Title: CONTROLLED DRUGS – SECURITY, KEY HOLDING AND MISSING KEYS IN THE ACUTE AND COMMUNITY HOSPITALS (STANDARD OPERATING PROCEDURE FOR)

Ref No: 1568 Version: 2

Classification: Procedure

Directorate: Pharmacy

Due for Review: 05/05/20

Responsible for review: Clinical Governance Pharmacist & Medication Safety Officer

Ratified by: Clinical Director of Pharmacy Care and Clinical Policies Group Chief Nurse Medical Director

Applicability: As indicated below

**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 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 may 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.

**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
- determine the last time the keys were used
- contact staff from previous shift to determine if key was taken home inadvertently
- 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
- 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 a root cause analysis 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**

Misuse of Drugs Act (1971)
Medicines Act (1968)
Misuse of Drugs Regulation (2001)
Collated by Clinical Effectiveness

Controlled drugs – Security, Key Holding and Missing Keys in the Acute and Community Hospitals (Standard Operating Procedure for)

Version 2 (May 2017)

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.

Ref No: 1568

Document title: Controlled drugs – Security, Key holding and Missing Keys in the Acute and Community Hospitals (Standard Operating Procedure for)

Purpose of document: Protocol

Date of issue: 5 May 2017  Next review date: 5 May 2020

Version: 2  Last review date: 17 July 2017

Author: Clinical Governance Pharmacist and Medication Safety Officer

Directorate: Pharmacy

Equality Impact: 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 & religion or belief

Committee(s) approving the document: Care & Clinical Meeting
Chief Nurse
Medical Director
Clinical Director of Pharmacy

Date approved: 19 April 2017

Links or overlaps with other policies:
All TSDFT Trust Strategies, policies and procedure documents
1763 - Controlled Drugs, Medicines Policy for Torbay and South Devon NHS Foundation Trust
0806 Trust Medicines Policy;
1394 – Controlled Drugs Management, Ordering, Receipt and Returns by Wards and Department – Operating Procedures;
1569 – Controlled Drugs – Reporting Stock Discrepancies - Operating Procedure

Does this document have training implications? Yes ☐ No ☐

If yes please state:

Does this document have financial implications? Yes ☐ No ☐

If yes please state:

Is this document a direct replacement for another? Yes ☐ No ☐

If yes please state which documents are being replaced:
<table>
<thead>
<tr>
<th>Date</th>
<th>Version no.</th>
<th>Amendment summary</th>
<th>Ratified by:</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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<tr>
<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</td>
<td>Extended 2 Years to 3 Years</td>
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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 iCare

http://icare/Operations/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>
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<tr>
<th>Policy Title (and number)</th>
<th>Version and Date</th>
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Policy Author

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 favorably than the general population?

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

| Age | Yes ☐ No ☐ Gender Reassignment | Yes ☐ No ☐ Sexual Orientation | Yes ☐ No ☐ |
| Race | Yes ☐ No ☐ Disability | Yes ☐ No ☐ Religion/Belief (non) | Yes ☐ No ☐ |
| Gender | Yes ☐ No ☐ Pregnancy/Maternity | Yes ☐ No ☐ Marriage/ Civil Partnership | Yes ☐ No ☐ |

Is it likely that the policy could affect particular ‘Inclusion Health’ groups less favorably than the general population? (substance misuse; teenage mums; carers; travellers; homeless; convictions; social isolation; refugees)

Yes ☐ No ☐

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

Is inclusive language used throughout? Yes ☐ No ☐ NA ☐

Are the services outlined in the policy fully accessible? Yes ☐ No ☐ NA ☐

Does the policy encourage individualised and person-centred care? Yes ☐ No ☐ NA ☐

Could there be an adverse impact on an individual’s independence or autonomy? Yes ☐ No ☐ NA ☐

EXTERNAL FACTORS

Is the policy a result of national legislation which cannot be modified in any way? Yes ☐ No ☐

What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)

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

Yes ☐ No ☐

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>
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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
Valuated by (line manager) | Signature