a visual check of liquids is required; the actual volume does not need to be measured, unless a discrepancy is suspected – see section 19).
- The registrant will administer the CD in the presence of the competent witness, and both will sign the controlled drugs record book on completion of administration.
- For oral CDs the patient should be observed to ensure swallowing.

14.11.3 Should the patient decline or be unable to take the CD after it has been prepared, the dose should be discarded in accordance with the section 17.4 of The destruction and disposal of controlled drugs in community hospitals and community nursing services. and witnessed by a competent witness (registered nurse). The omitted dose must be documented in the patient's records and identified on the Prescription and Medication Administration Record, including rationale. The Standard Operating Procedure for Omitted and Delayed Medicines will be followed and the omission will be discussed with a medical practitioner, and the outcome documented.

14.11.4 The competent witness must challenge any step of the checking / witnessing process if procedures are not followed and / or the records do not tally at any point.

14.11.5 The registered practitioner is accountable for completing the administration record on the Prescription and Medication Administration Record.

14.11.6 In exceptional circumstances, where it is necessary for a registered medical practitioner to administer a controlled drug within a Torbay and Southern Devon Health and Care NHS Trust unit or service, the administration must be clearly documented in the patient's clinical record, and will be witnessed by a Torbay and Southern Devon Health and Care NHS Trust employee who will act and sign as the competent witness during all steps of the process (administration, record keeping and reconciliation of stock balances).

14.12 Administration process in Community Nursing Services:

Follow points 14.2, 14.4 – 14.10 and:

14.12.1 Medicines in the community setting are the property of the person for whom they are prescribed and dispensed. Registered and non-registered staff has a supportive, educational and monitoring role in patient self-administration. However, some medication will need to be administered by appropriately trained staff.

14.12.2 Staff must ensure that they have access to the completed Prescription and Medication Administration Record in the home environment and that the authorisation chart is up to date (written within previous 4 weeks).

14.12.3 Staff must ensure that the medication is available within the home environment.

14.12.4 Staff working in the community should not routinely become involved in the delivery or custody of prescribed medicines. Only in exceptional circumstances where transportation of CDs is required in the community, refer to Section 8 (Collection of CDs in the Community).

14.12.5 Registered practitioners delegating the administration of a medicinal product must ensure that team members have the appropriate competence to undertake the procedure and the relevant information to enable the task to be performed safely.

14.12.6 A signed record of any drug administration (including CDs), must be maintained in accordance with clinical record keeping policy, to include the name, form and strength of medicine, dose given, the date, time, route of administration, site of injection if appropriate and any dilution or calculations made. The names of the persons administering and witnessing the drug must also be recorded. Where the CD is witnessed by another member of staff, they must also sign the documentation.

14.12.7 Administration by continuous infusion: Staff must be aware of and adhere to the professional codes of practice, relevant policies, protocols and guidelines ratified by Torbay and Southern Devon Health and Care NHS Trust.

14.12.8 Where other services are involved in the administration of a controlled drug in a patient's own home environment, it is best practice to advise them that there may be a stock balance sheet in the home for them to complete.

15. Controlled Drugs (CDs) Stock and Balance Checking Procedures in Community Hospitals and Units and Community Nursing Services

Hospitals and Units

15.1 A full stock balance check and reconciliation of the physical stock against the running balances for each drug record in the controlled drugs record books (ward stock and patient's own CDs) must be undertaken by a registered practitioner. This must be entered in the CD record book, and checked and countersigned by a competent witness for each CD **on a daily basis** (see below for liquids). The stock balance check counter signatures must be entered on each page corresponding to each CD stocked.

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

15.3 A visual check of oral liquids will also be undertaken. If a discrepancy of more than 20% is suspected on the basis of the visual check, this discrepancy must be investigated and further advice and guidance must be sought from the Medicines Optimisation Team.

15.4 A CD balance check and reconciliation will be undertaken by medicines optimisation staff every three months, by checking and reconciling the CD record and order books against the issue record from the supplying Trust pharmacy. This check must be countersigned by a competent witness.

15.5 If non-stock CDs and/or excess ward stock are identified and its original pack then medicines optimisation team liaise with the supplying Torbay Hospital pharmacy to see if the CDs may be returned according to Section 16 of this document "Return of controlled drugs ward stock in community hospital"

15.6 Any discrepancies found as part of the stock and balance check, must be dealt with according to Section 19 of this document "Dealing with Discrepancies".

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15.7 A full stock balance check and reconciliation of the physical stock against the running balances for each drug record in the controlled drugs record documentation must be undertaken by a registered practitioner. This must be entered in the CD record documentation for each CD **at each visit** and countersigned by a competent witness if available (see below for liquids). The stock balance check counter signatures must be entered on each page corresponding to each CD stocked.

NB: The exception to this rule is that when the registrant is involved with administration of controlled drug transdermal patches, stock reconciliation should be made on the day when patches are changed

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

15.9 All CDs associated with a specified community nurse episode of care (including discontinued CDs) must have a full stock balance, chart and reconciliation at each visit.

15.10 It is recommended that discontinued CDs should only be retained in the home setting for a period of up to seven (7) days after which they should be disposed of (see 17.8 – 17.12).

16 Return of Controlled Drugs (CDs) Ward Stock in Community Hospitals and Units

16.1 Return of ward controlled drug stock will only be in exceptional circumstances and with the prior agreement with the supplying Torbay Hospital pharmacy. This will apply to excess, in date ward stock only, which is in complete, untampered and in original packs.

16.2 The medicines optimisation team pharmacist or technician will be informed that excess CD ward stock needs to be removed, who will make arrangements for the excess stock to be returned, according to the supplying Torbay Hospital pharmacy agreement.

16.3 When returning ward CD stock to the supplying Torbay Hospital pharmacy, a record of the returned stock will be will be made in the ward CD order book, with the page clearly annotated to identify the return.

16.4 When returning ward CD stock to the supplying Torbay hospital pharmacy, an entry will be made in the controlled drugs record book, which includes the running stock balance, which is checked against any physical stock remaining. The entry will be made by the registered practitioner and countersigned by the pharmacist or technician returning the stock to the supplying Trust pharmacy. Controlled drug should be written clearly by the registered practitioner on the controlled drug requisition book with one item per page and this includes full controlled drug name, formulation, strength and quantity to be returned. This entry will be countersigned by the Medicines Optimisation Pharmacist or Technician. Returnable controlled drugs should be securely transferred to the Torbay hospital pharmacy in a sealed Envopak medical carrier which ensures safe and secure transportation of controlled drugs.

16.5 Controlled drugs must not be returned to the supplying Torbay hospital pharmacy in the pharmacy box, bag or by any other means, other than the procedures outlined above.

16.6 If it is not possible to return excess CD ward stock to the supplying Trust pharmacy, the stock will need to be destroyed (see section 17).

17 Destruction and Disposal of Controlled Drugs in Community Hospitals and Units and Community Nursing Services

In Community Hospitals and Units:

17.1 **Ward / Unit stock Schedule 2 CDs** must be destroyed in the presence of an Authorised Person or Witness. The medicines optimisation team are able to advise who is able to act as an Authorised Person or Witness, and will decide who is required to witness CD ward stock destruction.

17.2 A CD Destruction Report sheet (**Appendix 8**) must be completed, signed by the registered professional and the authorised witness.. A copy must be retained on the unit to provide an audit trail.

17.3 In the case of an unexpected / sudden or suspicious death, all medicines, including controlled drugs, relating to the care of that patient must be regarded as evidence and must not be removed or destroyed without the instruction from the Coroner (see relevant Standard Operating Procedures).

17.4 Controlled Drugs ward stock must be denatured and disposed of on the ward / unit ensuring that:

- CDs are denatured prior to safe disposal, following the methods specified in **Appendix 9.**
- CDs are rendered irretrievable so that they cannot be reconstituted or re-used, using a CD denaturing kit prior to safe disposal in a pharmaceutical waste bin.
- A CD destruction kit must be ordered by the ward / unit prior to arranging destruction with the Authorised Witness.
- A 250ml controlled drug denaturing kit DOOP (Destruction of Old Pharmaceuticals) will usually be sufficient for most routine CD destruction, unless large quantities of CDs, particularly liquids, are to be destroyed, in which case a larger volume kit (e.g. controlled drug denaturing kit DOOP 1000ml) will be required.
- Once activated (water added to the indicated level), the CD denaturing kit must be stored in the CD cupboard until it is placed in a pharmaceutical waste bin, which must be kept in a secure location until collected.
- CD denaturing kits can be ordered via the ordering system.

17.5 For ward / unit stock, an entry will be made in the controlled drugs record book, to include the reason for destruction and updated running balance, which will be checked and reconciled with the remaining stock held by the Authorised witness. The Authorised witness will counter sign the CD record book, and will state their professional registration number and authority.

17.6 Small amounts of CDs (below 20 mL or less) that are prepared but not administered can be destroyed by a registered practitioner and witnessed by a competent witness. For example, the surplus CD remaining when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a prepared dose is not used, must be rendered irretrievable by emptying into an appropriate yellow sharps bin with yellow lid and be recorded in the ward controlled drug stock record book. The contents of the container must be

emptied into the bin, together with the emptied vial, ampoule or syringe. When the bin is sent for destruction it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration"*

17.7 Stock that is damaged or broken (vials or ampoules) on the ward must be disposed of in the presence of an Authorised or competent witness, following the procedures described above and reported in accordance with Torbay and Southern Devon Health and Care NHS Trust Incident Reporting Policy. The unfit stock will be clearly marked and stored separately from the in-date controlled drugs ward stock / patient's own CDs until destroyed.

In Community Nurse Services:

17.8 Patients own CDs are and remain the property of that person. Staff working in the community should not themselves routinely remove unwanted or expired medicines, including CDs from a patient's home or possession, either during their care of after the death of a patient. The patient, their representative or family member should be advised to return unwanted or expired medicines to the local community pharmacy for safe disposal.

17.9 In the case of an unexpected / sudden or suspicious death, all medicines, including controlled drugs, relating to the care of that patient must be regarded as evidence and must not be removed or destroyed without the instruction from the Coroner (See Standard Operating Procedure for the Management of Unexpected/Sudden or Suspicious Death of a patient).

17.10 In exceptional circumstances, and for non-Coroner cases, where a risk assessment has been undertaken the medication will be denatured (e.g. using absorbent paper) and placed in a sharps bin for safe disposal. The destruction will be witnessed by a competent witness (which may include a family member where this is appropriate, and will not cause additional distress). In such circumstances it is advisable to obtain written consent for the destruction of medication. Actions taken must be documented.

17.11 When a proportion of a Controlled Drug (CD) remains in a syringe driver or giving set, the residual CD must be denatured on the premises (e.g. using absorbent paper). Disposal must be in a yellow sharps bin with yellow lid. The contents of the container must be emptied in to the bin, together with th emptied vial, ampoule or syringe. When the bin is sent for destruction it should be labelled " *contains mixed pharmaceutical waste and sharps – for incineration*"

17.12 For destruction and disposal of patients own CDs, please see section 18.

18 Patient's Own Controlled Drugs (CDs)

Patient's own controlled drugs are defined as any controlled drug that has been prescribed and dispensed for a specific patient. They are therefore classed as patient property and remain the personal property of that patient.

In Community Hospitals and Units:

18.1 Patient's own controlled drugs must never be considered as ward stock and must not be administered to any other patient.

18.2 **Consent for patients own medication (including Controlled Drugs CD's)** is included in our trust Consent form A, which will be completed (**from i-care website**) on admission, or when any patient's own controlled drugs are brought into the hospital, including 'TTA' (To Take Away) controlled drug medicines from another hospital or Trust, or ordered in readiness for discharge. The patient or carer will sign this form as a record of controlled drugs brought into hospital and consent for destruction if required. The completed form will be kept in the patient's clinical record.

18.3 A separate record book will be kept for recording patient's own controlled drugs received by the ward which will meet the criteria listed in Section 10, using a separate page for each individual controlled drug for each patient, with the patient's name will be recorded at the top of each page.

18.4 Unless a patient is self-administering their medication, any controlled drugs belonging to the patient must be stored within the controlled drugs cupboard / cabinet, in a clearly identifiable, separate area for patient's own controlled drugs.

18.5 In exceptional circumstances, if ward stock is not available which will lead to an unacceptable delay in treatment, the patient's own controlled drug can be administered to them (from a signed Torbay and Southern Devon Care Trust Prescription and Medication Administration Record) until a stock supply has been received by the ward or unit, and providing the patient's own CD is confirmed as the correct drug, be in date and within the original named dispensed container.

18.6 If a patient's own CD is administered to them, an entry must be made in the patient's own controlled drugs record book by the registered practitioner as soon as possible after administration. The entry will include recording the running balance, which will be checked and reconciled against the physical stock remaining and will be checked and countersigned by a competent witness.

18.7 On discharge, if the patient still requires the controlled drug/s belonging to them or a 'TTA' has been ordered (listed on the patient's own controlled drugs record); these will be given to the patient or carer at the point of discharge. An entry must be made in the patient's own controlled drugs record book by the registered practitioner giving the medication, which must be witnessed and countersigned by a competent witness. The patients' own medication record must also be completed and signed as indicated, which must then be filed in the patient's clinical record.

18.8 If the patient's own controlled drugs cannot be returned to the patient, are no longer required, no longer suitable for treatment or are deemed unsuitable for use, these can be denatured and safely disposed of on the ward (See section 17) by a registered practitioner, and witnessed by another registered

practitioner (competent witness), providing that the patient's consent has been given and documented (**Consent form A on i-care**).

18.9 A CD Destruction Report sheet (**Appendix 8**) must be completed, signed by the registered professional and the authorised witness. A copy must be retained on the unit to provide an audit trail

18.10 Once the patient's own controlled drugs have been destroyed, the registered practitioner will record the destruction in the patient's own controlled drugs record book, including the reason for destruction, witnessed and countersigned by the second registered practitioner.

19. Dealing with Discrepancies in Community Hospitals and Units and Community Nursing Services

19.1 If a discrepancy is found between the requisition for CDs ordered and CDs received the supplying Torbay hospital pharmacy should be contacted as soon as possible to investigate the discrepancy.

19.2 If a discrepancy is found between recorded stock and physical stock, check back through the entries for that drug and ensure that there has not been a book-keeping or numerical error in the record. This should be carried out as a priority as soon as a discrepancy is identified.

19.3 If the discrepancy is resolved, a note should be made in the CD record book correcting the discrepancy in the balance and witnessed. Do not cross out or alter any entries, but make a note in the margin or new line or as a footnote in the controlled drugs record book. It is also essential that appropriate records are made of the action taken and the incident / discrepancy reported in accordance with the Trust Incident Policy.

19.4 If the source of the discrepancy cannot be identified the Matron, Senior Nurse, Line Manager or Cluster / Zone Manager within Torbay and Southern Devon Health and Care NHS Trust Services or the senior manager on call must be informed and the incident / discrepancy reported in accordance with the Trust Incident Policy.

19.5 All incidents involving CDs must be brought to the attention of the Accountable Officer for CDs by systems agreed within the incident reporting process and within 24 hours. If in doubt, please contact medicines for advice.

19.6 The Accountable Officer will advise on further action

20. Audit

20.1 The controlled drugs record books (ward stock and patient's own) must be kept in the clinical area to which the record relates and be available for inspection at any time.

20.2 Particulars of stock, receipts and supplies made in relation to controlled drugs must be available and be furnished on request by authorised persons.

20.3 Records relating to the procedures outlined within this Standard Operating Procedure (record books, order records, receipt records and invoices) must be kept for a minimum of two years from the date of the last entry or transaction.

21. Monitoring Tool

Each unit should develop monitoring procedures to show how it will monitor these SOPs. The Accountable Officer, Torbay and Southern Devon Health and Care NHS Trust will request monitoring information as determined by the Medicines Governance Group or in response to a specific incident that he/she is investigating.

Standards:

Item	%	Exceptions
All registered staff to have knowledge of this SOP	100%	nil
How will monitoring be carried out?	Internal audit and signatory sheet	
When will monitoring be carried out?	Annually (or sooner if required)	
Who will monitor compliance with the guideline?	Service leads managerially responsible for delivering care	

References

Safer Management of Controlled Drugs: Changes to Requirements for Requisitions for the Supply of Schedule 1,2 and 3 Controlled Drugs (Department of Health 2007)

A guide to good practice in the management of controlled drugs in primary care (England) (National Prescribing Centre 2009)

Safer management of controlled drugs: guidance on Standard Operating Procedures for controlled drugs (Department of Health 2007)

Safer management of controlled drugs: Monitoring and Inspection work-Primary Care (Department of Health 2006).

Torbay Care Trust SOPs

NHS Devon End of Life Policy Final Version 1.0 October 2009, and associated Standard Operating Procedure.

NHS Devon Provider Services Standard Operating Procedure for the Management of Unexpected/Sudden or Suspicious Death of a patient in NHS Devon Provider Services.

NHS Devon Policy for Waste Management Version 7 and associated health technical memorandum

Nursing and Midwifery Council: The Code. Standards of conduct, performance and ethics for nurses and midwives 2008.

Nursing and Midwifery Council: Standards for medicines management. 2007 updated 2010.

Nursing and Midwifery Council Record Keeping: Guidance for nurses and midwives 2009.

General Pharmaceutical Council: Standards for conduct, ethics and performance. 2014.

General Medical Council: Good Medical Practice. 2006.

The Mental Capacity Act 2005
Safer Management of controlled drugs; A guide to good practice in secondary care(www.dh.gov.uk)

Appendix 1

List of Commonly Prescribed Schedule 2 and Schedule 3 Controlled Drugs covered by this Standard Operating Procedure

Below is a list of the most commonly prescribing controlled drugs. This list is not comprehensive but includes those most commonly prescribed:

Schedule 2 controlled drugs(CD POM)	Schedule 3 controlled drugs:
Diamorphine Hydrochloride Injection	Phenobarbital tablet, Oral liquid
	Buprenorphine patch
Fentanyl Injection, patch	Midazolam buccal oral liquid, injection
	Pentazocine
Methadone liquid	Temazepam tablet, liquid
Methylphenidate	Flunitrazepam
Morphine Sulphate Injection, M/R capsule, tablet and oral liquid[#]	Diethylpropion
Oxycodone capsule, MR tablet, injection and oral solution	
Pethidine Injection	
Tramadol capsule	

[#] Oral morphine solution 10mg in 5mls is classified as a Schedule 5 controlled drug and is therefore not included in the above list but is treated as a controlled drug subject to the requirements of this Standard Operating Procedure.

[##] Ketamine is classified as a Schedule 4 (Part 1) controlled drug and is therefore not included in the above list but is subject to the requirements of this Standard Operating Procedure, including the counter signature of a medical practitioner in the controlled drugs order book.

Appendix 2

Signing by a Medical Practitioner (or ward pharmacist) of Controlled Drug Orders for Ward Stock used in a Community Hospital Setting.

Guidance summary:

- Community Hospital Controlled Drug stock orders now requires countersignature by a Medical Practitioner (or Torbay and Southern Devon Health and Care NHS Trust employed pharmacist)
- The signature is a legal requirement to confirm the stock order however Torbay and Southern Devon Health and Care NHS Trust will not hold medical prescribers responsible for any other aspect of CD stock management on the ward/unit.
- Without this signature the supplying Trust pharmacy is not able to supply the controlled drugs to the ward.

Changes to the primary legislation and the Misuse of Drug Regulations 2001 were introduced by the Government to strengthen the governance arrangements for controlled drugs (CDs). This includes changes relating to the prescribing, record keeping and destruction of controlled drugs. The Health Act 2006 enabled Regulations to be laid relating to governance and monitoring of CDs. This came into effect in England on 1st January 2007[1].

The governance arrangements emphasised the roles and responsibilities of health care professionals involved in the management of controlled drugs. To be compliant all organisations appointed an Accountable Officer for CDs to develop and use standard operating procedures (SOPs) that enable good practice to be embedded into every day practice.

The Law in respect to the purchasing and supply of controlled drugs has not changed but the new legislation has made it clearer that there has been a lack of compliance with aspects of the law relating to ordering of CDs from acute trust pharmacies by community hospitals.

The law states:
'Schedule 2 drugs may be possessed by the person or acting person in charge of a hospital or nursing home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions. In other such circumstances a licence is required. Such requisitions must be countersigned by a doctor or dentist who work there.'[1]

This statement is further clarified by:
'Where a hospice, community hospital or private hospital does not employ a pharmacist, the person or acting person in charge may obtain CDs via a requisition signed by a doctor (or dentist) employed or engaged there. This requisition may be presented to a wholesaler, community pharmacy or the pharmacy department of a NHS Trust with whom a service level agreement (SLA) is in place. Establishments with employed pharmacists can obtain CD stock via a requisition, which complies with the Regulations described earlier.'[2]

To ensure that we operate within the law Controlled Drug Standard Operating Procedures developed for Torbay and Southern Devon Health and Care NHS Trust

Community Hospitals will reflect this requirement and state that a medical prescriber's signature (or Torbay and Southern Devon Health and Care NHS Trust employed pharmacist) is required to obtain all schedule 2 & 3 controlled drug stock items.

Co-operation of all medical practitioners who provide medical cover to the community hospitals is therefore required in signing the Controlled Drug Order Book when requested by a member of the nursing staff. Without this signature the supplying acute Trust pharmacy department will not be able to supply the controlled drugs.

In order to facilitate this process a sample witnessed signature will need to be obtained from the medical prescriber using the designated proforma which must be forwarded to the supplying Trust pharmacy for verification of signed orders.

Importantly, the medical prescriber's signature against the order for a specific CD preparation would confirm that the nurse ordering the controlled drug is employed on that ward /unit and that the controlled drug ordered was required for ward stock. Torbay and Southern Devon Health and Care NHS Trust will not hold medical prescribers responsible for any other aspect of CD stock management on the ward/unit.

Each ward should have a controlled drug stock list that must be kept up to date and reflect the prescribing patterns on that unit. The list includes a suggested stock level for each item and prescribers may find this a useful reference when requested to sign an order. The ward should review this list on a regular basis with the clinical pharmacist/pharmacy technician/supplying pharmacy.

List of Schedule 2 and 3 Controlled Drugs that must be Stored within a Controlled Drug Cupboard, Recorded in the Controlled Drug Register and Ordered with a medical prescribers counter signature.

All forms and preparations of the following drugs:

Barbiturates	Methylphenidate
Buprenorphine	Midazolam
Diamorphine Hydrochloride	Morphine Sulphate- all preparations **except** Oramorph 10mg in 5ml*
Dipipanone Hydrochloride (Diconal)	Oxycodone
Fentanyl	Pentazocine
Hydromorphone Hydrochloride (Palladone)	Pethidine
Ketamine	Temazepam
Methadone	Tramadol

References:

1. A Guide to good practice in the management of controlled drugs in primary care (England), Third Edition, December 2009, National Prescribing Centre.
   Safer Management of Controlled Drugs: a guide to good practice in secondary care. England. October 2007 Department of Health/ Royal Pharmaceutical Society of Great Britain
2. Medicines, Ethics & Practice, July 2013, Royal Pharmaceutical Society

Appendix 3

Torbay and Southern Devon Health and Care NHS TRUSTS
PHARMACY ORDERS FOR CONTROLLED DRUGS

AUTHORISATION FORM FOR THE ORDERING OF CONTROLLED DRUGS

Due to the legal requirements for the supply of controlled drugs (CDs), **ALL** personnel involved in the requisitioning of CDs must have the prior approval of the supplying Acute Torbay hospital pharmacy by providing a sample signature using the form below.

Whilst nurses may initiate a requisition for a CD order and are responsible for the safe keeping and management of CDs, a supply can only be made when the order is countersigned by an authorised doctor, dentist or pharmacist working in that ward/department or unit.

To be completed annually by wards/departments/units supplied by the designated Torbay Hospital pharmacy

Name (block capitals).....

Profession..... Registration no: .....

Employing Organisation: .....

Ward(s) or Department(s) where ordering /signing for CDs:.....

.....

Contact details: Tel no: .....Fax no: .....

Email.....

I certify that I am currently authorised to order or counter sign controlled drugs for the above ward(s) or department(s). I understand that I must inform the designated Acute Trust Hospital pharmacy immediately should this no longer be the case.

Signature.....**Date**.....

Please note that orders will not be processed without a completed and in date Authorisation Form.

All forms must be witnessed by: Modern Matron, Pharmacist or Unit Manager:

Witness Name (Block letters)	Profession	Registration No.	Signature	Date

For Pharmacy Use only

Registration Verified By	Date

A copy of this form is to be retained by the ward or department by the matron and the original submitted to the Torbay hospital pharmacy.

Authorised Signatories list for the ordering of Controlled Drugs from Torbay hospital pharmacy.

Community Hospital/ Ward/ Department ……

Date ……..

Name of Nurse (Capital Letters)	Usual Signature	Authorised by (Name & Signature)

Validated by Medicines Optimisation Pharmacy Team: **Date:**

Appendix 4

Torbay and Southern Devon Health and Care NHS Trust Recommendations for Controlled Drugs cupboards / cabinets:

Introduction:
Controlled drugs (CDs) must be stored in such a way to meet legally defined criteria which are laid out in Regulations, which describe the specifications for the safe custody of controlled drugs, including controlled drugs cupboards / cabinets requirements.

A number of factors should be considered when choosing a controlled drugs cupboard / cabinet, to ensure that the cupboard / cabinet (referred to as 'cupboard' herein) is fit for purpose and meets the safe custody requirements:

1. The cupboard within which controlled drugs are stored must comply with the requirements of The Misuse of Drugs (Safe Custody) Regulations 1973:

- When purchasing a cupboard for controlled drugs storage, ensure that the product description and specification made by the manufacturer / supplier includes a statement saying that the cupboard meets the Misuse of Drugs (Safe Custody) Regulations 1973.
- The CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the pharmacy department. This is a minimum security standard and may not be sufficient for areas where there is not a 24-hour staff presence, or easy control of access. In this case the advice of security specialists or crime prevention officers should be sought.

2. Positioning of the cupboard within the unit:

- The steel cupboard must be rigidly and securely fixed to a retaining wall or floor.
- The position of the cupboard within the room should be risk assessed, taking into consideration that controlled drugs may be a target for theft according to the following criteria:
    - The position of the cupboard in relation to external windows
    - Whether the cupboard is located within a room that is accessible by patients / the public
    - Whether the cupboard is located within a locked room that is not accessed by patients / the public
- The position of the cupboard must be such that the medicines stored therein are kept stored according to the requirements of the Torbay and Southern Devon Health and Care Trust Medicines Policy and associated Standing Operating Procedures.

3. Capacity and dimensions of the cupboard:

- The capacity size of the cupboard should be sufficient to:
    - Store controlled drugs ward stock
    - Store record books for controlled drugs
    - Store requisition/order books
    - Store patient's own controlled drugs separately
    - Meet National Patient Safety Agency (NPSA) requirements for:

- Ensuring safer practice with high dose ampoules of morphine and diamorphine
  (NPSA Safer Practice Notice 12)

o Other controlled stationery according to local need (e.g. FP10 script pads)

4. General considerations for the cupboard:

- It is not necessary for the cupboard to have a light indicating when the cupboard is open, although some cupboards have this feature.
- Nothing on the outside of the cupboard should draw attention to the fact that controlled drugs are stored within.
- No other items should be stored in the cupboard.
- The CD cupboard should be situated within a locked room and the CD cupboard should be locked at all times.
- Store used controlled drug denaturing kits, which can be ordered when needed.

Appendix 5

Torbay and Southern Devon Health and Care NHS Trust procedures for controlled drugs storage during community hospital / ward / unit deep cleaning or closure

When community hospitals, wards or other units undergo deep cleaning or are closed, it is a legal requirement that the safe custody and storage of controlled drugs is maintained.

Reviewing ward stock prior to deep cleaning / closure:

Preparing for a deep clean or closure is an ideal time to review the ward / unit stock levels of controlled drugs held, with excess stock or stock removed, following Torbay and Southern Devon Health and Care NHS Trust Policies and Procedures.

Patient's own controlled drugs may be destroyed on the ward, following the procedures laid out in the Medicines Policy and Controlled Drug Standard Operating Procedure.

Procedures for maintaining safe custody of controlled drugs will vary, according to a number of factors that must be considered:

- Whether the controlled drugs cupboard / cabinet is being cleaned
- Whether individual areas, wards or bays are closed
- Whether the community hospital / unit is remaining open or is being closed and the anticipated length of closure
- Staffing during the deep clean or closure

Taking all of the above considerations into account, the scenarios outlined below should assist in deciding the most appropriate course of action to take, in order to ensure Safe Custody requirements for controlled drugs are maintained:

1. **If the controlled drugs cupboard / cabinet is being cleaned:**
   Suitable alternative arrangements must be made for the storage of any controlled drugs and record books to ensure Safe Custody requirements are met at all times while the cupboard is being cleaned.

   A lockable, metal cupboard or safe, which is securely bolted to a floor or wall (which meets the requirements for controlled drugs storage), in a non-patient area would be suitable as an alternative storage area, providing this is used for the shortest possible time (e.g. until the end of that shift), with access to the safe remaining under the direct supervision of the registered practitioner in charge at all times. If controlled drugs are placed in the safe, they should first be placed in a pharmacy bag or other container that does not draw attention to the contents.

   If it is not possible to store the contents in an alternative cupboard or safe, the controlled drugs must be returned to the supplying Trust pharmacy (see Section 5) for Safe Custody until the cupboard is ready for use, when the controlled drugs and record books can be returned.

2. **If individual areas, wards or bays are closed, but some areas of the hospital / unit remain open:**
   Providing the controlled drugs cupboard is not being cleaned and the hospital / unit remains staffed, controlled drugs can remain *in situ,* and all policies and procedures will continue to apply. If the cupboard is being cleaned, procedures in Section 1 will apply.

3. **Hospital / unit cleaning or closure for less than one week:**
   Providing the controlled drugs cupboard is not being cleaned, if it is anticipated that the hospital / unit deep cleaning or closure will last for less than one week and the unit remains staffed, controlled drugs can remain *in situ,* and all policies and procedures will continue to apply. If the cupboard is being cleaned, procedures in Section 1 will apply.

4. **Hospital / unit cleaning or closure for one week or more:**
   If it is anticipated that the hospital / unit deep cleaning or closure will last for one week or more, arrangements must be made for alternative safe and secure storage. Seek advice from the medicines optimisation team (providermmteam.t-sd@nhs.net)

These procedures do not apply to 'Drugs of Diversion', which will be considered as any other medicine during hospital / unit deep cleaning or closure and are outside of the scope of this document.

Appendix 6

1 Reducing Dosing Errors with Opioid Medicines in Torbay and Southern Devon Health and Care NHS Trust **NPSA Rapid Response Report 05**

2 This guidance must be accessible to all practitioners prescribing, dispensing and administering opioid medicines in Torbay and Southern Devon Health and Care NHS Trust

This guidance relates to the following opioid medicines:
alfentanil, buprenorphine, diamorphine, dipipanone fentanyl, hydromorphone, meptazinol, methadone, morphine, oxycodone, papaveretum, pethidine

Are you prescribing, dispensing or administering an opioid medicine?

Patients taking an opioid medicine

- If the patient is new to you, try to use at least **two sources** of information to confirm the **dose** they are taking (admission documentation, patient/relatives, GP surgery, previous drug charts)
- If dose has increased by more than **50%** from previous prescription check that this is intentional

Patients newly starting an opioid medicine

- Be familiar with the usual **starting dose** of the medicine prescribed (look in the current BNF and local Joint Formulary)

2.1 If changing opioids or route or setting up a syringe driver and advice is required contact:

- Rowcroft Hospice **01803 210800;** St Luke's Hospice **01752 401172**
- **Pharmacy Medicines Information:** Torbay **01803 655304** Derriford **01752 439976**
- **Out of hours:** DDOC **01392 824600 (0845 6710 270)** NHS Direct **0845 46 47** or Pharmacy On-Call via Acute Trust switchboards /On-Call Clinician

All patients

- If unfamiliar with the drug, **check** dose range, frequency of dosing, symptoms of overdose and common side effects
- When prescribing **liquid** formulations (oral or injectable) - always state a dose in **milligrams (mg)** or **micrograms**, not millilitres (ml)
- If a dose is prescribed in ml, **seek clarification**

A GUIDE TO EQUIVALENT DOSES FOR OPIOID DRUGS

This is to be used as **a guide** rather than a set of definitive equivalences. Most data on doses is based on single dose studies so is not necessarily applicable in chronic use. Individual patients may metabolise different drugs at varying rates. The advice is always to calculate doses using morphine as standard and to adjust them to suit the patient and the situation. Some of these doses have by necessity been rounded up or down to fit in with the preparations available.

Oral Morphine			Subcutaneous Morphine		Subcutaneous Diamorphine		Oral Oxycodone			Subcutaneous Oxycodone		Fentanyl Transdermal	Subcutaneous Alfentanil		Subcutaneous Fentanyl***	
4 hr dose (mg)	12hr SR dose (mg)	24hr Total dose (mg)	4 hr dose (mg)	24 hr total dose (mg)	4 hr dose (mg)	24 hr total dose (mg)	4hr dose (mg)	12hr SR dose (mg)	24hr total dose (mg)	4 hr dose (mg)	24 hr total dose (mg)	Patch strength (mcg)	4 hr dose (mg)	24hr total dose (mg)	4 hr dose (mcg)	24hr total dose (mcg)
5	15	30	2.5	15	1.25	10	2.5	7.5	15	1.25	7.5	12mcg	0.125	1	25	200
10	30	60	5	30	2.5-5	20	5	15	30	2.5	15	25mcg	0.25	1.5	50	300
15	45	90	7.5	45	5	30	7.5	25	50	3.75	25	25mcg	0.5	3	100	600
20	60	120	10	60	7.5	40	10	30	60	5	30	50mcg	0.75	4	Syringe pump volume issues likely above 500mcg/24hours	
30	90	180	15	90	10	60	15	45	90	7.5	45	50mcg	1	6		
40	120	240	20	120	12.5	80	20	60	120	10	60	75mcg	1.25	8		
50	150	300	25	150	15	100	25	75	150	12.5	75	75mcg	1.5	10		
60	180	360	30	180	20	120	30	90	180	15	90	100mcg	2	12		
70	210	420	35	210	25	140	35	105	210	17.5	100	125mcg	2.5	14		
80	240	480	40	240	27.5	160	40	120	240	20	120	125mcg	2.5	16		
90	270	540	45	270	30	180	45	135	270	22.5*	135	150mcg	3	18		
100	300	600	50	300	35	200	50	150	300	25*	150	150mcg	3.5	20		
110	330	660	55	330	37.5	220	55	165	330	27.5*	165	175mcg	3.75	22		
120	360	720	60	360	40	240	60	180	360	30*	180	200mcg	4	24		

Reproduced with kind permission of Margaret Gibbs, St Christopher's Hospice (original chart 2010).

* this dose requires using 50mg in 1ml injection as it would otherwise be too large a volume for a sc injection. **Caution with this strength.**
**Amendment (June 2013) to original chart to incorporate availability of Fentanyl 12 micrograms per hour transdermal patch.
***Addition (February 2013) to original chart to incorporate use of Subcutaneous Fentanyl.

24 hour advice line (Rowcroft Hospice) 01803 210800. Calls go through to the hospice. The senior nurse will be able to answer queries or ask the doctor on call to ring you back.

Appendix 7

Controlled Drug CALCULATION RECORD

Name of Patient:	**NHS Number:**
Date of Birth:	**Prescriber:**

Drug Name, Formulation and Strength: **Dose:** **Calculation:**		**Drug Name, Formulation and Strength** **Dose:** **Calculation:**	
Signature: **Date:**	**Time:**	**Signature:** **Date:**	**Time:**

Drug Name, Formulation and Strength **Dose:** **Calculation:**		**Drug Name, Formulation and Strength** **Dose:** **Calculation:**	
Signature: **Date:**	**Time:**	**Signature:** **Date:**	**Time:**

To be attached to the patient's medication administration recording sheet

Appendix 8

CONTROLLED DRUG DESTRUCTION REPORT SHEET

DATE	
NAME OF HOSPITAL / WARD / UNIT	
NAME OF REGISTERED PROFESSIONAL PRESENT	

MEDICATION(S) DESTROYED AND QUANTITY

Name of Controlled Drug,Formulation and Strength	Quantity	Ward CD Stock/ Patient's Own CD	CD Record book page number

COMMENTS

SIGNED (Authorised to destroy)	**PRINT NAME (Authorised to destroy)**
SIGNED (Authorised to witness destruction)	**PRINT NAME (Authorised to witness destruction)**

Copy to be kept in CD file

Please keep a completed copy in controlled drug file and keep on the ward for audit purposes.

NB: * Patient's own medication must be destroyed after appropriate permission has been obtained. If in doubt contact the provider medicines management team at providermmteam.t-sd@nhs.net or on 01803 217393

Appendix 9

Methods of Denaturing Controlled Drugs

Adapted from guidance issued by the Royal Pharmaceutical Society

Solid dose formulations
Tablets and capsules must be removed from their outer packaging, removed from blister packaging and placed in a CD destruction kit. If a person is removing tablets / capsules from blister packs they should wear gloves.

Liquid dose formulations
A CD liquid can be poured from its container and added to the CD destruction kit where it will mix with the other waste materials, thus rendering it irretrievable.

Empty bottles must be rinsed with a small amount of water and the resultant liquid poured into the CD destruction kit. The empty bottle must then be placed in the pharmaceutical waste bin to ensure safe disposal.

Parental formulations
Liquid ampoules should be opened and as much of the content as possible emptied into the CD destruction kit. The ampoule should be disposed of in the CD destruction kit.

Ampoules containing the CD in a powder form can be opened, water added to dissolve the powder and the resultant mixture emptied into the CD destruction kit. The ampoule can then be disposed of in the CD destruction kit.

These are the ideal methods of denaturing ampoules. Suitable gloves should be worn by the person breaking open glass ampoules as a safety measure and to minimise the risk of injury from sharps.

Fentanyl and buprenorphine patches
The active ingredient in the patches can be rendered irretrievable by removing the backing and folding the patch over on itself and then placing it in the CD destruction kit. Gloves must be worn by the person destroying the CD.

Aerosol formulations
Aerosol formulations should be expelled into water (to prevent droplets of drug entering the air). As a further precaution, it would be advisable for a facemask to be worn by staff undertaking the activity and to ensure that the area where the destruction takes place is well ventilated. The resulting solution can then be disposed of in accordance with the above guidance on destruction of liquid formulations.