Safe and Secure Handling of Controlled Drugs Policy
<table>
<thead>
<tr>
<th><strong>Policy Title:</strong></th>
<th>Policy on the Safe Management of Controlled Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Executive Summary:</strong></td>
<td>This policy forms part of the Trusts Safe &amp; Secure Handling of Medicines Policy, and together with the Standard Operating procedures (SOPs) provide guidance to all Trust staff on the procedures relating to the safe and secure handling and storage of controlled drugs in accordance with the legal and good practice guidance specified by the Department of Health, the Care Quality Commission and the General Pharmaceutical Council.</td>
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<tr>
<td><strong>Supersedes:</strong></td>
<td>Version 2.0</td>
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<tr>
<td><strong>Description of Amendment(s):</strong></td>
<td>Legislation change – Temazepam to FULL CD Schedule 3 status Update Appendix 18 – Use of CDs in Radiology</td>
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<td><strong>This policy will impact on:</strong></td>
<td>All Trust Clinical staff</td>
</tr>
<tr>
<td><strong>Financial Implications:</strong></td>
<td>Delivering training and releasing staff for training may have a financial impact</td>
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<tr>
<td><strong>Policy Area:</strong></td>
<td>Trust Wide</td>
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<tr>
<td><strong>Version Number:</strong></td>
<td>3.0</td>
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<tr>
<td><strong>Supersedes:</strong></td>
<td>Version 2.0</td>
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<tr>
<td><strong>Effective Date:</strong></td>
<td>February 2017</td>
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<tr>
<td><strong>Issued By:</strong></td>
<td>Chief Pharmacist &amp; Trust Accountable Officer for Controlled Drugs</td>
</tr>
<tr>
<td><strong>Review Date:</strong></td>
<td>January 2019</td>
</tr>
<tr>
<td><strong>Author:</strong></td>
<td>Karen Burton – Pharmacy Operational Manager</td>
</tr>
<tr>
<td><strong>Impact Assessment Date:</strong></td>
<td>December 2016</td>
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## APPROVAL RECORD

<table>
<thead>
<tr>
<th>Committees / Group</th>
<th>Date</th>
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<tbody>
<tr>
<td>Consultation:</td>
<td>December 2016</td>
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<tr>
<td>Pharmacy Team</td>
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<td>Matrons</td>
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<tr>
<td>Head of Nursing (Professional Practice)</td>
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<thead>
<tr>
<th>Approved by Director:</th>
<th>Date</th>
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<tbody>
<tr>
<td>Medicines Management Group (MMG)</td>
<td>February 2017</td>
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<tr>
<td>Medical Director</td>
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</tbody>
</table>

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<tr>
<th>Received for information:</th>
<th>Date</th>
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<tbody>
<tr>
<td>Carol Seddon (Deputy Director of Nursing Quality and Performance)</td>
<td>February 2017</td>
</tr>
</tbody>
</table>
## Contents:

1.0 **Policy Statement** ................................................................................................................................. 5  
2.0 **Definitions**............................................................................................................................................. 5  
3.0 **Roles and Responsibilities** ...................................................................................................................... 6  
3.1 The Chief Executive ...................................................................................................................................... 6  
3.2 The Accountable Officer .............................................................................................................................. 6  
3.3 Directorates .................................................................................................................................................. 6  
3.4 Clinical and service managers ..................................................................................................................... 6  
3.5 Ward/departmental managers ..................................................................................................................... 6  
3.6 Nurse/Midwife/Operating Department Practitioner (ODP) in charge ......................................................... 7  
3.7 Ward/Departmental staff ............................................................................................................................ 7  
3.8 Pharmacy staff ............................................................................................................................................ 7  
3.9 Individual Members of Staff ....................................................................................................................... 7  
3.10 The Trust Medicines Management Group (MMG) .................................................................................... 7  
4.0 **Planning & Implementing** ....................................................................................................................... 8  
5.0 **Legislation**............................................................................................................................................... 8  
6.0 **Governance** .......................................................................................................................................... 11  
7.0 **Monitoring** ............................................................................................................................................ 11  
8.0 **Incident reporting** ................................................................................................................................. 11  
9.0 **Review** .................................................................................................................................................. 11  
10.0 **Prescribing Controlled Drugs** ............................................................................................................. 12  
10.1 Prescribing for in-patients ....................................................................................................................... 12  
10.2 Prescribing for discharge patients ......................................................................................................... 13  
10.3 Prescribing for Out-patients .................................................................................................................... 13  
11.0 **Administration of Controlled Drugs** .................................................................................................. 14  
11.1 Patient Group Directions (PGD’s) ........................................................................................................... 14  
12.0 **Safe and Secure Handling of Controlled Drugs on Wards and Departments** ................................. 15  
12.1 Controlled Drug stationery ...................................................................................................................... 15  
13.0 **Returns/ Disposal of Controlled Drugs** .............................................................................................. 16  
13.1 Returning controlled drugs to Pharmacy ............................................................................................... 16  
13.2 Disposal of Controlled drugs on wards or departments ......................................................................... 16  
14.0 **Safe and Secure Transportation of CD’s** ......................................................................................... 18  
14.1 Transfer of CD’s will include the following: ........................................................................................... 18  
14.2 Methods of transfer .................................................................................................................................... 18  
14.3 Records transfer ......................................................................................................................................... 18  
14.4 Messengers ................................................................................................................................................ 18  
14.5 Transfer from ward to ward or theatre to ward ...................................................................................... 18  
14.6 Patients’ own controlled Drugs .............................................................................................................. 19  
14.7 Patients receiving CDs by infusion devices ........................................................................................... 19  
14.8 Controlled drug discharge medicines ..................................................................................................... 20  
14.9 Receipt of CDs by out-patients .................................................................................................................. 20  
14.10 Controlled Drugs for Clinical trials ...................................................................................................... 20  
14.11 Storage and records .................................................................................................................................. 20  
14.12 Labelling .................................................................................................................................................. 20  
14.13 Disposal .................................................................................................................................................. 21  
14.14 Clinical trial CD’s returned by patients ................................................................................................. 21  
15.0 **Controlled drugs for Midwives** ........................................................................................................... 21  
15.1 Midwives Working in Hospital ................................................................................................................. 21  
15.2 Administration of Epidural......................................................................................................................... 21
<table>
<thead>
<tr>
<th>Page</th>
<th>SOP</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.0</td>
<td>Illicit substances</td>
<td>................................................................. 21</td>
</tr>
<tr>
<td>16.1</td>
<td>Drug Misusers</td>
<td>................................................................. 21</td>
</tr>
<tr>
<td>17.0</td>
<td>Management of CD’s in Theatres and Theatre Recovery</td>
<td>................................................................. 21</td>
</tr>
<tr>
<td>18.0</td>
<td>Management of CD’s in Radiology</td>
<td>................................................................. 21</td>
</tr>
<tr>
<td>19.0</td>
<td>Management of CD’s in Cardio- Respiratory</td>
<td>................................................................. 21</td>
</tr>
<tr>
<td>20.0</td>
<td>Management of CD’s in the Community Setting</td>
<td>................................................................. 22</td>
</tr>
<tr>
<td>20.1</td>
<td>Community Nurses</td>
<td>................................................................. 22</td>
</tr>
<tr>
<td>Appendix 1</td>
<td>Glossary of terms</td>
<td>................................................................. 23</td>
</tr>
<tr>
<td>Appendix 2</td>
<td>Audit Proforma – CD 3 monthly check</td>
<td>................................................................. 24</td>
</tr>
<tr>
<td>Appendix 3</td>
<td>Controlled Drug Prescription Requirements</td>
<td>................................................................. 26</td>
</tr>
<tr>
<td>Appendix 5</td>
<td>Storage and entry of controlled drugs into the controlled drug record book (Register)</td>
<td>................................................................. 29</td>
</tr>
<tr>
<td>Appendix 6</td>
<td>Administration of controlled drugs to patients</td>
<td>................................................................. 31</td>
</tr>
<tr>
<td>Appendix 7</td>
<td>Checking Controlled Drug stock and handling discrepancies</td>
<td>................................................................. 33</td>
</tr>
<tr>
<td>Appendix 8</td>
<td>Return of unwanted / out-of-date controlled drugs to pharmacy</td>
<td>................................................................. 34</td>
</tr>
<tr>
<td>Appendix 9</td>
<td>Disposal of prepared/partly-used controlled drugs not administered to patients</td>
<td>................................................................. 35</td>
</tr>
<tr>
<td>Appendix 10</td>
<td>Recording and administering of patients’ own Controlled drugs</td>
<td>................................................................. 36</td>
</tr>
<tr>
<td>Appendix 10a</td>
<td>Flow Chart. Patients Own Controlled Drugs</td>
<td>................................................................. 38</td>
</tr>
<tr>
<td>Appendix 11</td>
<td>Security of controlled Drug keys and handover</td>
<td>................................................................. 39</td>
</tr>
<tr>
<td>Appendix 12</td>
<td>Obtaining controlled drugs when the Pharmacy is closed</td>
<td>................................................................. 40</td>
</tr>
<tr>
<td>Appendix 13</td>
<td>Removal of Illegal or suspicious substances from patients</td>
<td>................................................................. 41</td>
</tr>
<tr>
<td>Appendix 14</td>
<td>Dealing with suspected abuse of controlled drugs by staff members</td>
<td>................................................................. 42</td>
</tr>
<tr>
<td>Appendix 15</td>
<td>Management of Controlled Drugs on temporary Ward closure and transfer of Wards</td>
<td>................................................................. 43</td>
</tr>
<tr>
<td>Appendix 16</td>
<td>Controlled Drugs stored in Mediwell Automated Cabinets</td>
<td>................................................................. 45</td>
</tr>
<tr>
<td>Appendix 16a</td>
<td>Controlled Drug SOP Accountability Record</td>
<td>................................................................. 46</td>
</tr>
<tr>
<td>Appendix 17</td>
<td>Safe and Secure Handling of Controlled Drugs in Theatres</td>
<td>................................................................. 47</td>
</tr>
<tr>
<td>Appendix 18</td>
<td>SOP for the use of PETHIDINE, MIDAZOLAM AND FENTANIL IN RADIOLOGY within East Cheshire Trust</td>
<td>................................................................. 51</td>
</tr>
<tr>
<td>Appendix 19</td>
<td>SOP for the use of FENTANYL WITHIN CARDIO-RESPIRATORY DEPT within East Cheshire Trust</td>
<td>................................................................. 53</td>
</tr>
<tr>
<td>Appendix 20</td>
<td>SOPs Management of CDs in the Community</td>
<td>................................................................. 55</td>
</tr>
</tbody>
</table>

SOP 1 | Transportation of CD’s in the community setting |
SOP 2 | Storage of CD’s in the community setting |
SOP 3 | Assessment of patients own CD’s in the community setting prior to administration |
SOP 4 | Recording of CD’s in the community setting |
SOP 5a | Administration of CD’s in the community setting |
SOP 5b | Administration of CD’s in the community setting within the complex care service |
SOP 6 | Destruction of CD’s in the community setting |
SOP 7 | Theft or loss of CD’s in the community setting |
1.0 Policy Statement

This policy together with the standard operating procedures (SOPs) provide guidance to all Trust staff on the policy and procedures relating to the safe and secure handling and storage of controlled drugs in accordance with the legal and good practice guidance specified by the Department of Health, the Care Quality Commission and the General Pharmaceutical Council. The Policy will ensure that:-

- Staff are clear on the standards that are expected of them in relation to the handling and storage of controlled drugs
- Patients, staff and visitors are not put at risk as a result of the incorrect handling of controlled drug medicines
- All legislation and guidance is adhered to with respect to controlled drugs
- Risks associated with the incorrect handling and storage of controlled drugs are reduced to a minimum
- Provide robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording and disposal of CD’s safely.

In accordance with the Government’s response to the Shipman enquiry, NHS bodies and the private sector must have arrangements in place for the management of controlled drugs (CDs) by all healthcare professionals who they employ or with whom they contract.

Additionally, NHS bodies are required to appoint an Accountable officer to monitor the use of controlled drugs within their organisation and take appropriate action where necessary. The designated Controlled Drugs Accountable Officer (CDAO) for East Cheshire NHS Trust is the Chief Pharmacist.

2.0 Definitions

Controlled drugs (CD’s) defined in this policy are those substances contained within Schedules 2, 3, 4 and 5 of the Misuse of Drugs Act 1971. The Trust has additional security measures in place to include other substances that are open to abuse, are high risk medicines or ‘controlled’ for other reasons. These substances include Midazolam, Ketamine, mifepristone and strong potassium chloride injection/solutions. See Table 1 (Page 10).
3.0 Roles and Responsibilities

3.1 The Chief Executive
The responsibility for ensuring that the policy for the safe and secure handling of controlled drugs is being adhered to ultimately rests with the Chief Executive who may delegate this to the Director of Nursing Quality and Performance, and they must ensure action is taken in response to deficiencies reported following audit reviews/incidents/areas of concern expressed by their staff or the Pharmacy department. The Chief Executive is responsible for notifying the CQC promptly when the controlled drugs accountable officer for their organisation changes, to ensure that this is not overlooked in a period of change. The Chief Executive and the controlled drugs Accountable Officer should work collaboratively on areas of mutual concern to ensure that the processes for oversight of controlled drugs are suitably robust.

3.2 The Accountable Officer
The Accountable officer for East Cheshire NHS Trust is the Chief Pharmacist. The Accountable Officer’s responsibilities are set out in the Handbook of Controlled Drug Accountable Officers in England (1st edition), and require that he or she be a fit and proper suitable person who does not routinely supply/administer or dispose of controlled drugs as part of his/her duties (Appendix 1). The Accountable Officer must be notified to the Controlled Drugs Regulation team at the CQC and any change to this must be promptly registered. The newly-appointed accountable officer must also make contact with the accountable offer leading the local intelligence network (LIN). The Accountable Officer is also responsible for appointing authorised witnesses for the destruction of controlled drugs.

3.3 Directorates
It is the responsibility of the Clinical Directors and Associate Directors to ensure that all staff are trained to carry out the tasks required of them in the prescribing, administration and management of controlled drugs.

3.4 Clinical and service managers
Clinical and Service Managers will oversee the application of this policy into their services and ensure its implementation is undertaken within their management structure, with the necessary controls to achieve the policy’s aim. They will liaise with members of the Pharmacy department to obtain expert advice when necessary. They will promote the policy to consultants and then, in turn to their teams.

3.5 Ward/departmental managers
are responsible for ensuring:-

• there are local approved standard operating procedures (SOPs) for the storage, handling and security of CDs in their designated area
• pharmacy are informed of any new/amendments to these local procedures
• these approved procedures are followed
• Daily checks and expiry date checking is undertaken
• all staff have been trained on the handling and storage of CDs and sign acceptance to these procedures
• a robust system is in place for ordering CDs and that appropriate stock levels are maintained
• identify any areas of significant risk and take action to control the risk
3.6 Nurse/Midwife/Operating Department Practitioner (ODP) in charge
Are responsible for all CDs whilst in charge of that ward/department. In the event of any discrepancies or apparent loss, they are responsible for ensuring pharmacy is informed and an incident report is made using the Trust Incident Reporting Scheme.
NB. Operating Department Practitioners (ODPs) as registered with the Health Professions Council are legally entitled to order, possess and supply CDs for administration to patients in accordance with the directions of a doctor, dentist, supplementary/independent prescriber in the department within which they work.

3.7 Ward/Departmental staff
Have a responsibility to:-
- Adhere to all policies and procedures for the storage and handling of CDs.
- Support the ward manager in ensuring that the security of CDs and their own local procedures concerning CDs are being followed.
- Ensure CD cupboard keys are held by and/or passed to suitably qualified staff.
- Report all incidents involving CDs to the nurse/midwife in charge.
- They are responsible for ensuring the Trust Accountable Officer is informed immediately of any incidents reported relating to CD’s
- Filling in an incident report using the Trust Incident Reporting Scheme when appropriate.

3.8 Pharmacy staff
Are responsible for:-
- Providing information and advice to Trust staff on the handling and storage of CDs used within the Trust.
- Assisting where appropriate in formulating local procedures at ward/departmental /Service Line level.
- Undertaking checks on wards/departments and audits on the safe handling and storage of CDs every 3 months
- Ensuring that the laws relating to the safe and secure handling and storage of CDs are complied with
- Removing/disposing of any CDs no longer required from that ward/department
- Assisting with the training on the storage and handling of CDs to Trust staff.

3.9 Individual Members of Staff
- All members of staff involved in delivery of the service relating to CDs must keep up to date with this Policy and the relevant associated procedures.
- Changes/updates to this policy will be communicated to staff via the mechanism of email and updated policy on the Trust Internet.
- All staff will be required to sign that they have read and understood the policy and will abide by this. A form for this purpose will be held in each ward/area handling CD’s.

3.10 The Trust Medicines Management Group (MMG)
- MMG act as the approval body for the Trust Controlled Drugs policy.
- The committee will identify any required changes to the policy and allocate responsibility for amendments to the Chief Pharmacist.
- Amended policy documents will be approved by the committee.
- The committee will review results of Controlled Drugs audits and recommend actions to the Clinical Governance Committee and/or Risk Advisory Group, where appropriate. Results will also be provided to Service Lines in order for any local issues to be addressed.
4.0 Planning & Implementing

- This policy will be approved by the Medicines Management Group (MMG)
- All Clinical, Service and Ward/ Departmental managers, will be sent a copy of this policy to identify the change in policy guidance. This will be cascaded through the Directorate SQS meetings.
- The policy will be uploaded onto the Trust internet and an email highlighting the changes and a link to the policy will be sent to all staff, through the Policy Governance Group.
- It is the responsibility of the ward and department managers to inform their staff of the changes in the policy.
- Training requirements relating to the implementation of this policy are as follows:
  - Doctors will receive training regarding writing CD prescriptions as part of their induction and medicines management training.
  - Student nurses will be given CD supply, administration, storage and destruction training as part of their formal training.
  - ODPs will receive training on ordering storage and supply of controlled drugs as part of their formal training and updates will be delivered.
  - For Registered nurses, training and updates will be provided by the Trust training department in conjunction with the Pharmacy.
  - Pharmacists will receive formal training as part of their pre-registration competency training programme and updates will be delivered through Pharmacy updates.
  - Pharmacy technicians must have completed the Trusts competency based training package before they are allowed to dispense CD’s.

5.0 Legislation

The core pieces of legislation applicable to controlled drugs are

- The Misuse of Drugs Act (1971) as amended (herein referred to as “The 1971 Act”)
- The Misuse of Drugs Act Regulations 2001 as amended (herein referred to as “The 2001 Regulations”)
- The Misuse of Drugs (Safe Custody) Regulations 1973 as amended (herein referred to as “The Safe Custody Regulations”)
- The Health Act (2006).

The 2001 Regulations classify controlled drugs into five schedules according to the different levels of control attributed to each:

- Schedule 1 (CD Lic POM)
- Schedule 2 (CD POM)
- Schedule 3 (CD No Register POM)
- Schedule 4 (CD Benz POM and CD Anab POM)
- Schedule 5 (CD INV P and CD INV POM)

The legal requirements pertaining to the main groups of CDs are summarised in Table 1 below.
## Table 1 - Summary of various characteristics of controlled drugs (Schedules 2, 3, 4 and 5)

<table>
<thead>
<tr>
<th>Schedule (refers to schedules of the Misuse of Drugs Regulations)</th>
<th>Schedule 2 Includes – Opiates, (e.g. diamorphine, morphine, methadone), major stimulants (e.g. amphetamines) and quinalbarbitone</th>
<th>Schedule 3 Includes minor stimulants and other drugs, (temazepam, buprenorphine, midazolam, phenobarbital, tramadol)</th>
<th>Schedule 4, Pt I Includes benzo-diazepines, zopiclone and ketamine</th>
<th>Schedule 4, Pt II Includes most of the anabolic and androgenic steroids, clenbuterol and growth hormones</th>
<th>Schedule 5 Includes low strength opioids</th>
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<tbody>
<tr>
<td>Designation</td>
<td>CD POM</td>
<td>CD No Reg POM</td>
<td>CD Benz POM</td>
<td>CD Anab POM</td>
<td>CD Inv POM/CD Inv P</td>
</tr>
<tr>
<td>Safe custody required</td>
<td>Yes, except quinalbarbitone Local practice: morphine sulphate 10mg/5ml solution is stored and treated as a schedule 2 CD</td>
<td>Yes, except midazolam, tramadol and Phenobarbital Local practice: Midazolam, phenobarbital injection and tramadol are stored as a CD</td>
<td>No Local practice: ketamine injection is stored as a CD</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Prescription requirements</td>
<td>• Signature • Date • Prescribers address • Dose • Formulation • Strength • Total quantity • Quantity prescribed • Name of patient • Address of patient</td>
<td>Yes Local practice: morphine sulphate 10mg/5ml solution must be written as full CD, observing full CD prescription requirements</td>
<td>Yes</td>
<td>No, except zopiclone MUST be denatured</td>
<td>No</td>
</tr>
<tr>
<td>Requisitions necessary?</td>
<td>Yes Local practice: morphine sulphate 10mg/5ml solution must be ordered using the CD order book.</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Records to be kept in CD register</td>
<td>Yes Local practice: morphine sulphate 10mg/5ml solution must be recorded in the CD register</td>
<td>No Local practice: Midazolam, temazepam tramadol and Phenobarbital injection must be recorded in the CD register</td>
<td>No Local practice: ketamine injection must be recorded in the CD register</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacist MUST ascertain the identity of the person collecting CD</td>
<td>Yes Local practice: Proof of identity must be ascertained when collecting prescriptions for morphine sulphate 10mg/5ml solution</td>
<td>No</td>
<td>No Local practice: Proof of identity must be ascertained when collecting prescriptions for ketamine injection</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Emergency supplies allowed</td>
<td>No Local practice: Emergency supplies for morphine sulphate 10mg/5ml solution are not allowed</td>
<td>No, except Phenobarbital for epilepsy</td>
<td>Yes Local practice: Emergency supplies for ketamine injection are not allowed</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Schedule (refers to schedules of the Misuse of Drugs Regulations)</td>
<td>Schedule 2 Includes – Opiates, (e.g. diamorphine, morphine, methadone), major stimulants (e.g. amphetamines) and quinalbarbitone</td>
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</tr>
<tr>
<td>Designation</td>
<td>CD POM</td>
<td>CD No Reg POM</td>
<td>CD Benz POM</td>
<td>CD Anab POM</td>
<td>CD Inv POM/ CD Inv P</td>
</tr>
<tr>
<td>Validity of prescription</td>
<td>28 days</td>
<td>28 days</td>
<td>28 days</td>
<td>28 days</td>
<td>6 months (if POM)</td>
</tr>
<tr>
<td>Local practice: Prescriptions for morphine sulphate 10mg/5ml solution will only be valid for 28 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum duration that may be prescribed</td>
<td>30 days as good practice</td>
<td>30 days as good practice</td>
<td>30 days as good practice</td>
<td>30 days as good practice</td>
<td>30 days as good practice</td>
</tr>
<tr>
<td>Local practice: Maximum duration of Morphine sulphate 10mg/5ml solution is restricted to no more than 30 days</td>
<td></td>
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Table adapted from the Medicines, Ethics and Practice Guide (July 2012)

Prescriptions for schedule 2 and 3 CDs may be typed or computer generated but **MUST** be signed by the prescriber. (SI 2005 No.2864)
The Trust has local agreements in place for the safe and secure handling of Temazepam and Midazolam. Please refer to Table 1 above and also the Trusts Use of Midazolam in Adults Policy

6.0 Governance

The Controlled Drug Accountable Officer is responsible for all aspects of the safe and secure management of CDs in their organisation. The Chief Pharmacist is the Accountable Officer for East Cheshire NHS Trust and is responsible for ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents relating to CDs.

The regulations also require Accountable Officers to complete a periodic declaration covering whether or not their organisation keeps stocks of controlled drugs and whether there are special circumstances that might explain any seemingly unusual patterns of prescribing or supply. This will be incorporated into the Annual CDAO report to the Trust Board.

- Standard operational procedures (SOPS) will include details of ordering, collection/transport, receipt, storage, administration, returns, checking and audit trail, destruction and disposal, use of patient own CD’s, borrowing of CD's out of hours in an emergency and dealing with patients/staff suspected of illicit drug usage.
- SOPS will also cover the documentation systems in place for requisitioning medical devices for PCAs and when patients are transferred with PCAs from theatre to a ward and also the devices and CD’s available on the ward. These form part of the Acute Pain policy and procedures.
- Pharmacy SOP’s will cover the responsibilities within the Pharmacy and the interface with the wards/department and will include all aspects of stock control/security, issue and supply to patients, control of CD stationary and signature verification
- All SOPs should be approved by the Controlled Drug Accountable Officer.

7.0 Monitoring

The Care Quality Commission (CQC) will be using their existing self-assessment methods to assess whether Healthcare Organisations are meeting National Standards. This will be incorporated in the Core Standards in the National Standards for Better Health. The CQC will report specifically on any points of concern about controlled drugs in secondary care including hospital pharmacy. They will do this as part of their routine assessment of whether a Trust is meeting core standards and through the clinical audit programme. The General Pharmaceutical Council may also carry out occasional inspections.

8.0 Incident reporting

The Trust Incident Reporting system should be used to record any incidents or near misses relating to any aspect of controlled drug management. Additionally, the Controlled Drug Accountable Officer or Ward Pharmacist should be contacted directly if there are any concerns regarding the clinical use or management control of controlled drugs. Incidents will be reviewed at the Safe Medicines Group in order to ascertain if there are any trends or other wider issues arising.

If there are any particular issues that need escalating these will be escalated through the clinical governance committees for the Directorates.

9.0 Review

Audit Framework - 3 monthly stock checking audit’s will be carried out on all wards and departments.
This Safe and Secure Handling of controlled drugs policy will be reviewed at a minimum every two years by the Accountable officer and will take into account the findings of the audit and any incidents reported.

10.0 Prescribing Controlled Drugs

Since April 2012, Schedule 2, 3, 4 or 5 controlled drugs can be prescribed to a patient by:

- A doctor, dentist, pharmacist independent prescriber or nurse independent prescriber acting in their own right
- A supplementary prescriber (including a pharmacist supplementary prescriber) acting in accordance with a clinical management plan
- When controlled drugs are prescribed and administered in anything other than acute emergencies, the healthcare practitioner concerned or their clinical supervisor should:
  - Confirm any recent opioid dose, formulation, frequency of administration and any other medicines prescribed for the patient.
  - Ensure where a dose increase is intended, that the calculated 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).
  - Ensure they are familiar with the following characteristics of the medicine and formulation; usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.

- Whilst dose increments should be in line with this guidance, it is recognised that in palliative care higher than normal doses may be required.
- All standard Trust prescribing guidelines must be followed as detailed in the Medicine Policy. In addition the following specific requirements apply to in patient, discharge and out-patient prescriptions:

10.1 Prescribing for in-patients

Please see Appendix 3 – Controlled Drug Prescription Requirements

For hospital in patients, CD’s can be prescribed on in patient medicines chart or the patient’s epidural/PCA prescription or on the anaesthetics record/prescription sheet in theatre. The requirements for controlled drugs on these charts are the same as of other prescribed medicines.

The prescription must contain:
- Patient’s full name, Date of Birth, hospital number and allergy status
- Generic drug name, form and strength
- Dose
- Route
- Frequency (if prescribed ‘when required’ a minimum interval should be specified e.g. every six hours and a maximum total quantity to be administered in 24 hours
- Include a finish date if appropriate
- Start date
- Signature of prescriber
- Computer generated prescriptions are acceptable providing the prescription is signed and dated by the prescriber

Page 12 of 69
10.2 Prescribing for discharge patients
Prescriptions for discharge medicines must be written on the Trust CD TTO prescription form. This prescription complies with the Misuse of Drugs Regulations and its amendments in 2001 for a controlled drugs prescription.
An entry on the electronic discharge notification form (eDNF) must also be made to ensure that the patient's GP is informed of all discharge medication including controlled drugs.

Medical doctors who have not achieved full registration with the GMC (F1’s) are permitted to prescribe CD’s on these prescription forms and on in patient charts as far as it is necessary for their employment.

In addition to the prescribing requirements above, the total quantity of the preparation OR the total number of dosage units to be supplied must be stated in words and figures on the prescription (see Appendix 3).

10.3 Prescribing for Out-patients
Prescriptions for out-patients for schedule 2 and 3 controlled drugs (with the exception of Temazepam but including Midazolam requirement from 1st January 2008) must be written in accordance with the Misuse of Drugs regulations (Regulation 15). A standard hospital out-patient prescription can be used and must be written by hand, typed or computer generated and contain the following details:

- Patient full name, address and where appropriate age
- Hospital number (also NHS number if available)
- Allergy status
- Drug name, form and strength
- Route
- Dose to be taken
- Frequency
- Total quantity in words and figures
- Signature of prescriber
- Date

The use of pre-printed addressograph labels can be used but the prescriber must ensure that all copies of the prescription have a sticky label and that the label cannot easily be removed. It is good practice to sign over the sticky label to safeguard it being tampered with.
Medical doctors who have not achieved full registration with the GMC (F1’s) are not permitted to prescribe CD’s on these prescription forms for out-patients.

A maximum of 30 days supply may be supplied and only will be exceeded if officially requested in writing to the Chief Pharmacist.

Where a prescription for a schedule 2 or 3 controlled drug contains a minor typographical error or spelling mistake, or where either the words or figures (but not both) of the total quantity has been omitted, a pharmacist can amend the prescription indelibly so that it becomes compliant with legislation. The pharmacist needs to have exercised due diligence, be satisfied that the prescription is genuine and that the supply is in accordance with the intention of the prescriber. The prescription should also be marked to show that the amendments are attributable to the pharmacist (e.g. name, date, signature and GPhC registration number). Pharmacists cannot correct other amendments or omissions (e.g. missing date, incorrect dose, form or strength). These should be corrected by the original prescriber or, in an emergency, another prescriber authorised to prescribe controlled drugs. Amendments cannot be made by covering letter from the prescriber.
The doctor must be contacted and asked to amend any prescription for a CD that does not comply with any other of the legal requirements, before it can be supplied. It is illegal for a doctor to issue and for a pharmacist to dispense an incomplete or incorrectly written prescription for a controlled drug, with the exception described as a minor technical error above.

11.0 Administration of Controlled Drugs

Administration of Controlled drugs must follow the general principles laid out in the Medicines policy for administration of medicines.

In addition:
- There must be two members of staff involved in the administration of a controlled drug one of whom must be a registered general nurse (RGN) or midwife, doctor or ODP. The second person (the witness) can be an RGN, midwife, doctor, pharmacist, registered ODP or an Assistant Practitioner that has completed the required training. In community hospitals an appropriately trained nursing auxiliary may be appropriate but only where one registered nurse is on duty and a doctor is unavailable.
- Student nurses may be the witness for a qualified nurse but this will depend on experience and the complexity of the controlled drug that is being administered. Refer to the Trust Administration of Medicines Policy.
- Anyone checking the administration of a CD must have received training and been assessed as competent (CD workbook).
- Controlled drugs must not be administered if the prescription is unclear, illegible or ambiguous or there is any reason for doubt, e.g. patient condition/response to previous dose.

Note - Under no circumstances must a verbal order be taken for controlled drugs.

- It is important that controlled drugs are administered at the specified time and if not the reason documented.
- When removing CD’s from the CD cupboard for administration it is important that the stock balances are checked at the same time. Discrepancies must be reported immediately to the nurse in charge and investigated. See Appendix 7.
- The CD must be prepared by an RGN, doctor, midwife or ODP and checked by a second person deemed competent as detailed above.
- The nurse administering the CD must have the administration of the CD witnessed by the second person and must record the administration in the CD register and sign that the drug has been administered, this must be counter-signed by the witness and if any excess or waste, that this has been destroyed and recorded according to the procedure for disposal of prepared partly used controlled drugs.
- The reason for any doses drawn up and not given must be recorded in the controlled drug register.

11.1 Patient Group Directions (PGD’s)

Certain controlled drugs may be supplied and administered under Patient Group Directions (PGDs) by named nurses, paramedics and other specified health professionals in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No 3) Regulations (SI 2003 No.2429).

A PGD may be used only in the following circumstances:
- Supply and administration of Diamorphine by registered nurses in emergency departments and coronary care units in hospitals for the treatment of cardiac pain.
- Supply and administration of midazolam, any schedule 4 or 5 CD (except anabolic steroids and injectable formulations to addicts) by registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists,
physiotherapists, radiographers, occupational therapists and orthotists or prosthetists.

12.0 Safe and Secure Handling of Controlled Drugs on Wards and Departments

Please refer to Appendices 4 to 16 – The Standard Operating Procedures (SOPs) Storage & Handling of Controlled Drugs (CD’s) on the wards

12.1 Controlled Drug stationery

• Definition

All stationery which is used to order, return or distribute CD (Controlled stationery) should be stored securely and access to it should be restricted. This includes:

- Controlled drug requisition books
- Controlled drug record books
- Local CD documents including consignment note books
- CD Discharge Prescriptions

• Secure storage

CD stationery which is kept in wards, theatres or departments must be kept in a secure area that is locked. The CD order book should be kept where practical in the CD cupboard.

Stocks of CD stationery held in the Pharmacy are kept securely in the CD room which is kept locked when no-one is present to supervise the room.

• Supply of CD stationery

CD stationary should be issued from the Pharmacy against a requisition. The Ward CD order book is used for this purpose. Requisition number 99 should be routinely used for this purpose.

CD order books are numbered sequentially to provide a means of tracking.

The Pharmacy keeps a record of all Controlled stationery issued detailing:

- Date
- Ward/Department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- Serial numbers of the stationery
- Signature of person making the supply

Any unused stationery returned to Pharmacy will be recorded as a return with all details as above.

• Loss or theft of CD stationery

Loss or theft of CD stationery which may be used to order CD’s should be reported to the Accountable officer immediately.

• Use of CD stationery

Only one CD requisition book per ward or department should normally be in use

When a new CD register is started, the balance of CD’s in stock should be written into the new book promptly by the ward staff. This should be witnessed by a nurse, midwife or ODP.

Completed ward requisition books and CD register must be retained for a minimum of two years from the date of the last entry.
13.0 Returns/ Disposal of Controlled Drugs

13.1 Returning controlled drugs to Pharmacy

Please refer to SOP 5 in Appendix 4

13.2 Disposal of Controlled drugs on wards or departments

Please refer to Appendix 6

CD’s should be destroyed in a way that renders the drug irretrievable so that it cannot be re-used. Where denaturing is carried out on the wards the methods used will comply with the guidelines laid down by the Royal Pharmaceutical Society of Great Britain (Guidance for Pharmacists on the safe destruction of controlled drugs).

Denaturing kits will be necessary in those areas where large quantities of CD’s are used and large volumes of part used ampoules, vials, syringes, and infusion bags is high. A ward SOP is in place to instruct wards on how to safely denature the CD’s.

For purposes of best practice, a small amount will be defined as 5 millilitres or less. Volumes in excess of 5 millilitres will be classed as large amounts. All destruction should be documented in the ward CD register and witnessed by a second nurse, midwife or ODP with signatures.

- Method of disposal of Controlled Drugs

Small amounts of CD’s (i.e. 5 millilitres or less) should be destroyed immediately on the wards (see Table 3 below) and rendered irretrievable by emptying into a sharps bin. When the bin is sent for disposal it should be labelled according to the Trust Waste disposal policy.

Large amounts of CD’s (i.e. volumes in excess of 5 millilitres) should be destroyed immediately on the wards (see Table 3 below) and rendered irretrievable by using a CD denaturing kit. When the kit is sent for disposal it should be labelled according to the Trust Waste disposal policy.

- Destruction of Patients Own controlled drugs

If patient’s own CDs are no longer required and if the patient or a relative agrees then they should be destroyed on the ward or in pharmacy. If returned to the Pharmacy the Pharmacist will document in the register that the Patients Own CD’s have been removed from the ward and returned to Pharmacy for destruction. The register entry will be witnessed by the RGN, midwife or ODP. The Patients Own CD’s will be placed in a blue transit bag and tagged. The CD requisition book will be completed with details of the Patients Own CD and taken together with the sealed bag to Pharmacy. The destruction will be carried out by the Pharmacist in the Dispensary CD Room and witnessed by a second Pharmacist or pharmacy technician. A record of the destruction will be made in the Patients Own CD’s register and witnessed by a second Pharmacist or pharmacy technician (Refer to Appendix 10 – Recording and Administration of Patients Own Controlled Drugs).

If a denaturing kit is available on the ward then the destruction may take place on the ward carried out by the Pharmacist and a nurse as a witness. This local practice is approved by the CD Accountable Officer provided they are informed of when the destruction taking place.
<table>
<thead>
<tr>
<th><strong>Table 3- Disposal of Controlled Drugs</strong></th>
<th><strong>Where destruction should take place</strong></th>
<th><strong>Person who should destroy drug + method</strong></th>
<th><strong>Person who should witness destruction</strong></th>
<th><strong>Register entry</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient’s own – unsuitable for use or no longer required</strong></td>
<td>Pharmacy or on the Ward where denaturing kits are available</td>
<td>Pharmacist or registered CD technician</td>
<td>Pharmacist or registered CD technician or nurse on the ward</td>
<td>Pharmacy CD patients own destruction Register or patients own CD register if on the ward</td>
<td>The patient or relative SHOULD consent to the destruction as patient property (where appropriate)</td>
</tr>
<tr>
<td><strong>Patient’s own – unsuitable for use (handed in directly to Pharmacy by patient (e.g. Outpatients))</strong></td>
<td>Pharmacy</td>
<td>Pharmacist or registered CD technician</td>
<td>Pharmacist or registered CD technician or nurse on the ward</td>
<td>Pharmacy CD patients own destruction Register</td>
<td>The patient or relative SHOULD consent to the destruction as patient property (where appropriate)</td>
</tr>
<tr>
<td><strong>Patient’s own – Patient deceased</strong></td>
<td>Pharmacy or on Ward where denaturing kits are available</td>
<td>Pharmacist or registered CD technician</td>
<td>Pharmacist or registered CD technician or nurse on the ward</td>
<td>Pharmacy CD patients own destruction Register or patients own CD register if on the ward</td>
<td>Patient’s own CDs for deceased patients can be destroyed without the consent of the patient’s estate (or relatives).</td>
</tr>
<tr>
<td><strong>Ward stock – unfit for Use</strong></td>
<td>Pharmacy</td>
<td>Pharmacist or registered CD technician</td>
<td>Authorised Witness as designated by the CDAO</td>
<td>Ward CD Register + Pharmacy CD destruction register if returned to pharmacy</td>
<td>Designated Trust Executives. Yearly dates scheduled in advance</td>
</tr>
<tr>
<td><strong>Wastage from part doses drawn up on ward for individual patient (volume 5 mL or less)</strong></td>
<td>On the ward</td>
<td>Registered nurse or midwife Empty into sharps bin</td>
<td>Registered nurse, midwife, doctor, pharmacist</td>
<td>Ward CD Register</td>
<td>Ward register should show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted</td>
</tr>
<tr>
<td><strong>Wastage from part doses drawn up in theatre for individual patient, (volume 5 mL or less)</strong></td>
<td>In theatre</td>
<td>Registered nurse, midwife or ODP Empty into sharps bin</td>
<td>Registered nurse, midwife, doctor or pharmacist</td>
<td>Theatre CD Register</td>
<td>Theatre register should show name of patient and details of dose/wastage e.g. 5mg given/5mg wasted</td>
</tr>
<tr>
<td><strong>Dose drawn up on ward for individual patient but not given (volume 5 mL or less)</strong></td>
<td>On the ward</td>
<td>Registered nurse or midwife Empty into sharps bin</td>
<td>Registered nurse, midwife, doctor or pharmacist</td>
<td>Ward CD Register</td>
<td>Ward register should show name of patient and reason for non-administration</td>
</tr>
<tr>
<td><strong>Wastage from discontinued parenteral dose in infusion bag or syringe (volumes in excess of 5mL)</strong></td>
<td>on ward, or in theatre must be denatured</td>
<td>Registered nurse or ODP Denaturing kit</td>
<td>Registered nurse, midwife, doctor, pharmacist or registered technician</td>
<td>Wasted</td>
<td>Details of amount administered and amount discarded should be recorded in medical record</td>
</tr>
<tr>
<td><strong>Dose drawn up in theatre for individual patient but not given (volume 5 mL or less)</strong></td>
<td>In theatre</td>
<td>Registered nurse, midwife, ODP or anaesthetist Empty into sharps bin</td>
<td>Registered nurse, midwife, ODP doctor or pharmacist</td>
<td>Theatre CD Register</td>
<td>Theatre register should show name of patient and reason for non-administration</td>
</tr>
<tr>
<td><strong>Pharmacy stock unfit for use (schedule 1 and 2 only)</strong></td>
<td>Pharmacy</td>
<td>Pharmacist or registered CD technician</td>
<td>Trust Authorised Person</td>
<td>Pharmacy CD Register and Pharmacy destruction register</td>
<td>Designated Trust Executives. Yearly dates scheduled in advance</td>
</tr>
</tbody>
</table>
14.0 Safe and Secure Transportation of CD’s

14.1 Transfer of CD’s will include the following:
   - Collection by ward staff from the Pharmacy
   - Collection by porters from the Pharmacy
   - Delivery by Pharmacy staff to wards, departments, theatres
   - Collection by patient or representative for out-patient items only
   - Delivery by Trust porter/driver
   - Delivery by taxi (out of hours)

14.2 Methods of transfer

CD’s must be transferred in a safe and secure manner. In this Trust CD’s for stock will be transferred in Red Envopak bags with a uniquely number seal and require a signature for receipt of the sealed bag using consignment notes. Discharge drugs containing CD’s will be transferred in the blue envopak bags in a similar way. These bags are labelled as containing a CD to alert the ward staff to the contents of the bag. Similarly a signature for collection and receipt is required on a consignment note. It should be explicit as to who has custody of the controlled drugs at any point in time.

14.3 Records transfer

At each point a controlled drug moves from the authorised possession of one person to another, a signature should be obtained by the person handing over the drug and the person receiving it. The Pharmacy CD consignment note is used for this purpose.

14.4 Messengers

Where staff are used as a messenger for CD’s, i.e. they are carrying a sealed bag, they are responsible for the intact bag. The person acting as the messenger should be made aware that:
   - They know the destination of the bag
   - Be aware of the safe storage and security and the importance of handing over the item to an authorised person and obtaining a signature for delivery on the consignment note. The consignment note should then be returned to Pharmacy for retention.
   - Have a valid ID badge
   - Where a taxi driver or courier is used they should have valid company ID. They should be asked to show their valid company ID, as for other medicines. Also the drivers should not be made aware that CD’s are being transported as this may increase the potential for diversion or discourage taxi drivers from carrying CDs.

14.5 Transfer from ward to ward or theatre to ward

Local SOPs are in place to define safe, secure and auditable methods to transfer CD’s from ward to ward when a patient moves as follows:
   - When a patient has his/her own CD’s for self-administration
   - When a patient is receiving a CD by means of a syringe pump (PCA pump) or infusion.

Patients own controlled drugs should be transferred according to Appendix 10 – Recording and Administration of Patients Own Controlled Drugs
14.6 Patients’ own controlled Drugs

It may be appropriate that patients’ own CD’s are used whilst they are in hospital where the Controlled Drug is not available from the Pharmacy. This may occur for non-formulary or non-stocked drugs. These drugs should be checked for suitability to use as per usual procedure.

In addition the following should be followed:

If the patient or patient’s representative agrees, the medicines may be sent to the Pharmacy for safe destruction if they are no longer required or disposed of on the ward by a Pharmacist.

Patients’ own CDs should be transferred from ward to ward with the patient in line with local procedures for transferring all other medicines and properties belonging to that patient. An entry should be made in the CD register for patients’ own drugs on both wards.

If the patient agrees the medicines should be returned home via an authorised adult. Responsibility is given to that adult for safe storage or they should be advised to send to the Pharmacy for destruction if they cannot be stored safely or are no longer required by the patient.

Patients own CD’s that are not required for self-administration should not routinely be kept on the ward. Temporary storage may be necessary whilst awaiting collection or removal to the Pharmacy or to the patient’s home. These should be kept separate from ward stock CD’s and the local SOP should be adhered to.

Patient’s own CD’s should never be used to treat other patients.

Please see Appendix 10a - Flow Chart: Patients Own Controlled Drugs

14.7 Patients receiving CDs by infusion devices

Controlled drugs will require transfer in the following situations:

- When a patient is receiving a CD by means of a syringe pump (Patient Controlled Analgesia – PCA)
- When a patient is receiving a CD by means of a syringe driver (usually palliative opioids for analgesia)
- When a patient is receiving a CD by means of a infusion (epidural infusions, etc)
- Transfer of patient own drugs in use on the ward

Infusion devices must preferably be locked during transfer of a patient in order that they may not be tampered with.

Robust SOPs must be in place on all wards/ clinical areas involved in the transfer of CDs in infusion devices, in order to maintain safe and secure storage. The procedures must include:

- A description of the CD preparations available and the medical devices (e.g. pumps, syringe drivers)
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (e.g. prefilled syringes, infusion bags)
- Specification of the entries required in the CD register
- Arrangements for documentation when the patient is moved from theatre to wards
- Arrangements for recording administration
- Arrangements for disposal of surplus CDs.
14.8 Controlled drug discharge medicines

When CD discharge medicines are sent to the ward several hours before they are required for discharge the medicines may be stored in a separate part of the CD cupboard in the sealed bag received from Pharmacy, and recorded in the ward CD register as such. When the patient is ready to leave the ward, the CD should be booked out of the register by the registered nurse, midwife or ODP.

If the patient is being transferred to Congleton War Memorial Hospital it is best practice to transport these in a Blue Envopak sealed bag. A signature for collection and receipt must be obtained on a consignment note.

When CD’s are collected from Pharmacy, the person collecting them will be asked to sign for the receipt of the CD’s on a Trust CD consignment note.

14.9 Receipt of CDs by out-patients

Patients or their representatives will be asked to provide evidence of their identity when collecting CD’s. This became a requirement from July 2006. The dispenser will ask for evidence of the person’s identity and may refuse to supply if that evidence is not provided.

Where the person collecting the CD is a healthcare representative the dispenser must obtain the name and address of the person and must unless acquainted with the person request evidence of the person’s identity, but may use their discretion and supply even if the identity has not been provided if by not supplying the patient’s treatment may be compromised.

From 1st February 2008 the details of the person collecting the CD and their relationship to the patient and whether evidence was provided with the details of the evidence provided must be entered into the CD register.

14.10 Controlled Drugs for Clinical trials

Any clinical trials that involve CDs must comply with the Misuse of Drug regulations in addition to local policies governing the management of clinical trial medicines in addition to clinical trials legislation and MHRA guidance on clinical trials.

14.11 Storage and records

All clinical trial CD’s should be stored separately from stocks CD’s in a segregated part of the cupboard. A separate page in the register should be used to record the receipt and issues in addition to keeping the clinical trial documentation.

If a discrepancy is identified then it should be reported on the local drug incident reporting system and a note made on the clinical trial documentation. The sponsor and investigator should be informed and also the Accountable officer.

For double blind trials in which only one arm involves a CD, pharmacy may be unaware of which is a CD in which case all stock should be treated as a CD.

For trials that involve the use of a schedule 1 CD such as a cannabinoid, a license from the home office must be obtained before the item is received into stock or supplied. The license will be held by the Accountable officer. A copy should be kept with the trial protocol.

14.12 Labelling

All clinical trials must be labelled and dispensed in accordance with the specific trial protocol in addition to the MDR requirements.
14.13 Disposal
Clinical trial CD’s must be destroyed in the same way as other CD’s. However this must be carried out following the monitoring instructions with the trial sponsor.

14.14 Clinical trial CD’s returned by patients
Drug accountability records should be completed promptly when clinical trial CD’s are returned by patients. The CD’s should be safely stored and destroyed according to procedure for destruction of patient own CD’s.

15.0 Controlled drugs for Midwives

15.1 Midwives Working in Hospital
The Midwives working for East Cheshire NHS Trust now operate as integrated teams known as Midwifery Group Practice Midwives.

Midwives working within the hospital setting must follow the general guidance for administration. Administration of controlled drugs and other medicines by midwives working within the hospital setting is in accordance with this policy.

15.2 Administration of Epidural
The epidural is a close circuit system that is set up by the Anaesthetist and Midwife at the point of insertion of the epidural - with the loading dose, continuous infusion and bolus dose pre-set in a locked container. Midwives no longer give top ups of epidural and should this be required this is in the remit of the Anaesthetist

16.0 Illicit substances
If large amounts of illicit or unidentified drugs are found on patients’ possession, or there is intent to deal or supply then the police should be informed immediately.

Please refer to Appendix 13 - Removal of Illegal or suspicious substances from patients

- Holding an illegal substance with the intent to destroy is not an offence if it is part of recognised trust policy.
- It is illegal to return an illicit drug to the patient as this could be seen as ‘supplying’.

16.1 Drug Misusers
Please refer to the Trusts Policy for in-patient and out-of-hours management of drug misusers

17.0 Management of CD’s in Theatres and Theatre Recovery
Please refer to Appendix 17 – Handling and Storage of Controlled Drugs in Theatres

18.0 Management of CD’s in Radiology
Please refer to Appendix 18 – Use of Pethidine in Radiology

19.0 Management of CD’s in Cardio- Respiratory
Please refer to Appendix 19 – Use of Fentanyl in Cardio-Respiratory
20.0 Management of CD's in the Community Setting

20.1 Community Nurses

Standard Operating Procedures for the Management of Controlled Drugs by Community Nurses within East Cheshire Trust – see appendix 20 (p56.)
**Appendix 1 - Glossary of terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled Drug Accountable Officer</td>
<td>Officer in a healthcare organisation who is responsible for the safe and effective use of and management of controlled drugs. Appointment required by Controlled Drugs Supervision and Management of Use Regulations 2006</td>
</tr>
<tr>
<td>Controlled Drugs (CDs)</td>
<td>The drugs listed in schedule 1-5 of the Misuse of Drugs regulations 2001 (as amended) Drugs listed in different schedules have different requirements. Trust policy states what level has been applied locally to comply with the minimum requirements at least.</td>
</tr>
<tr>
<td>ODP</td>
<td>Registered Operating Department Practitioner</td>
</tr>
<tr>
<td>PCA</td>
<td>Patient controlled analgesia</td>
</tr>
<tr>
<td>CMP</td>
<td>Clinical management plan</td>
</tr>
<tr>
<td>RGN</td>
<td>Registered general nurse</td>
</tr>
<tr>
<td>CD record Book (CDRB)</td>
<td>Bound book in which records are made of CD’s received and administered in wards, theatres and departments</td>
</tr>
<tr>
<td>CD Register</td>
<td>A ‘register’ as specified in the misuse of drugs regulations 2001 (as amended) means either bound book, which does not include any form of loose leaf register or card index or a computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under Section 2 of the National Health Service Act 1977</td>
</tr>
<tr>
<td>Discrepancy</td>
<td>Difference between the amount shown in the register or record book and the amount that is physically present</td>
</tr>
<tr>
<td>MDR</td>
<td>Misuse of Drugs regulations</td>
</tr>
<tr>
<td>PODs</td>
<td>Patient own drugs. In this context patient own drugs brought into hospital by the patient on admission.</td>
</tr>
<tr>
<td>Registered nurse, midwife or ODP in charge</td>
<td>The registered nurse, registered midwife or registered operating department practitioner (ODP) who is nurse in charge for the time being (senior registered nurse, midwife or ODP on duty) and is therefore responsible for management of Controlled drugs.</td>
</tr>
<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>A standard operating procedure specifies in writing what should be done, when where and by whom in order to manage safely and accountably any set processes, in this case around the total management of CD’s</td>
</tr>
</tbody>
</table>
**Appendix 2 - Audit Proforma – CD 3 monthly check**

**Ward/Dept:** ________________________________  **Date:** ________________________________

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Y / N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>Is the cupboard and lock in a safe and secure condition?</td>
<td>Y / N</td>
</tr>
<tr>
<td>1b</td>
<td>Is there a BS (british standard) sticker in or on the CD cupboard?</td>
<td>Y / N</td>
</tr>
<tr>
<td>2</td>
<td>Do all balances in the register match stock held in cupboard? (If N, detail discrepancies, report on Datix incident reporting system, and attach copy of incident form to this audit proforma)</td>
<td>Y / N</td>
</tr>
<tr>
<td>3</td>
<td>Are there any patients own CDs that are either expired or patient no longer on ward? (investigate and/or destroy on ward if appropriate as per SOP and record in register)</td>
<td>Y / N</td>
</tr>
<tr>
<td>4</td>
<td>Are there any expired Ward CD stock? (return to pharmacy for destruction as per SOP and record in register)</td>
<td>Y / N</td>
</tr>
<tr>
<td>5</td>
<td>Does any stock need returning to pharmacy? (If Y, please fully document the return in the controlled drug requisition book, and follow the Pharmacy Dept SOP’s to complete the destruction/ register for destruction process)</td>
<td>Y / N</td>
</tr>
<tr>
<td>6</td>
<td>Does the ward stock high strength opiates?</td>
<td>Y / N</td>
</tr>
<tr>
<td>7</td>
<td>Are high strength opiates stored in an appropriately labelled section of the controlled drug cupboard? (If N, explain)</td>
<td>Y / N / NA</td>
</tr>
<tr>
<td>8</td>
<td>For Q8 and Q9, a random sample of CD requisitions and prescriptions should be checked as follows: Have the controlled drug requisitions been entered in the register correctly? (If N, detail discrepancies, report on Datix incident reporting system, and attach copy of incident form to this audit proforma)</td>
<td>Y / N</td>
</tr>
<tr>
<td>9</td>
<td>Has the individual prescription entry been made correctly? (If N, detail discrepancies, report on Datix incident reporting system, and attach copy of incident form to this audit proforma)</td>
<td>Y / N</td>
</tr>
<tr>
<td>10</td>
<td>Where part ampoules are administered, is the amount given and amount wasted both recorded in the CD register? Review a sample of pages in the CD register e.g. Morphine 10mg ampoules</td>
<td>Y / N</td>
</tr>
<tr>
<td>11</td>
<td>Does the ward need a new Ward Controlled Drug Register?</td>
<td>Y / N</td>
</tr>
<tr>
<td>12</td>
<td>Is the list of authorised signatures up to date? (Review a copy with the Senior Sister/ Charge Nurse)</td>
<td>Y / N</td>
</tr>
<tr>
<td>13</td>
<td>Is the CD key held in accordance with Safe &amp; Secure Storage of Controlled Drugs Policy?</td>
<td>Y / N</td>
</tr>
<tr>
<td>14</td>
<td>Is the controlled drug requisition book stored in a secure area that is locked?</td>
<td>Y / N</td>
</tr>
<tr>
<td>15</td>
<td>Does the ward/ clinical area stock Naloxone? (If N, detail reasons why)</td>
<td>Y / N</td>
</tr>
<tr>
<td>16</td>
<td>If the ward/ clinical area uses midazolam, does it stock Flumazenil? (If N, detail reasons why)</td>
<td>Y / N</td>
</tr>
</tbody>
</table>

In completion of the inspection of each item, enter “Stock & running balance check complete and correct” and then sign the entry in the record book. If incorrect, then make an entry detailing the correct balance and ask the appointed practitioner in charge to complete an incident form.

Check undertaken by ____________________________________________  
*Signature and Print name*

Witnessed by appointed practitioner in charge ____________________________
*Return Completed form to ECT Chief Pharmacist (Accountable Officer)*
Additional Notes:

Please document full details and report any discrepancies using the Trust Incident Reporting system (Datix). Escalate identified discrepancies to the Chief Pharmacist (Accountable Officer) upon completion of the audit.
Appendix 3 - Controlled Drug Prescription Requirements

A prescription for Schedule 2 and 3 Controlled Drugs (with the exception of temazepam) must contain the following details, written so as to be indelible (i.e. written by hand, typed or computer-generated):

- The patient’s full name, address and - where appropriate - age.
- The generic name and form of the drug, even if only one form exists*. **Check in BNF to confirm form.**
- The strength of the preparation, where appropriate.
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied **in both words and figures. Please check BNF for pack sizes.** (e.g. Zomorph® capsules are in packs of 60, Oxycontin® tablets are in packs of 56).
- The prescription must be signed by the prescriber with his/her usual signature, in his own handwriting (this must be handwritten).
- Dated by the Prescriber (the date does not have to be handwritten).

In addition, please include the patient’s NHS number on the prescription if available. This is a national requirement from December 2009.

**Good Practice Points:**

Prescribe both as generic and brand product name (this ensures that patients are continued on the same brand as started in hospital).

Pre-printed addressograph labels may be used on prescriptions, however it is not recommended. Addressograph labels used should be tamper-evident and if used, Prescribers should sign the over the label to ensure it is secure as possible.

Up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a note of the reasons in the patient’s notes, and contact the Trust Chief Pharmacist to discuss the logistics of making a supply beyond 30 days.
Appendix 4 - Ordering and receipt of controlled drugs from pharmacy

1. This procedure applies to ordering Controlled Drugs from Pharmacy during their opening hours, or by arrangement with the on call pharmacist. See separate procedure for obtaining doses of Controlled Drugs when Pharmacy is closed SOP 09.

2. The registered nurse or midwife in charge of the ward is responsible for ordering Controlled Drugs for use in that area, but may delegate the task of preparing an order to another registered nurse, midwife or OPD.

3. Controlled Drugs must be ordered in the Controlled Drug order book specific to that ward or department. If the ward has more than one Controlled Drugs cabinet, then each cabinet must have an order book and register, specific to that cabinet.

4. Controlled Drugs should be ordered Monday to Friday, and should only be ordered at the weekend if it is an urgent supply. Topping up CDs at weekends is not appropriate.

5. The Controlled Drugs order book should be kept in a locked cupboard or drawer preferably the CD cabinet. Should an order book go missing, the nurse or midwife in charge must immediately inform the Associate Director of the business unit and pharmacy. An incident report must be completed.

6. Only an authorised signatory may order Controlled Drugs. A list of authorised signatures is maintained in Pharmacy. This will be updated on request from Pharmacy.

7. A separate page must be used for each item.

8. Indelible, preferably black ink should be used.

9. If an error is made on entry it must be cancelled by striking across the page with the words cancelled order written across and a new order made.

10. Ensure the carbon paper is inserted between the duplicate pages, with the carbon facing down.

11. When the Controlled Drugs are ready in pharmacy they will either be delivered by the porter or pharmacy will telephone the ward to collect.

12. If the ward sends an approved member of staff, known as the messenger, to collect the Controlled Drugs. The member of staff must be a Trust employee with a full, permanent Trust identity card. The card must be on display when receiving the Controlled Drugs from Pharmacy.

13. CD discharges will be sealed in a blue bag. The words “CD Discharge – Mr/Mrs Joe Bloggs – Ward …” and the seal number will be clearly visible on the consignment note. Ward stock CD’s will be sealed in a red CD bag.

14. The messenger or porter with a member of the pharmacy staff, checks that the delivery bag is sealed.

15. The messenger or porter signs and dates the consignment note and checks that the number on the seal corresponds to the numbered seal on the bag.

16. The ordered stock must be taken directly to the ward or department by the messenger or porter in the sealed bag.

17. On arrival at the ward, a non-qualified messenger or porter must hand the goods to an appropriate individual. This should be the registered nurse or midwife in charge, or another
registered nurse or midwife. In theatres, this may be the registered nurse in charge, another registered nurse or OPD, to be arranged locally.

18. As a matter of good practice, the receiving person should not be the same person who ordered the controlled drugs.

19. The Registered nurse receiving the controlled drugs must immediately check that the seal on the bag is intact and that number on the consignment note and on the bag match and sign for receipt of the sealed bag. The completed Consignment Note is then returned to Pharmacy and filed.

20. Out of hours it may be necessary for the Trust contract taxi service to collect CD’s and deliver to outlying wards or to patient’s own home. In this circumstance a consignment note must always be completed and signed by the taxi driver. The taxi driver must provide identification before the CD’s are released for transportation. It is good practice to note the registration of the vehicle if possible. This can be made on the consignment note.
Appendix 5 - Storage and entry of controlled drugs into the controlled drug record book (Register)

1. All record keeping in the Trust must comply with the Department of Health guidance which was updated in 2007.

2. Each ward or department that holds CD stocks must keep a record of CD's received and administered in the CD record book (register). The registered nurse, midwife, ODP in charge is responsible for keeping the record book in good order and up to date.

3. All records must be stored for a minimum of two years from the date of the last entry in the register.

4. Each Controlled Drugs cabinet must have a Controlled Drugs register specific to that cabinet (or cabinets if these cabinets are in close proximity).

5. Once the Controlled Drugs have reached the ward or department they become the ultimate responsibility of the sister or acting sister who at that time is in charge of the ward or department.

6. The authorised person receiving the CD’s must inspect each individual item, check there is the correct quantity and sign the receipt section on the pink copy of each order sheet.

7. Any discrepancies must be reported to pharmacy immediately.

8. Each controlled drug should be entered on a separate page, taking care to clearly distinguish between different strengths of controlled drugs and different formulations.

9. Full details of the drug identification must be written at the top of each page. These details should include
   a. Approved name of controlled drug
   b. Strength of preparation
   c. Formulation (e.g. liquid, tablet, patch)
   d. Brand (where appropriate)

10. All entries must be made in black ink and be otherwise indelible, and must be in chronological order with a running balance kept.

11. The register entry must include
   a. the date the CD was received
   b. quantity received
   c. signature of receiver
   d. signature of the witness
   e. new stock level
   f. Confirmation of correct balance in register.

12. All entries should be signed in full (initials are not allowed) by a registered nurse, midwife or ODP and witnessed by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available then the transaction can be witnessed by another registered practitioner (e.g. Doctor, Pharmacist, pharmacy technician) or by an appropriately trained healthcare assistant.

13. No cancellation, obliteration or alteration of any entry may be made. Errors in the register are to be bracketed and endorsed “error”, signed, dated and as good practice countersigned by a witness. Corrections must made be by way of marginal notes or footnotes.
14. All high strength opiates must be stored in a separate section of the CD cupboard to low strength opiates and the section labelled clearly as “high strength opiates”. High strength opiates have been identified as
   a. Morphine 30mg/ml (60mg/2ml)
   b. Diamorphine Injection 30mg
   c. Diamorphine injection 100mg
   d. Diamorphine injection 500mg
   e. Oxycodone 50mg/ml Injection

15. Wards must also ensure that Naloxone injection is available on the ward where opiates are used. This is in accordance with the NPSA Safer Practice Notice “Ensuring Safer Practice with high dose ampoules of diamorphine & morphine” May 2006.

16. Wards must also ensure that Flumazenil injection is available on the ward where Midazolam is used.
Appendix 6 - Administration of controlled drugs to patients

1. When an authorised prescriber has prescribed a Controlled Drug for a patient, an entry must be made in the Controlled Drugs register against the item each time a dose is administered.

2. If the required Controlled Drug is not available and Pharmacy is closed, follow the procedure for obtaining CDs when the Pharmacy is closed SOP 9.

3. Administration of Controlled drugs must follow the general principles laid out in the Medicines policy for administration of medicines and also to the principals in the introduction of section 10.9 of the Policy for Safe Management of Controlled drugs.

4. Appropriate monitoring of the patient must be undertaken after administration.

5. Administration of Controlled Drugs must involve two members of staff. One of the people must be a registered nurse, midwife, doctor or ODP. Anyone checking the administration of a CD must have received training and assessed as competent (the CD workbook).

6. All aspects of the reconstitution and preparation of the CD must be under the direct supervision of the person who is going to administer the drug.

7. A second person must check all aspects of the administration, including:
   - Preparation of the CDs to be administered
   - Entry in the CD register (the balance must be checked before administration to the patient)
   - The administration of the CD to the patient
   - The destruction of any surplus drug.

8. The second person may be:
   - A registered nurse
   - A registered midwife
   - A registered ODP/ODA in theatres
   - A doctor
   - A pharmacist
   - An Assistant Practitioner that has completed the required training
   - A radiographer.
   - In community hospitals an appropriately trained nursing auxiliary may be appropriate but only where one registered nurse is on duty and a doctor is unavailable
   - Student nurses may be the witness for a qualified nurse but this will depend on experience and the complexity of the controlled drug that is being administered.

9. The following should be recorded in the CD register:
   - Date and time of administration of the dose
   - Name of the patient
   - Quantity administered
   - Form (formulation and strength, e.g. liquid 10mg/5ml)
   - Name/signature of nurse/authorised person who administered the dose
   - Name/signature of witness
   - Balance in stock.

10. If the dose prescribed is made up of two presentations then two entries are required in the CD Register, each entry giving the patient’s total dose as well as the quantity/dose booked out for that item. E.g. A dose of morphine sulphate m/r 40mg requiring one 30mg and one 10mg capsule.
11. Liquid doses of less than 5ml must be measured out using an appropriate oral syringe.

12. If part of a vial is administered to the patient, the nurse, midwife or registered health professional should record the amount given and the amount wasted in the CD register. E.g. “2.5mg given and 2.5mg wasted”. This must be witnessed by a second person as above.

13. Individual doses of CDs which have been prepared but not administered should be destroyed by a registered nurse, midwife or registered health professional on the ward or department in the presence of a witness (as above) and the reason documented in the CD register.

14. Small amounts of CD’s (i.e. 5 millilitres or less) should be destroyed immediately on the wards (see Table 3 below) and rendered irretrievable by emptying into a sharps bin. When the bin is sent for disposal it should be labelled according to the Trust Waste disposal policy. Large amounts of CD’s (i.e. volumes in excess of 5 millilitres) should be destroyed immediately on the wards (see Table 3 below) and rendered irretrievable by using a CD denaturing kit. When the kit is sent for disposal it should be labelled according to the Trust Waste disposal policy. Refer to Section 13.2 of the Trust CD Policy for further information.

15. If a mistake is made in the CD register it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by a second registered nurse, midwife or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction.

16. In the event of a Controlled Drug being administered to the wrong patient, medical staff must be informed immediately. The ward manager must be informed and an incident report must be submitted using the Trust drug incident form. The Accountable Officer must be informed of all incidents relating to controlled drugs.

17. Controlled drugs must not be administered if the prescription is unclear, illegible, ambiguous or illegal or there is any reason for doubt. E.g. patient condition/response to previous dose.

18. Before administration confirm any recent opioid dose, formulation, frequency of administration and any other medicines prescribed for the patient.

19. Ensure where a dose increase is intended, that the calculated 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).

20. Ensure familiarity with the following characteristics of the medicine and formulation; usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, common side effects.
Appendix 7 - Checking Controlled Drug stock and handling discrepancies

1. The stock balance of all CDs entered in the CD register should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way.

2. These checks MUST be carried out at least once a day and preferably at each handover of keys at shift change. A reason should be stated if the procedure deviates from this recommendation.

3. The registered nurse or midwife in charge is responsible for ensuring that the regular CD stock check is carried out by staff on the ward or department.

4. The balance in the register must be checked against the quantity of each Controlled Drug by two registered nurses, midwives or registered health professionals.

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

6. Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

7. A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the Controlled Drugs register.

8. This record should state the date and time of the reconciliation check and include wording such as “check of stock level” and be signed by the registered nurse, midwife or ODP and the witness.

9. A balance check must also be made each time there is stock movement of a Controlled Drug.

10. If a discrepancy is found it should be investigated without delay. If the discrepancy is less than 10% for liquids, the need for an investigation should be taken following discussion with the ward pharmacist.

11. All discrepancies must be and recorded on the Trust Incident reporting system

12. On discovering a discrepancy, action should include
   - Recounting balance again and by another individual authorised to do so
   - Rechecking all receipts have been recorded
   - Rechecking the balance has been calculated correctly
   - Stock has not been separated and stored in another area of the Controlled Drugs cabinet

13. If the discrepancy cannot be resolved, the nurse or midwife in charge of the ward must be informed.

14. The ward manager must inform the Pharmacy and a drug incident report should be completed.

15. Major incidents are to be reported to the Associate Director, and the Trust Accountable Officer.
Appendix 8 - Return of unwanted / out-of-date controlled drugs to pharmacy

1. Where controlled drugs are not required or are time expired then contact the Ward Pharmacist who will return the stock back to Pharmacy either for destruction or re-use. CD stock no longer required can be re-issued by the Pharmacy provided it was initially supplied by the Pharmacy and has at all times been under the control of the hospital.

2. The Pharmacy will carry out a risk assessment of CD's returned to Pharmacy to ensure they are fit for use. As a rule the Pharmacy will only accept for reuse CD’s that have at least 6 month’s usable shelf life. Expired CD’s or those that are unfit for use (e.g. opened liquids) should be brought back from the ward/clinical area by the ward Pharmacist for safe destruction and disposal. This must be by arrangement with the ward Pharmacist.

An entry must be made in the CD register as follows:

- Date and time of the removal
- Reason for removal of the CD
- Enter the appropriate stock balance – checking against the stock in the CD cupboard and indicating if it is correct by initialing the balance figure

3. The designated nurse, midwife or ODP will countersign the entry as a witness

4. A record of the controlled drug for return must then be made in the ward controlled drug requisition book stating name, form, strength and quantity for return and reason for return. This entry must be signed by both the ward Pharmacist and the designated nurse. One page may be used to record several items for return.

5. The ward pharmacist will return the controlled drug to the Pharmacy complete with the top copy of the requisition. The top copy will be kept with the returned CDs as Pharmacy record and the 2nd copy will remain on the ward to complete the audit trail.

6. CD’s will be returned to Pharmacy in a secure way, using the red envopak bag or in a blue transit bag and secured with a security seal.

7. The appropriate returns entry will be recorded in the Pharmacy CD Register by the person returning the Controlled Drug and on the day it is returned to Pharmacy.
Appendix 9 - Disposal of prepared/partly-used controlled drugs not administered to patients.

1. A dose of a controlled drug that is prepared and not administered or only partly used for whatever reason e.g. contaminated, fell on the floor, broken tablet or capsule, remains of part of a dose given can be destroyed at ward level.

2. If the dose or part of a dose is 5 millilitres in volume or less, it can be destroyed by a registered nurse, midwife, doctor or ODP and a suitably qualified witness by emptying into a purple lidded sharps bin.

3. When the sharps bin is sent for disposal it should be labelled according to the Waste Disposal policy.

4. Large volumes of partially used controlled drugs for destruction (i.e. more than 5 millilitres in volume) e.g. PCA bags, must be destroyed by denaturing.

5. The method of denaturing is to use Gel vac sachets which can be obtained from Pharmacy and a purple lidded sharps bin.

INSTRUCTIONS FOR USE (Gel Vac sachets)

- Liquids should be poured directly into a yellow sharps bin. This bin should be used only for the purpose of denaturing the controlled drug liquid.
- Add the contents of one or two Gel-Vac sachets dependent on the volume of liquid for denaturing.
- The mixture should congeal within 2 to 3 minutes; the purple lid may then be permanently attached.
- Shaking may produce quicker results, however, as Sharps bins are not designed to hold large quantities of liquid, care must be taken. A side to side shaking action will minimise the risk of spillage.
- The date and time of the denaturing should be added to the lid of the sharps bin by marker pen along with the initials of the staff performing the process.
- The sharps bin must be locked in a designated cupboard for 24 hours to allow full denaturing of contents to take place.
- The sharps bin should then be sent for incineration in the normal way.
Appendix 10 - Recording and administering of patients’ own Controlled drugs

It should be noted that Controlled Drugs belonging to patients should, as with other patient’s own medicines, be treated as the patient’s own property.

1. Two registered nurses must be involved with the handling and administration of patient own controlled drugs at all times.

2. All patients’ own drugs brought into hospital MUST be recorded in the Patient’s Own Controlled drug record book.

3. Record on a new page the details of the patient name, drug, strength and quantity of the controlled drug.

4. The patient own controlled drug should then be placed in a clear plastic envoseal bag and sealed with a tag; the seal number must then be recorded in the register. A sticker must then be placed on the front of the drug administration chart indicating that patient own CD’s are in the CD cupboard.

5. Once a drug history has been taken then one of the following options should be taken and all actions recorded in the CD register for patients’ own drugs:

Patients own drug not needed for administration

6. During daily checks it is unnecessary to break the seal. Check the seal is intact and the seal number corresponds to the initial entry.

7. If the patient or their representative agrees, medicines may be sent to the pharmacy for safe destruction. They should be stored in the CD cupboard until removed by a pharmacist who will take responsibility for destruction.

8. If the patient wishes, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. If the medicines are not safe and/or not appropriate for use, then the patient and/or patient’s representative should be advised and they should be encouraged to send them to pharmacy for safe destruction. If they agree, see step 4.

9. If a patient has died, Controlled Drugs belonging to that patient cannot be legitimately handed back to a representative; however in the eyes of the law they are part of the deceased’s Estate and should be removed by a pharmacist who will take responsibility for destruction. The Pharmacist and nurse in charge will have to discuss this sensitively with the representative. If the representative is unwilling for the Pharmacist to destroy the controlled drugs, they must remain on the ward/ clinical area in safe custody, and the issue escalated to the Accountable Officer.

10. If a patient’s therapy is changed and/or they no longer require a controlled drug preparation, then it is justifiable to ask for the drugs to be destroyed by the pharmacy. The patient or their next of kin should be informed of this action.
Patient own controlled drug needed for administration:

11. It may be necessary to use one or more doses of a CD belonging to a patient before a supply can be provided by the pharmacy. Their own drugs may be used if they meet the criteria for use of patients’ own drugs as stated in the Patients’ Own Drugs (Pods) Policy.

12. The left hand page in the CD register for patients’ own drugs should be used to record the administration of Patient own controlled drugs.

13. Break the seal on the clear envopak bag and remove the dose with another RGN and then count/measure the remainder of POD ands record in the CD register.

14. Any drug wasted e.g part of an ampoule should be recorded in the appropriate column

15. During daily checks ensure that the drug quantity, strength is checked with another RGN and that balance is correct and signed in the record book. This must be done at least every 24 hours.

16. If an additional supply of the CD is required during admission, then this should follow the normal procedure for ordering controlled drugs for use on the ward. This will not be a patient own drug.

17. Patients own controlled drugs must be stored in the ward CD cupboard whilst in use.

18. If a patient is transferred to another ward then their controlled drugs must be transferred with them.

19. A record of the transfer must be made in the patients own drug book and the book must accompany the patient to the receiving ward with the drugs.

20. The drugs must be signed out of the patients own drug book on the first ward and signed into the patient own drug book on the second ward

21. Once the drugs have been received and signed for the patients own drug book must be immediately returned to the original ward. The patient own drugs are then receipted into the patients own drug book on the new ward and signed for by both nurses involved.
Appendix 10a – Flow Chart. Patients Own Controlled Drugs

PATIENT OWN CONTROLLED DRUGS

This flowchart explains the process for the handling, transfer and storage of Patient’s Own Controlled Drugs within the Trust.

Patient brings in own controlled drugs (CDs)

Patients own CD's used

Record patients’ name/drug/strength and quantity into CD register

Ward stock CD’s used

Record on page with other patients unused CDs

1. If patient requires a dose of their CD dispense a dose with another RGN. Count/measure remainder and record in CD register on patients’ individual page

2. During daily checks, ensure quantity/strength and drug is checked with another RGN and balance is correct and signed for.

3. If patient transferred to another ward please ensure their CDs are transferred with them and entry made in CD register to record transfer. CD entry must be made by 2 RGN. Transfer with 1 RGN.

4. When patient arrives on new ward, the patients’ own CDs must be recorded in the CD register on a separate page if still in use

5. When patient discharged and still requires CDs, return drugs to patient and record in register. If CDs not required, contact pharmacist for their destruction

1. Place CD in clear envoseal bag and seal with tag. Once sealed record seal number beside entry in CD register

2. During daily checks it is unnecessary to break seal. Check seal intact and seal number corresponds to initial entry

3. On patient transfer send sealed bag with them and record transfer in CD register (signed by 2 RGN) and annotating ‘receiving ward informed of CD transfer’

4. When patient arrives on new ward, open sealed envoseal bag and record patients’ name/drug/strength/quantity in CD register. If CDs are still not in use, repeat step 1.

5. When patient discharged and still requires CDs, remove from bag and return to patient and record in register. If CDs not required, contact Pharmacist for their destruction
Appendix 11 - Security of controlled Drug keys and handover

1. Controlled Drugs keys must be kept separate from other ward/department keys.

2. The legal responsibility for Controlled Drugs keys lies with the registered nurse or midwife in charge or ODP in theatres.

3. The Controlled Drug keys must be in the possession of an authorised staff member at all times.

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

5. At Handover, the keys must be returned to the shift leader of that shift who will pass them over to the shift leader taking over.

6. It is good practice to do the balance check of all Controlled Drugs (see Procedure for Checking of Controlled Drugs) at Handover. This may be done by the two shift leaders since they hold the responsibility for the Controlled Drugs during their respective shifts.

7. If Controlled Drugs keys are found to be missing, an investigation must commence immediately.

8. If the keys cannot be located following a thorough search and if duplicate keys are available then they may be obtained from the Pharmacy. Not all ward CD cupboards have duplicate keys, if available they are held in the Trust Electronic key cabinet. The night sisters and on call Pharmacists have access to these keys.

9. In normal working hours the Accountable Officer should be informed who will authorise the spare keys to be obtained from the electronic key cabinet.

10. Out of Pharmacy opening hours the On call Pharmacist must be called who may authorise the night sister to obtain the spare keys if available.

11. Consideration should be given to contacting the police.

12. An incident report must be completed using the green drug incident form for all occasions where the keys are missing.
Appendix 12 - Obtaining controlled drugs when the Pharmacy is closed

1. Check whether the Controlled Drug you need to administer is available in your Controlled Drugs cabinet.

2. It is acceptable to obtain ONE dose only for the patient, from another ward/clinical area, without calling the on-call Pharmacist for authorisation. (Authorisation should be sought from the Night Sister in this situation.

3. If further doses of the controlled drug are required for the same patient, bleep the on call pharmacist through switchboard.

4. Discuss with the pharmacist whether it is appropriate to obtain a further dose of the Controlled Drug from another ward or whether they will come to the Pharmacy to dispense. If several doses are required prior to the next Pharmacy opening time, a supply from Pharmacy will usually be appropriate.

5. If agreed that another ward can supply the dose, telephone the other ward to ensure they have the drug and are willing to supply.

6. Take the patient’s drug prescription and your ward CD register with you to obtain the dose.

7. Make an entry in the donor ward’s CD register to state “transferred to ward xx for administration to pts name”.

8. Enter the dose into the receiving ward’s CD register to state “Obtained from ward xx for administration to pts name.”

9. A nurse from the donor ward and the receiving ward should sign both registers.

10. The dose may then be administered following the procedure for administration of a Controlled Drug and another entry made in the CD register.
Appendix 13 - Removal of Illegal or suspicious substances from patients

1. It is an offence to possess an illegal substance on Trust premises. Contact a pharmacist for advice if any doubt exists over the legality of a substance.

2. If a patient is in possession or suspected of being in possession of an illegal drug, he/she should be advised that possession is unlawful and asked to hand it over voluntarily to a member of staff. Call security if the patient refuses to hand over an illegal drug. Do not put your own safety at risk whilst removing such substances from patients.

3. If a patient is unconscious or is unable to voluntarily hand over a suspicious or illegal substance then it should be removed. The registered nurse/midwife in charge should record the matter in full in the CD register.

4. Illegal drugs that have been handed over voluntarily or removed from an unconscious patient should be placed in a sealed container. The sealed container should be placed immediately in the CD cupboard and an entry made in the Patients own CD register on a clean page stating the patient's name, the date and the time. Sealing of the container and placing in the CD cupboard must be witnessed.

5. Make a record in the nursing notes that the substance has been retained. This should be countersigned by the nurse-in-charge.

6. Inform medical staff responsible for the patient's care.

7. The sealed container should either be removed by a ward Pharmacist or be taken to the Pharmacy at the earliest opportunity, together with a record in the patient's own CD register.

8. The pharmacist and the nurse or midwife in charge must sign the register when the illegal substance is taken to Pharmacy.

9. The pharmacist must make an entry in the pharmacy CD destruction register detailing a description of the product including weight, dimensions and number of dose units where appropriate. The entry MUST include a date and be given a reference number as per the Pharmacy departmental policy.

10. If the patient refuses to hand over the illicit substance then the police should be informed.

Security and the police

11. The police should be informed if large quantities are involved or a patient is suspected of dealing illegal substances. The consultant clinician is responsible for contacting the Police and Trust Security Manager.

12. The Trust security manager or duty manager should agree the next step. Under no circumstances should the item be returned to the patient. This would constitute unlawful supply of a controlled drug.

13. If personal use is assumed, the items will be destroyed as for any other illicit controlled drug.

14. If the item is suspected as being used for dealing illegal substances, the item will be removed from the ward/clinical area by the ward Pharmacist and quarantined in the Pharmacy Department CD Room, and then transferred into safe custody with the Police when required to do so.
Appendix 14 - Dealing with suspected abuse of controlled drugs by staff members

1. If staff suspect another member of staff, including prescribing staff, of abusing Controlled Drugs; they should confide their suspicions with a more senior staff member. If the suspecting staff member would rather, then they can make contact with the Controlled Drugs Accountable Officer (Chief Pharmacist) to discuss their suspicions with him/ her

2. All actions concerning this will be dealt with in a confidential way.
Appendix 15 - Management of Controlled Drugs on temporary Ward closure and transfer of Wards

Temporary Ward Closure

This SOP details what actions should be taken when a ward is closed either for the short term or long term. A risk assessment should always be carried to determine whether the controlled drugs should be returned to Pharmacy. This will depend on the length of closure and the security and access arrangements to the ward during the closure. In general, if the ward does not have an authorized nurse etc. on duty then the CD’s should be returned to Pharmacy. For long term closure or in the short term where the ward is not manned by an authorized accountable nurse then the Controlled drugs must always be returned to Pharmacy, this will include:

1. Contact the Ward Pharmacist to arrange to remove the controlled drugs for storage in the Pharmacy.
2. The Ward Pharmacist and the Nurse in charge will annotate the Ward CD register with the details that the drugs have been returned to Pharmacy. This requires both signatures.
3. A CD requisition should be completed as a full audit trail of the return. More than one drug can be added to a requisition.
4. The CD stationery must then be returned with the controlled drugs to Pharmacy for secure storage whilst the ward is closed.
5. The drugs should be placed in red envopak bags and sealed by both the Pharmacist and the Nurse in charge.
6. If the ward is closed for a short period of up to one week then the sealed red envopak bags will be stored separately in the Pharmacy controlled drug cabinets.
7. When the ward reopens after a short period of up to one week the Pharmacist will return the sealed red bags and the CD stationery to the ward and the drugs will be checked by both the nurse in charge and the Pharmacist and a record annotated in the register that the drugs have been returned to the ward with both signatures.
8. If the ward is to be closed for periods longer than one week then the stock should be returned as per the Pharmacy procedure for return of controlled drugs. (Appendix 8).
9. Arrangements should then be agreed on a date for restocking if appropriate.
10. Pharmacy will annotate the list of authorized signatures with ward temporary closed.
11. When the ward reopens this list must be updated.
Transfer of Wards

When a ward moves to another location it **MUST** be assessed as to whether the CD’s and CD record books are transferred or where swapping of wards occurs, left on the ward. This is very much dependent on the appropriateness of the stock list and how long the ward will be unoccupied in the move.

12. A risk assessment should be carried out to determine whether it is feasible to swap wards and leave the controlled drugs in situ. This will include whether the stocks are appropriate.

13. If the CD stocks and record books remain on the wards but the nurses transfer then arrangements should include the time that the reconciliation is carried out by both accountable nurses. This will involve reconciliation on both wards and in both CD registers.

14. It should be documented in both registers that the stock has been checked and a reconciliation carried out this should be signed by both accountable nurses.

15. If it is assessed as appropriate that the CD’s and registers transfer then the CD’s must be transferred in a secure way.

16. Arrangements should still be made for checking and reconciliation of stocks by two nurses and this should be recorded in the ward CD register before the CD’s are moved to their new location.

17. On storage in the new CD cupboard this reconciliation should be repeated to ensure that all stocks have been moved successfully. This reconciliation should be documented in the Ward CD register by the two authorised nurses.

18. Note the nurse in charge of the ward remains accountable at all times for the controlled drugs on transfer.

19. Pharmacy should be contacted to ensure that the stock lists and the authorised signature lists reflect the new ward location and number/name.
Appendix 16 - Controlled Drugs stored in Mediwell Automated Cabinets

The automated cabinets are accessed using a combination of swipe access of the authorised persons ID card and finger print.

1. Upon receipt of controlled drugs from Pharmacy, the authorised person must enter each item into the Mediwell Automated cabinet sequentially. As each one is entered, a stock reconciliation can be performed whilst the cabinet drawer is opened. The stock reconciliation is performed as in Appendix 7.

2. The Controlled Drug required for patient administration will be requested by the Authorised Person using the Mediwell Cabinet Interface Screen.

3. If a high strength opioid is requested the interface screen will prompt the authorised person to confirm the request of a high strength opioid.

4. The drawer in which the CD is stored will light up and the authorised person will open the drawer to the location of the Controlled drug and remove the pack. The drawer will “lock out” at the exact location the controlled drug has been positioned in the cabinet. Opening the drawer fully will not be possible if the item you require is positioned, for example, at the front of the drawer.

5. The dosage required will be removed from the pack and booked out of the CD register (see Appendix 6).

6. The pack MUST be replaced in the exact drawer and location it was withdrawn from, or stock control may be compromised.

7. All high dose opioids will be stored at the back of each drawer, in order to minimise the risk of high strength opioids being picked in error. To reduce risks further, opioids of the same generic drug name available in different strengths (For example Diamorphine 10mg and 100mg) should be stored on different drawer levels.

8. The authorised person MUST NOT open the Mediwell automated cabinet and remove a Controlled Drug for another colleague using their personal identification.
**Appendix 16a - Controlled Drug SOP Accountability Record**

**SOP (number and name)..............................................................................................................**

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STANDARD OPERATING PROCEDURE:
HANDLING AND STORAGE OF CONTROLLED DRUGS WITH IN THEATRES

INTRODUCTION

This SOP has been developed to establish an agreed system for ordering and security of controlled drugs within the operating department which complies with guidance produced by the Department of Health (DoH 2008) and the AAGBI (2006) and is in compliance with the current Trust Policy on the Safe Management of Controlled Drugs and the Trust Medicines Policy

1. ACCOUNTABILITY AND RESPONSIBILITIES

   o THE RN/ODP IN CHARGE OF THE THEATRE DEPARTMENT:
     
     ▪ Is legally responsible for the safe and appropriate management of CDs during his/her shift.
     ▪ Will delegate control access (key holding) to the CD cupboard to the RN or ODP allocated to anaesthetic or recovery duties.
     ▪ Has responsibility for all CDs up to the point where these medicines are issued to an anaesthetist and their signature is obtained.
     ▪ Must fully investigate any inaccuracies reported and where discrepancies remain should report them to the accountable officer in pharmacy immediately and complete an incident report in relation to the discrepancy promptly

   o THE ODP/RN ALLOCATED TO THE ANAESTHETIC ROOM:
     
     ▪ Has delegated control access to the CD cupboard in their anaesthetic room for the duration of their shift
     ▪ Is responsible for collecting the CD cupboard keys from the Recovery room staff prior to the beginning of their operating list
     ▪ Will carry out and document a stock check with a second RN or ODP prior to commencing their operating list
     ▪ Will maintaining stock levels at an appropriate level (see SOP 1 Storage and Handling of Controlled Drugs on wards: Ordering and Receipt of Controlled Drugs From Pharmacy)
     ▪ Issues CDs to the Anaesthetist on request
     ▪ Maintains an accurate record of CDs issued and used in the CD record book including the signature of the prescribing anaesthetist
     ▪ Will carrying out and document a stock check at the close of the operating list or, if applicable, on shift change with the RN/ODP taking over the shift
     ▪ Is responsible for returning the CD cupboard keys to the recovery room staff on completion of the operating list.
     ▪ Will report any inaccuracies immediately to the RN/ODP in charge of the theatre

   o THE ODP/RN/EN ALLOCATED TO THE RECOVERY ROOM:
     
     ▪ Has delegated control access to the CD cupboard in the recovery room for the duration of their shift
     ▪ Is responsible for collecting the CD cupboard keys from the Main Recovery room (or prior key holder) at the beginning of the operating lists
     ▪ Will carry out and document a stock check with a second RN or ODP prior to commencing the operating lists
- Will maintain stock levels at an appropriate level (see 3.1: Ordering Controlled Drugs)
- Can administer prescribed CDs as per medicines management policy
- Will maintain an accurate record of CDs administered in the CD record book including relevant signatures
- Carries out and documents a stock check at the close of the operating list or, if applicable, on shift change with the RN/ODP taking over the shift
- Is responsible for returning the CD cupboard keys to the main recovery room staff for safe keeping on completion of the operating list
- Will report any inaccuracies immediately to the RN or ODP in charge of the theatre

**THE ANAESTHETIST/DOCTOR ADMINISTERING IN A THEATRE OR RECOVERY AREA**

- Is responsible for prescribing CDs to patients in his/her care.
- Administers prescribed CDs as per medicines management policy
- Maintains an accurate record of CDs administered in both the patient’s anaesthetic record and the CD record book including their own signature as the prescribing anaesthetist/doctor
- Will report any inaccuracies immediately to the RN or ODP in charge of the theatre
- Will correctly dispose of any unused CDs in compliance with the current Trust Policy on the Safe Management of Controlled Drugs and the Trust’s Medicines Policy and in accordance with Appendix A: “Risk assessment for the disposal of small amounts of CD stock by the anaesthetist in theatre”

### 2. STORAGE OF CDs WITHIN THE THEATRE SUITE

Locked metal cabinets for the storage of CDs are located in the following areas:

**Main theatre:**
- Theatre 1 anaesthetic room (NB: maintained by Maternity Unit)
- Theatre 2 anaesthetic room (Keys stored in Main Recovery CD Cupboard)
- Theatre 3 anaesthetic room (Keys stored in Main Recovery CD Cupboard)
- Theatre 4 anaesthetic room (Keys stored in Main Recovery CD Cupboard)
- Recovery (Keys held by RN/ODP in charge or theatre/recovery)

**Orthopaedic Theatres (West Peaks):**
- Theatre 5 anaesthetic room (Keys stored in Orthopaedic Recovery CD Cupboard)
- Theatre 6 anaesthetic room (Keys stored in Orthopaedic Recovery CD Cupboard)
- Recovery (Keys stored in Main Recovery CD Cupboard)

**Day Case Unit:**
- Anaesthetic room (Keys stored in DCU Recovery CD Cupboard)
- Recovery (Keys stored in Main Recovery CD Cupboard)

**RECORDING, ORDERING AND SECURITY**
- Each CD cupboard has an individual CD Requisition book and CD Register.
- All CD cupboard keys are secured in a locked metal cabinet when the theatre is not in operation.

### 3. PROCEDURES

#### 3.1 ORDERING CONTROLLED DRUGS

3.1.1 Each anaesthetic room and recovery room has a separate requisition book which must be locked in the respective CD cupboard

3.1.2 The requisition book should be completed by an authorised member of staff (signature list for pharmacy) with only one entry per page.
3.1.3  The requisition book, once completed, should be returned to pharmacy in the red transport bag no later than 10am during week days.

3.1.4  All CDs will be issued directly to the corresponding anaesthetic or recovery room.

3.1.5  On receipt of CD stock, a stock check should be completed and the CD register amended to reflect the stock received by entering:
   i)  The requisition number from the order book
   ii) The date of receipt
   iii) The words: “Received from pharmacy”
   iv) The number of ampoules received
   v) The amended stock level
   vi) The signature of the receiving RN or ODP.
   vii) The signature of the witness to this stock reconciliation

3.2. ISSUE OF CDs TO THE ANAESTHETIST (OR OTHER PRESCRIBER)

3.2.1  CD stock must be issued on an individual patient basis and ampoules must not be shared between patients

3.2.2  CDs must not be transferred from the anaesthetic room/theatre to the recovery room in any circumstances.

3.2.3  The Controlled Drug issued must be checked by the anaesthetist with the RN/ODP and the controlled drug register signed by both.

   NB: The anaesthetic room/theatre CD record book: the countersignature (ODP/RN) confirms the issue of and reconciliation of controlled drugs to the medically qualified prescriber and does not confirm witness to any administration or disposal of CDs used during the anaesthetic/surgical procedure.

3.3. UNUSED/ACCIDENTAL WASTAGE OF CDs

3.3.1  Where part of an ampoule is to be discarded due to dosage requirements, this should be recorded in the CD record book by the person administering the CD as amount given (A) and amount wasted (W)

3.3.2  The dose of or part of a CD dose (small quantity only) can be destroyed un-witnessed by a medically qualified prescriber only in circumstances outlined in Appendix A: “Risk assessment for the disposal of small amounts of CD stock by the anaesthetist in theatre.”

3.3.3  Where CDs are destroyed by an ODP or RN this must be done in the presence of a suitably qualified witness and in accordance with current Trust policy for the safe disposal of CDs.

3.3.4  Where an ampoule is accidentally wasted this should be recorded in the CD record book as “accidental wastage” and must be countersigned by a witness in all cases.

3.3.5  Where large or whole doses of CDs are to be destroyed this must be recorded in the CD record book, witnessed and countersigned by a suitably qualified person in all cases.

3.4. EXPIRED CDs

3.4.1  Where CDs have passed expiry date they should be:
     i.  Clearly labelled in order to avoid accidental use
     ii. Reported to the pharmacy promptly so that return can be arranged
     iii. Counted as part of the stock check until pharmacy have arranged removal
Abbreviations

CD: Controlled Drug
RN: Registered Nurse
ODP: Operating Department Practitioner
AAGBI: The Association of Anaesthetists for Great Britain and Ireland

References

East Cheshire NHS Trust: Policy of the Safe Management of Controlled Drugs

Department of Health. (2008) Safer Management of Controlled Drugs: Changes to Record Keeping Requirements

Appendix 18 – SOP for the use of PETHIDINE, MIDAZOLAM AND FENTANIL IN RADIOLOGY within East Cheshire Trust.

PROTOCOL FOR THE USE OF PETHIDINE, MIDAZOLAM AND FENTANIL WITHIN THE RADIOLOGY DEPARTMENT

ORDERING/ RECEIVING AND STORING OF PETHIDINE AND FENTANIL IN RADIOLOGY

1. Use CD order book (located in CD area of Drug cupboard) and Red Pharmacy Bag (located in Stock Room)
2. The order must be signed by a Radiology Doctor (all specimen signatures are kept within the drug cupboard) – All ordering books must be kept for a minimum of 2 years.
3. Take documentation to Pharmacy
4. Order should arrive from Pharmacy in a sealed Red Pharmacy Bag – check seal is intact.
5. Check the number on the seal corresponds with the number on the CD Consignment note and sign the note for receipt. This note is then returned to Pharmacy.
6. All entries should be made in the CD Record book with the date, the words “Received from Pharmacy” the requisition number by the Radiographer and counter checked by a second member of staff (A suitably qualified member of staff can countersign if a second qualified member is not available).
7. The number of ampoules should be checked at the time of receipt of an order of Pethidine, Midazolam or Fentanil and initialled as being correct by the Radiographer and a second member of staff.
8. All “Receiving In” should be written in Black Pen.

USE OF PETHIDINE, MIDAZOLAM AND FENTANIL IN RADIOLOGY

1. All usage recording should be entered in the CD Record book in black pen.
2. Date, time, Patients Name, Prescribing Doctor, Drs signature, number of ampoules given and remaining quantity must be recorded.
3. Record must be made in the Patients notes of drugs administered.
4. Stock check to be undertaken at the end of the list and countersigned by Radiographic staff.
5. Record use of any drugs on CRIS system
6. It is only used on ERCP & stent insertion patients currently on a ETU list

DAILY REQUIREMENTS

1. Drug cupboard keys are held by the Radiographer in room 1 on each shift.
2. Where there is a Fluro list running, the keys may be carried by the Radiographer in the Fluro Department for the duration of that list.
3. Daily stock take by Radiographer at the start of the day.
4. Entry to be made in CD Record book to record this using Black pen and
signed by radiographer and countersigned by a second member of staff.
5. Drug book to be located in door of drugs cupboard
6. Keys to be returned to the Radiographer in room 1 once Fluro list has finished.

DEPARTMENT STAFF RESPONSIBILITY

1. To read and adhere all policies and procedures for the storage and handling of controlled drugs.
2. Support the Department manager in ensuring that the security of controlled drugs and their own local procedures concerning controlled drugs are being followed.
3. Ensure controlled drug cupboard keys are held by and/or passed to suitably qualified staff.
4. Report all incidents involving controlled drugs to the senior radiographer/Department Manager and Datix.
5. The Trust Accountable Officer is informed immediately of any incidents reported relating to CD’s. This MUST also be reported promptly using the Datix reporting system.
6. Flumazenil to be kept as stock on Radiology for emergency use
Appendix 19 - SOP for the use of FENTANYL WITHIN CARDIO-RESPIRATORY DEPT within East Cheshire Trust.

PROTOCOL FOR USE OF FENTANYL WITHIN CARDIO-RESPIRATORY DEPT

Ordering of Fentanyl from Pharmacy

- Use CD Record book (located in CD area of Drug cupboard) and Red Pharmacy Bag (located in Stock Room) see Trust Policy for the Safe Management of Controlled Drugs version 1.5.
- Must be signed by a Medical Practitioner (a copy of the specimen signature list to be kept within Drug Cupboard and in Pharmacy)
- Take the Red Bag/Order book to Pharmacy (on day of the session)
- CD will arrive back in sealed Red Pharmacy Bag
- Check number on the seal corresponds with the number on the CD Consignment note and sign the note for receipt. This process may be completed by the Physiologist(s) on duty in the Department.
- All entries in the CD Record book should then be made with the date, the words (or similar) "Received from Pharmacy", the requisition number and the Physiologist who signed for receipt of the Controlled Drugs and a second qualified Physiologist may witness the receipt.
- The number of ampoules should be checked at the time of receipt of an order of Fentanyl and initialled as being correct by the involved Physiologist(s) - (in black ink).
- The Controlled Drugs are then placed in the locked CD part of the drugs cupboard.

Use of Fentanyl

- Date, time, Patient’s name, Prescribing Doctor, Drs Sig, number of ampoules given and remaining quantity must be recorded
- A record must be made in patient notes of drugs administered
- Stock check to be undertaken at the end of list, countersigned by Physiology staff

Specialist Echo Sessional Stock Take Requirements

- Keys retrieved from CCU and signed for in the CD Key register (the date/time/Name and signature of the individual signing for the keys must be recorded
- Specialist Echocardiography sessional stock take by Physiologist and Clinician at start of the day of the session
- Entry to be made in Drug book to record this in BLUE ink and signed by Physiologist
- Keys will then be returned to CCU and signed back into the Drug cupboard by the Physiologist on duty – the time of return of the CD keys must be recorded
Department Staff Responsibility

7. To read and adhere to all policies and procedures for the storage and handling of controlled drugs.
8. Support the Department manager in ensuring that the security of controlled drugs and their own local procedures concerning controlled drugs are being followed.
9. Ensure controlled drug cupboard keys are held by and/or passed to suitably qualified staff.
10. Report all incidents involving controlled drugs to the senior Physiologist/Department Manager and Datix.
11. The Trust Accountable Officer is informed immediately of any incidents reported relating to CD’s. This **MUST** also be reported promptly using the Datix reporting system.
SOP 1. TRANSPORTATION OF CD’s IN THE COMMUNITY SETTING

PURPOSE

- To ensure that the security, safe handling and quality of controlled drugs are not compromised during transportation from the dispensing pharmacy to the patient’s home.

SCOPE

- Transportation encompasses the transport of all controlled drugs or prescription only medicines that have been prescribed for named patients and where it has been identified that there is no carer or relative available to transport the medicines at that time.

PROCEDURE

The patient’s family/carer should where possible arrange to collect controlled drugs from the pharmacy.

- Community Nurse’s should not routinely transport controlled drugs to and from the patient’s home.

- Only in exceptional circumstances can community nurses transport controlled drugs or prescription only medicines that have been prescribed for named patients.

- The senior nurse on duty must be informed and agree for the community nurse to transport the controlled drugs from pharmacy to the patient’s home.

- The rationale must be clearly recorded within the patient’s nursing records.

- The Community Nurse collecting the controlled drugs will be required to produce identification to the pharmacist in the form of their East Cheshire Trust Identification Badge.

- The controlled drugs must be transported directly from the dispensing pharmacy to the patient.

- The controlled drugs must be transported out of sight i.e. in a locked boot and should not be left unattended in a vehicle at any time.

- Any adverse incident near miss or dangerous occurrence which might have led to an adverse incident should be reported following the ECT incident reporting system [Datix system] and Community Service Manager to inform ECT Accountable Officers.
SOP 2. STORAGE OF CONTROLLED DRUGS IN THE COMMUNITY SETTING

PURPOSE

- To ensure controlled drugs prescribed for a specific patient are stored in an appropriate and safe place within the patient’s home.

SCOPE

- Encompasses all controlled drugs which are dispensed to patients for administration by community nurses.

PROCEDURE

- Community nurses have a responsibility to remind patients and their families/carers that controlled drugs can be dangerous if used inappropriately.

- Appropriate places for storing drugs must be discussed with patients and carers and a ‘safe place’ agreed. This is particularly important if there are young children resident, visiting or where there are confused/elderly members of the family.

- Community Nurses must record the outline of the discussion within the patient’s records.

- Controlled drugs remain the property of the patient for whom they are prescribed.

- Controlled Drugs should be stored in an environment which does not threaten their integrity.

- Where community nurses have highlighted concerns regarding ‘at risk’ households, stock levels should be kept to a minimum and concerns discussed with the relevant team leader/line manager and the patient’s general practitioner.

- Extreme care should be taken when different strengths of controlled drug for injection are in use as packaging of different products may appear similar.

  In particular, the NPSA Safer practice notice (12) highlighted the packaging similarities of different strengths of Diamorphine and Morphine ampoules e.g. 10mg and 30mg ampoules of Diamorphine and Morphine.

- Expiry dates should be observed, monitored and recorded on administration within the patient record.

- Any adverse incident near miss or dangerous occurrence which might have led to an adverse incident should be reported following the ECT incident reporting system [Datix] and Community Service Manager to inform ECT Accountable Officers.
SOP 3. ASSESSMENT OF PATIENT’S OWN CONTROLLED DRUGS IN THE COMMUNITY SETTING PRIOR TO ADMINISTRATION

PURPOSE

- To ensure the quality, efficacy and safety of CD’s that are in the possession of patients prior to their administration or supervision of administration by ECT community nursing staff.

SCOPE

- Any occasion where a Community Nurse administers a CD, supervises the self-administration of a CD or prompts a patient to use a CD, where the medicine has been obtained, stored or handled by the patient/parent/guardian/carer other than at an ECT managed premise or site.

PROCEDURE

- Advise patients on the safe storage of medicines as a routine part of administering patients own CD’s.

- The dispensing label should be typewritten and legible.

- The name on the dispensing label should be that of the patient.

- Check that the label on the container has the correct drug name and strength.

- Do not use if there are incorrect or confusing directions for use.

- Do not alter the directions on the labels.

- Check that the physical condition of the drugs and quality of the packaging is satisfactory.

- Check that the tablets/capsules/ampoules etc. in the container are the same to ensure the patient has not mixed different medications in the same container. Where possible loose tablets should also be identified by their appearance and markings.

- Check that the CD can be identified by checking that foil strips/ampoules have the same name and strength as the container and that these details are clearly visible on the strip/ampoule.

- Do not use if there is any doubt about the identity of any CD.

- Do not use if the expiry date has been exceeded. If the expiry date is not indicated, do not use it if it is more than 6 months from the date of dispensing. If there is any doubt that it may be short dated stock, check with the supply source or obtain advice from Pharmacy Department.

- For products with information that there is a shortened expiry date once opened check with the patient or carer that any such period has not been exceeded. If no date of opening can be identified, use the date of dispensing as the date of opening, as the product cannot have been opened before this date.

- Check the patient’s controlled drug prescription record to ensure that the CD’s to be administered are part of the patient’s current medication regimen.
• Products identified as being unsuitable for administration should be isolated. If possible the patient or relative should be advised to return the CD to a Community Pharmacist for disposal.

• A record should be made in the patient’s medical record of any instance whereby CD’s were not administered because the quality, efficacy or safety of the product could not be assured. The record should include the steps that were taken, if necessary to obtain replacement stock.

• If there are other reasons, not listed above, why the administering clinician feels the medicines are not suitable, they should take responsibility for not using the patient’s own controlled drugs.

• **Safety.** If there is any doubt about the process or the safety or quality of the product seek advice from the Lead Pharmacist for Integrated Care, Community Services Manager or Pharmacy before proceeding.

• Any adverse incident near miss or dangerous occurrence which might have led to an adverse incident should be reported following the ECT incident reporting system [Datix] and Community Service Manager to inform ECT Accountable Officers.
SOP 4. RECORDING OF CONTROLLED DRUGS IN THE COMMUNITY SETTING.

PURPOSE

- To ensure all patients requiring controlled drugs which have been prescribed by a doctor and will be administered by Community nurses, are accurately recorded within the ECT Controlled Drug/ Syringe Driver Prescription and Administration Record.

SCOPE

- This Standard Operating Procedure encompasses all controlled drugs dispensed to a named patient for administration by a Community nurse, employed by ECT.

PROCEDURE

- All new stock of controlled drugs dispensed for administration to a named patient by Community Nurses, must be recorded within the Controlled Drug prescription and Administration Record or patient related record.

- All community nurses have a responsibility to adhere to NMC guidance on recording and administration of controlled drugs.

- All new stocks of controlled drugs should be checked and accurately recorded within the ‘stock level’ section of the blue controlled patient administration record or relevant patient held record.

- The name, strength and quantity of the drug must be recorded and signed by the Community Nurse entering details.

- For patients within Residential or Nursing homes, where the controlled drugs are kept within the care home CD cupboard, and signed out by care staff, all Community nurses MUST sign for the administration of the CD within the care home CD book in ADDITION to the blue palliative drug booklet.

- Stock levels of all drugs should be checked against ‘stock level’ chart before and after each administration.

- Controlled drugs collected from the dispensing pharmacy by relatives/carers for administration by Community nurses should be checked and entered within the record at the next Community nurse visit.

- If GP’s visit and are required to administer controlled drugs which are entered on the Community nurses record, they should sign to say they have given the medicine and amend the ‘stock level’ accordingly.

- When an episode of care is completed the controlled drug prescription and administration record should be incorporated into the patient’s clinical record and archived as per Cheshire East Community Health Policy for Retention and Storage of Records Policy.

- Any discrepancies in the stock levels should be double checked and if still cannot be accounted for should be managed as per S.O.P. number 7.
SOP 5a. ADMINISTRATION OF CONTROLLED DRUGS IN THE COMMUNITY SETTING

PURPOSE

- To ensure the safe and secure handling of controlled drugs during their administration and to ensure safe administration of controlled drugs to patients.

SCOPE

- Any occasion where a Community Nurse administers a controlled drug or supervises the self-administration of a medicine to the patient.

PROCEDURE

- Administration is giving a medicine either orally, via enteral tube, by injection or transdermal.

- Prior to administration of a controlled drug the Community nurse must ensure the controlled drug administration record is completed and signed by the prescriber. A dated, handwritten authorisation is required from the prescriber detailing the drug, dose and route of administration and this should be filed in the patient’s record (as Community Nurses in the home do not have access to the prescription once it has been dispensed).

- Administration shall be by an appropriately qualified and competent person e.g. Registered General Nurse working within the community with competence to administer controlled drugs.

- The competence of community nurses to administer CD’s should be assessed at team level by a competent District Nurse including new starters and transfers from other teams. NMC standards for medicines management must be adhered to.

- Community nurses should apply their professional judgment, knowledge and skill in a given situation when medicines are administered to a patient.

- All reasonable endeavours will be made to gain the patient’s consent prior to administration (refer to CECH Policy for Consent to Examination or Treatment).

- Administration of drugs will comply with NMC guidance on the administration of controlled drugs.

- Each member of staff who administers a controlled drug should ensure they carry an ECT Anaphylaxis Pack and have attended anaphylaxis training within the last 12 months [mandatory]

- All staff administering controlled drugs via a syringe driver must have attended East Cheshire NHS Trust (ECT) ‘Syringe Driver Training’ at least bi-annually and ensure the ECT Syringe Driver Policy is adhered to at all times.

- In a patient’s home where a community nurse is administering controlled drugs, these may be checked, administered and recorded by one health care professional deemed competent.

- If a second Community Nurse or Health Care Assistant is available to provide a second check/signatory [and has been deemed competent] this must be utilised and they must also sign the Controlled Drug Administration Record.
• Where controlled drug dosage is complex or unfamiliar it is the responsibility of the Community nurse to ask another competent person to check the calculation.

• In recognised ‘high risk’ situations e.g. family/patients requiring extra support, unstable patient or environmental concerns, a second check should be sought.

• Community Nurses must record the following information on the controlled drug prescription and administration record.
  
  • The medication that is given
  • The dosage
  • Expiry date and batch number
  • The date and time of administration
  • The route of administration
  • The person who administers it.
  • The number and strength of the drug e.g. ampoules/patches remaining as stock.

• Any drugs that have been prepared but not administered or where only part ampoules are used must be accounted for on the controlled drug record sheet and disposed of in the Destruction of Old Pharmaceuticals (DOOP) denaturing kit. Part or used vials of above 5mls in volume must be denatured in a DOOP kit. Any quantities of 5mls or less should be disposed of in a sharps box.

• If ampoules are accidentally dropped or broken in transit this must be recorded within the Controlled Drug Administration Record and an IR1 Incident Form completed.

• When a discrepancy occurs on the recorded stock level on the Controlled Drug Administration Record the Community Nurse should attempt to verify the source of the discrepancy by recounting, explore possibility of another health professional administering the drug e.g. G.P.

• If the discrepancy CANNOT be accounted for refer to SOP number 7.

• If discrepancy verified with legitimate reason i.e. accidental damage to ampoule this should be recorded and a Datix is completed.

• If discrepancy relates to an inaccuracy in adding/subtracting totals, attending Community nurse should asterisk incorrect total and make a note next to this, informing the nurse this relates to, completing an incident report on Datix, and informing the relevant Community Service Manager or Head of service.

• If a discrepancy in stock level cannot be accounted for refer to SOP No 7 for theft/loss of controlled drugs.
**SOP 5b. ADMINISTRATION IN THE COMMUNITY SETTING WITHIN THE COMPLEX CARE SERVICE**

**PURPOSE**

- To ensure the safe and secure handling of controlled drugs during their administration and to ensure safe administration of controlled drugs to patients.

**SCOPE**

- Any occasion where a Health Care Assistant administers a controlled drug within the COMPLEX CARE SERVICE ONLY.

**PROCEDURE**

- Administration is giving a medicine orally, via enteral tube or transdermally.

- Prior to administration of a controlled drug the Health Care Assistant must ensure the controlled drug administration record is completed and signed by the prescriber. A dated, handwritten authorisation is required from the prescriber detailing the drug, dose and route of administration and this should be filed in the patient’s record (as Community Nurses in the home do not have access to the prescription once it has been dispensed).

- Administration shall be by a trained Health Care Assistant who has completed competency and theory based training for individual patients.

- All reasonable endeavours will be made to gain the patient’s consent prior to administration.

- Administration of drugs will comply with NMC guidance on the administration of controlled drugs.

- In a patient’s home where a Health Care Assistant is administering a controlled drug, these may be checked, administered and recorded by a health care assistant deemed competent.

- If a second Health Care Assistant is available to provide a second check/signatory [and has been deemed competent] this must be utilised.

- In recognised ‘high risk’ situations e.g. family/patients requiring extra support, unstable patient or environmental concerns, a second check should be sought.

- The following information must be recorded on the controlled drug prescription and administration record.
  - The medication that is given
  - The dosage
  - Expiry date and batch number
  - The date and time of administration
  - The route of administration
  - The person who administers it.
  - The number and strength of the drug e.g. capsules/patches remaining as stock.

- If a discrepancy in stock level cannot be accounted for refer to SOP No 7 for theft/loss of controlled drugs. Complete an Incident report on Datix and inform the relevant Community Service Manager or Head of service.
SOP 6. DESTRUCTION OF CONTROLLED DRUGS IN THE COMMUNITY SETTING

PURPOSE

- To ensure controlled drugs which are the property of the patient within the community are either returned to the community pharmacy or destroyed within the patient’s home in a safe and controlled manner.

SCOPE

- All controlled drugs which are the property of the patient but community nurses have been involved in their administration.

PROCEDURE

- Any drugs that have been prepared but not administered or where only part ampoules are used must be accounted for on the controlled drug record sheet and disposed of in the Destruction of Old Pharmaceuticals (DOOP) denaturing kit. Part or used vials of above 5mls in volume must be denatured in a DOOP kit. Any quantities of 5mls or less should be disposed of in a sharps box.

- If ampoules are accidentally dropped or broken in transit this must be recorded within the Controlled Drug Record and an IR1 Incident form completed.

- Individual doses of controlled drugs which have been prescribed for a patient and are no longer required, are the patient’s property. Community nurses should advise patients or carers to return the controlled drugs to a community pharmacy.

- It is the responsibility of the family/carer to return unwanted/unused controlled drugs to the community pharmacy when able.

- Only in exceptional circumstance shall Community nurses destroy controlled drugs in a patient’s house

  Exceptional circumstances will include:
  - Where Community Nurses feel there is a likelihood of abuse of the drugs which are left at the patient’s house or there is no identified carer to take the controlled drugs to the community pharmacy.
  - Community Nurses will not be able to gain access at any other time.

- In the case of the death of a patient who was using a syringe driver at the time of death, please refer to the syringe driver policy for the appropriate actions. If it is appropriate to remove and destroy the medicine in the syringe drive, it should be done as per the guidance in this SOP.

- In accordance with national guidance it is mandatory for two registered Community nurses to witness the destruction of drugs belonging to patients.

- If there is only one registered nurse on duty another professional or unregistered colleague may witness the destruction. A lay person, such as a patient’s relative should not be asked to witness the destruction.

- The destruction must be recorded on the controlled drug prescription and administration record and signed by the registered nurse and the witness.

- If it is not possible to obtain a suitable witness at a given time [e.g. at night] then arrangements should be made for the necessary staff to destroy the drugs within 72 hours [e.g. arrange with the day staff].
• If destruction of patients’ own controlled drugs is necessary, approval should be sought from the team leader and a Datix is completed. Controlled drugs for disposal should not routinely be transported by East Cheshire NHS Trust (ECT) staff but in exceptional circumstances ECT staff may transport controlled drugs to a community pharmacy for destruction. In this instance the community pharmacist should sign the controlled drug prescription and administration stock level sheet to verify their return.

• In cases where the death of a patient is classed as an unexpected death, patient’s controlled drugs should not be destroyed.

• In circumstances of the unexpected death requiring further investigation the Police may seize the patient’s controlled drugs as evidence and take responsibility for the appropriate disposal.

• All controlled drugs routinely administered by Community Nurses which have to be destroyed in the patient’s home should be destroyed within 72 hours and a record made on the controlled drug and administration record.

• Any suspected un-witnessed destruction or removal of controlled drugs, not recorded within the patients controlled drug prescription and administration record, should be treated as an untoward incident and an IR1 completed. It should be investigated to ascertain what has happened to the controlled drugs.

• Destruction of old Pharmaceuticals de-naturing kits should be used to destroy unused controlled drugs with the exception of Fentanyl patches. The DOOP container may then be disposed of as special waste i.e. within a sharps bin.

• Fentanyl patches can be rendered irretrievable by removing the backing and folding the patch upon itself. The patch may then be disposed of in a sharps bin.

• If Community Nurses are unable to gain entry to a patients home and destroy the controlled drugs [e.g. after patients death] this should be recorded in the clinical record, Community Services Manager informed and an incident report on Datix completed.

• The audit trail must be traceable.
SOP 7. THEFT OR LOSS OF CONTROLLED DRUGS IN THE COMMUNITY SETTING

PURPOSE

- To ensure the correct procedure is followed in the event of theft or loss of CD’s within the community nursing services of East Cheshire NHS Trust (ECT).

SCOPE

- Any instance where a discrepancy in the stock level of a CD appears and which after further investigation cannot be reconciled.

PROCEDURE

- The line manager must be informed immediately when controlled drugs are missing and the Community Nurse has been unable to verify the discrepancy and the CD’s are thought to be stolen or “lost”. An incident report on Datix, must be completed in line with the ECT Incident Reporting Policy and Procedure as soon as possible.

- Information on the incident report should be as detailed as possible including the following:
  - Name and strength of drug
  - Quantity
  - Date discrepancy identified
  - Date of last stock check and name of nurse
  - Any tampering or altering of records

- The line manager will inform appropriate Locality Manager who in agreement with the Trust Accountable Officer and Head of Service for Integrated Care or in their absence the most senior Director for ECT, who will inform the police if this is necessary.

- If the theft or loss occurs out of normal working hours, staff must inform the on-call manager for ECT. The on-call manager has the responsibility to inform the police if deemed appropriate and to inform the appropriate Locality Manager, Head of Service for Integrated Care and ECT Accountable Officer at the next working day.
Equality Analysis (Impact assessment)

1. What is being assessed?

The Trust policy for the management of controlled drugs

Details of person responsible for completing the assessment:

- **Name:** Kashif Haque
- **Position:** Chief Pharmacist
- **Team/service:** Pharmacy

State main purpose or aim of the policy, procedure, proposal, strategy or service:

This policy provides guidance relating to the safe and secure storage and handling of controlled drugs for all staff in East Cheshire NHS Trust (ECT).

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it.

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

**Age:** East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

**Race:**

- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

**Gender:** In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

**Disability:**

- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
• Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
• C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
• In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
• Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:
• CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at 18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
• CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.
• Christian: 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
• Sikh: 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
• Buddhist: 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
• Hindu: 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
• Jewish: 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
• Muslim: 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
• Other: 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
• None: 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
• Not stated: 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

Carers: In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

No - none aware of

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?

No
**Explain your response:** Where a patient’s or carer’s first language is not English, staff will follow the trust interpretation policy, where for example, discussions on consent to destroy/store own controlled drugs are needed.

**GENDER (INCLUDING TRANSGENDER):**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently? No
**Explain your response:** The Trust has a transgender policy and staff will be mindful of this.

**DISABILITY:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently? No
**Explain your response:** Where discussions are required on destruction/storage of own CDs then information can be made available in other formats such as large print, Braille or audio. BSL interpreters can be sourced for Deaf patients via the trust’s interpretation policy.

**AGE:**
From the evidence available does the policy, procedure, proposal, strategy or service, affect, or have the potential to affect, age groups differently? No
**Explain your response:** Parents/carers will be involved in any discussion re controlled drugs. Carers of older people may also be involved to ensure that the patient can be reminded if they have agreed to destruction of own CDs.

**LESBIAN, GAY, BISEXUAL:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently? No
**Explain your response:** Applies equally to all staff employed by the organisation.

**RELIGION/BELIEF:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently? No
**Explain your response:** Applies equally to all staff employed by the organisation.

**CARERS:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently? No
**Explain your response:** Carers will be involved in discussions with patients as appropriate in order to support patients’ understanding.

**OTHER:** EG Pregnant women, people in civil partnerships, human rights issues.
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently? No
**Explain your response:** No other impacts identified.

### 4. Safeguarding Assessment - CHILDREN

| a. Is there a direct or indirect impact upon children? | No |
| b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people: |
| c. If no please describe why there is considered to be no impact / significant impact on children. |

This policy relates to staff in relation to the storage and handling of controlled drugs and relates to patients n that there may be discussion re storage/destruction of own controlled drugs.
5. Relevant consultation
Having identified key groups, how have you consulted with them to find out their views and that the made sure that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Policy applies to all patient groups equally.

6. Date completed: 28/12/16   Review Date: January 2019

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

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8. Approval  
At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead:

[Signature]

Date: 28.12.16