Purpose of this Procedure

To ensure that controlled drugs (CD) are held securely in wards and departments, and to ensure the safe and effective implementation of the Trust Medicines Policy for Controlled Drugs (Ref 1763); to define the procedure to be followed when the keys to the CD cupboard are missing.

Responsibilities

The ward/department manager has responsibility for ensuring the safe and appropriate management of CDs in their area. The manager is responsible for ensuring that all staff are aware of, and understand, this procedure.

All staff authorised to access CD stocks, and to administer or check CDs have responsibility to follow this procedure.

The registered nurse, midwife or Operating Department Practitioner (ODP) in charge of a ward or department at a particular time is responsible for the safe and appropriate management of CDs in that area. While control of access (i.e. key-holding) to the CD cupboard can be delegated to another, such as a registered nurse or ODP, responsibility remains with the registered nurse, midwife or ODP in charge.

Storage of CDs

Ward CD cupboards must conform to BS2881 and The Misuse of drugs (safe custody) regulations 1973 or be otherwise approved by the Pharmacy Department. The cupboard must be constructed of metal and fixed securely to a wall or floor. Some cupboards may have a warning light to indicate when it is open, but it is not a requirement that it is present, or working.

Additional safeguards must be considered as part of a risk assessment for areas where there are large amounts of drugs in stock at a given time, and / or there is not a 24-hour staff presence, or easy control of access. (Guidance on quantities can be sought from pharmacy.) In these situations, a security cabinet that has been evaluated against the ‘Sold Secure’ standard must be used. In all cases, advice must be obtained from the Pharmacy department.
If a specific CD product is required to be kept in a refrigerator, then a suitable designated locked fridge must be used.

CDs must be stored in dedicated cupboards of adequate size which can only be opened by a person who can lawfully be in possession, such as a pharmacist or the registered nurse, midwife or ODP in charge, or a person working under their authority.

In certain circumstances, for example when CD discharge medicines (TTOs) are sent to the ward several hours before the patient leaves, the medicines must be stored in the CD cupboard. These medicines must be segregated from the ward CD stock.

General measures for storage of CDs include:
- cupboards must be kept locked when not in use
- the lock must not be common to any other lock in the hospital
- keys must only be available to authorised members of staff and at any time the key-holder must be readily identifiable
- there must be arrangements for keeping the keys secure. This is particularly important for areas that may not be operational at all times.

See appendix 4 of the Medicines Policy for Controlled Drugs (Ref 1763).

**Key-holding and Access to CDs**

The registered nurse, midwife or ODP in charge is responsible for the CD keys, and is therefore responsible for controlling access to controlled drugs on the ward or department for that shift. While key-holding may be delegated to other suitably-trained, registered healthcare professionals, the legal responsibility rests with the registered nurse, midwife or ODP in charge.

In order to minimise the likelihood of CD keys being mislaid, all staff members with lawful authority to hold CD keys (e.g. pharmacist, registered nurse, midwife, ODP) must ensure their responsibilities as described in the Trust Medicines Policy – Controlled Drugs are understood, and followed.

The CD cupboard keys must not be kept with any keys that may be accessed by staff who are not authorised to hold CD keys.

The CD cupboard keys must not leave the ward or department, and must be returned to the nurse, midwife or ODP in charge immediately after use by another registered member of staff. Keys may be stored in a separate locked cupboard accessible only to suitably-trained, registered healthcare professionals, if a department / ward manager has a completed Medicines Security Risk Assessment and this has been approved by the Medicines Governance Committee.
**Missing Keys**

When a member of staff authorised to hold the CD keys realises that the keys are missing, the following action must be taken:

- thoroughly check own uniform pockets
- question colleagues on the ward to check if the key has been transferred to another authorised person
- undertake an immediate and thorough search of the clinical area
- determine the last time the keys were used
- contact staff from previous shift to determine if key was taken home inadvertently
- inform the ward manager or deputy if the manager is unavailable. If out of hours inform the 110 bleep holder (Torbay Hospital) or clinician on-call (Community Hospitals).
- if the key is not found following the above, locate the spare CD key (if one exists) and undertake a full CD stock check.
- complete an incident form on the Trust incident reporting system, including the date the stock was last recorded as being correct

The responsibilities of the Manager of the ward or department (or Deputy if the Manager is unavailable) in this situation will be to:

- ensure a full stock check has been completed as above if possible
- ensure an incident report is completed as above
- inform relevant matron / senior manager of the loss of CD key
- inform the ward /department or on-call pharmacist that the CD key is missing
- inform the Accountable Officer for CDs (or Deputy if the Officer is unavailable) through the Pharmacy Department at Torbay Hospital
- inform the Local Security Management Specialist (LSMS)
- in order to preserve the security of the CDs while the keys are missing, and until the lock is changed, make every effort to keep the CD cupboard under direct observation. This should preferably be achieved by allocating a member of staff to this task, and who will be alert to any person attempting to access the CD cupboard (other than those already legitimately working in the area on the current shift)
- arrange for the CD drug cupboard locks to be replaced via Estates
- ensure that a person authorised to hold drug keys remains with the locksmith while the work is undertaken.
- on receipt of the replacement keys – destroy the old replacement CD key
- undertake a full stock check
Investigation

All incidents relating to lost keys will be the subject of an investigation lead by the relevant Manager.

The format and structure of the investigation will be determined in liaison with the Pharmacy Department, the relevant Clinical Governance Coordinator and the Matron. It may also be necessary to alert, and involve, Local Counter Fraud.

The names of those members of staff with access to the CD cupboard within the time since the last correct entry in the Ward Controlled Drugs Record Book will be collated, and an investigation undertaken.

The actions arising from the investigation will be specific to each incident, and may result in police involvement if theft is considered likely. In all cases the investigation report will be received by the Controlled Drug Governance Committee.

References

Medicines Act (1968)
Misuse of Drugs Act (1971)
Misuse of Drugs (Safe Custody) Regulations 1973
Misuse of Drugs Regulation (2001)
NICE guideline [NG46] Controlled drugs: safe use and management (April 2016)
### Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

<table>
<thead>
<tr>
<th>Ref No:</th>
<th>1568</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document title:</td>
<td>Controlled Drugs – Security, Key Holding and Missing Keys in the Acute and Community Hospitals</td>
</tr>
<tr>
<td>Purpose of document:</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>Date of issue:</td>
<td>14 August 2020</td>
</tr>
<tr>
<td>Version:</td>
<td>3</td>
</tr>
<tr>
<td>Date of next review:</td>
<td>14 August 2023</td>
</tr>
<tr>
<td>Last review date:</td>
<td>13 May 2020</td>
</tr>
<tr>
<td>Author:</td>
<td>Clinical Governance Pharmacist &amp; Medication Safety Officer</td>
</tr>
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<td>Directorate:</td>
<td>Pharmacy</td>
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<tr>
<td>Equality Impact:</td>
<td>The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity &amp; religion or belief</td>
</tr>
<tr>
<td>Committee(s) approving the document:</td>
<td>Clinical Director of Pharmacy, Chief Nurse, Care and Clinicals Policies Group, Medical Director</td>
</tr>
<tr>
<td>Date approved:</td>
<td>22 July 2020</td>
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<tr>
<td>Links or overlaps with other policies:</td>
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Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.  

<table>
<thead>
<tr>
<th></th>
<th>Yes ☐</th>
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<tbody>
<tr>
<td>Please select</td>
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<tr>
<td>Does this document have implications regarding the Care Act?</td>
<td>☐ ☐</td>
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<td>If yes please state:</td>
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<tr>
<td>Does this document have training implications?</td>
<td>☐ ☐</td>
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<td>If yes please state:</td>
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<td>Does this document have financial implications?</td>
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</table>
If yes please state:

Is this document a direct replacement for another?
If yes please state which documents are being replaced:

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Document Amendment History

<table>
<thead>
<tr>
<th>Date</th>
<th>Version no.</th>
<th>Amendment summary</th>
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<tr>
<td>4 July 2013</td>
<td>1</td>
<td>New</td>
<td>Chair, Trust Controlled Drugs Governance Committee and Trust Accountable Officer for Controlled Drugs</td>
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<td>17 July 2015</td>
<td>1</td>
<td>Date change</td>
<td>Chair, Trust Controlled Drugs Governance Committee and Trust Accountable Officer for Controlled Drugs</td>
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<tr>
<td>5 May 2017</td>
<td>2</td>
<td>Revised</td>
<td>Clinical Director of Pharmacy Care and Clinical Policies Group Chief Nurse Medical Director</td>
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<tr>
<td>20 February 2018</td>
<td>2</td>
<td>Review Date Extended 2 Years to 3 Years</td>
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<tr>
<td>14 August 2020</td>
<td>3</td>
<td>Minor Amendment</td>
<td>Clinical Director of Pharmacy Care and Clinical Policies Group Chief Nurse Medical Director</td>
</tr>
</tbody>
</table>
The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions.

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person’s ability to make a decision due to ‘an impairment of or disturbance in the functioning of the mind or brain’ the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual’s right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCON

https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.
**Rapid (E)quality Impact Assessment (EqIA) (for use when writing policies)**

<table>
<thead>
<tr>
<th>Policy Title (and number)</th>
<th>Version and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policy Author</strong></td>
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</table>

An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.

### Who may be affected by this document?

- Patients/ Service Users [ ]
- Staff [ ]
- Other, please state... [ ]

### Could the policy treat people from protected groups less favourably than the general population?

**PLEASE NOTE:** Any ‘Yes’ answers may trigger a full EIA and must be referred to the equality leads below

<table>
<thead>
<tr>
<th>Protected Group</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Age</td>
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<tr>
<td>Gender Reassignment</td>
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<tr>
<td>Sexual Orientation</td>
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<td>Age</td>
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<td>Gender</td>
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<tr>
<td>Disability</td>
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<tr>
<td>Religion/Belief (non)</td>
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<tr>
<td>Race</td>
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<tr>
<td>Disability</td>
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<tr>
<td>Pregnancy/Maternity</td>
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<td>Marriage/ Civil Partnership</td>
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### Is it likely that the policy could affect particular ‘Inclusion Health’ groups less favourably than the general population? (substance misuse; teenage mums; carers; travellers; homeless; convictions; social isolation; refugees)

- Yes [ ]
- No [ ]
- NA [ ]

Please provide details for each protected group where you have indicated ‘Yes’.

### VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
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<tbody>
<tr>
<td>Is inclusive language used throughout?</td>
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<tr>
<td>Are the services outlined in the policy fully accessible?</td>
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<tr>
<td>Does the policy encourage individualised and person-centred care?</td>
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<tr>
<td>Could there be an adverse impact on an individual’s independence or autonomy?</td>
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### EXTERNAL FACTORS

- Is the policy a result of national legislation which cannot be modified in any way? Yes [ ]
- What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?) Yes [ ]

### Who was consulted when drafting this policy?

- Patients/ Service Users [ ]
- Trade Unions [ ]
- Protected Groups (including Trust Equality Groups) [ ]
- Staff [ ]
- General Public [ ]
- Other, please state... [ ]

### What were the recommendations/suggestions?

- Does this document require a service redesign or substantial amendments to an existing process? **PLEASE NOTE: ‘Yes’ may trigger a full EIA, please refer to the equality leads below**

### ACTION PLAN: Please list all actions identified to address any impacts

<table>
<thead>
<tr>
<th>Action</th>
<th>Person responsible</th>
<th>Completion date</th>
</tr>
</thead>
</table>

### AUTHORISATION:

By signing below, I confirm that the named person responsible above is aware of the actions assigned to them

- Name of person completing the form
- Signature
- Validated by (line manager)
- Signature

Collated by Clinical Effectiveness

Version 3 (August 2020)

Controlled Drugs – Security, Key Holding and Missing Keys in the Acute and Community Hospital

Rapid (E)quality Impact Assessment
Consider any additional needs of carers/parents/advocates etc, in addition to the service user
2 Travelers may not be registered with a GP - consider how they may access/be aware of services available to them
3 Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
4 Consider how someone will be aware of (or access) a service if socially or geographically isolated
5 Language must be relevant and appropriate, for example referring to partners, not husbands or wives
6 Consider both physical access to services and how information/communication in available in an accessible format
7 Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy
Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet).

For more information:
- Contact the Data Access and Disclosure Office on dataprotection.tsdf@nhs.net,
- See TSDFT’s Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.