Policy Document

Reference: MM06

University Hospitals of North Midlands NHS Trust

Prescribing, Storage, Supply and Administration of Controlled Drugs

Version:	**6**
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Executive Lead:	**Medical Director**

Version Control Schedule

Final Version	Issue Date	Comments
1	12.03.08	Detail regarding controlled drug management taken out of the UHNM Policy MM03 and a stand-alone policy developed for controlled drugs. This was undertaken in response to new legalisation arising from the Shipman enquiry. Approved by the UHNM Safe Medication Group.
2	February 2014	Further changes in legalisation. Closure of the NSRI hospital site. Registration of pharmacy technicians. Authorising body for both pharmacists and pharmacy technicians is now the General Pharmaceutical Council. Post FftF and Sodexo now provide the portering service to the new FftF buildings. New prescription chart now in use with pre-printed sections for patient controlled analgesia and epidural infusions which replacement labels. Incorporation of Trust approved standard operating procedures for controlled drugs – see Appendices.
3	April 2017	Changes from last version: • Further changes in legislation – temazepam handwriting restrictions, tramadol schedule 3 ketamine schedule 2. • Now includes SOP for administration of CDs in theatres. • Merge with MSFT now have outpatients at County hospital • Change to prescribing of morphine sulphate solution 10mg/5ml • Schedule for auditing CDs
4	November 2017	To MEWs in MM06 – SOP - 4 changes to NEWs
5	May 2020	Addition of standard operating procedure for disposing of patient's own controlled drugs at ward level during the covid-19 pandemic. SOP approved at Trust Safe Medication Group and Covid-19 Clinical Sub-Group.
6	December 2020	Addition of a section on pandemics / significant incidents, change to legislation of Gabapentinoids, inclusion of radiographers. Change to management of documentation of errors in Controlled Drugs registers.

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

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1. INTRODUCTION

Medicines optimisation is a patient centred approach to improving outcomes from medicines. This encompasses: reducing harm from medicines; ensuring medicines use is as safe as possible; evidence based use of medicines and embedding good practice(s).

Controlled drugs (such as morphine, oxycodone, midazolam, codeine and diamorphine) are in the top 10 medicines involved in medicines related adverse incidents (e.g. storage; stock discrepancies) at UHNM.

The Misuse of Drugs Act 1971 controls 'dangerous or otherwise harmful drugs' which are designated as 'Controlled Drugs'. The primary purpose of the Misuse of Drugs Act is to prevent the misuse of Controlled Drugs (CDs) in particular their manufacture, supply and possession. It does this by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by Regulations or by licence from the Secretary of State.

The use of Controlled Drugs is permitted by the Misuse of Drugs Regulations 2001, as amended. These Regulations define the classes of person who are authorised to supply and possess controlled drugs while acting in their professional capacities. Other regulations deal with the safe custody of CDs and with the notification of and supply of drugs to misusers.

The legal framework affecting Controlled Drugs has been brought in to sharp focus by issues arising from the Shipman case and the publishing of the Shipman Inquiry's Fourth Report (2004). To implement the recommendations made in the Shipman Report a number of legal changes were made to the way that CDs are managed in England, Scotland and Wales.

Legislative changes have been made in the form of The Health Act 2006, the accompanying Controlled Drugs (Supervision of Management and Use) Regulations 2006 and amendments to the Misuse of Drugs Regulations 2001.

More recently, changes to the professional use of controlled drugs by pharmacists and nurses relating to independent pharmacist and nurse prescribers, patient group directions and compounding (mixing) came into effect in April 2012. The Department of Health (DH) published additional information about changes to the controlled drugs regulations, which came into effect on 1 April 2013.

In addition the DH and the Royal Pharmaceutical Society of Great Britain (RSPGB) jointly issued 'Safer Management of Controlled Drugs - A guide to good practice in secondary care (England)' in 2007.

The purpose of this policy is to:

- Ensure the Trust complies with the legal requirements of the Misuse of Drugs Regulations (1971), all other relevant Controlled Drugs Legislation and NHS Guidance including National Patient Safety Alerts.
- Provide clear, standards and procedures for all staff carrying out their duties involving Controlled Drugs. The aim being to reduce risk, minimise harm and reduce adverse incidents.
- Improve the governance arrangements in place and ensure that any risks associated with the use of controlled drugs are identified and managed.
- Ensure compliance with the CQC Essential Standards of Quality and Safety Outcome 9 – Management of medicines and NHS LA medicines management standards.
- Support professionals, encourage good practice and ensure that controlled drugs are available and used when clinically required by patients.

2. POLICY STATEMENT

The Trust is committed to reducing and managing risk and ensuring effective and safe practice with respect to medicines including controlled drugs. This includes reducing harm to patients from medication incidents.

This policy and associated SOPs outlines the management and supervision of Controlled Drugs (CDs) within UHNM to ensure their safe and secure storage, enhance their safe use and ensure compliance with all relevant statutory, legal and Department of Health requirements. This in turn should optimise their use, improve patient safety, minimise harm to patients and improve patient experience.

The UHNM has an Accountable Officer for Controlled Drugs – see responsibilities and Appendix 1.

Within the Pharmacy Directorate there are SOPs in place which cover all aspects of CD management. These are ratified via the Pharmacy Directorate Clinical Governance Group and are signed off by the Accountable Officer for Controlled Drugs.

Storage and security requirements may be increased locally at the discretion and direction of the Matron / Associate Chief Nurse in discussion with the Accountable Officer for Controlled Drugs (or nominated Deputy) and the Local Security Management Specialist.

Controlled Drugs can only be:

- Prescribed by registered Medical Practitioners and Independent Nurse, Pharmacist and Midwife prescribers in accordance with national guidance.
- Supplied and administered by a midwife according to Midwives exemptions.
- Supplied and administered under an approved UHNM Patient Group Direction (PGD) in accordance with national guidance and Trust Policy MM05 – see Appendix 17.

Discharge and out-patient prescriptions must conform to all requirements of the Misuse of Drugs Regulations for CD prescription. It is an offence for a prescriber to issue a prescription, which does not comply with the Misuse of Drugs Act and it is an offence for pharmacy to dispense such a prescription.

Only registered nurses, midwives, ODPs, pharmacists and pharmacy technicians can fulfil functions regarding CDs. When the Appointed Practitioner in Charge is not from one of these professions (e.g. radiographer) responsibilities regarding CDs can be delegated to a designated registered practitioner with the approval of the Clinical Director of Pharmacy and Medicines Optimisation, together with the relevant Directorate Senior Management team who must agree and authorise named professional roles to be given these responsibilities. This will be in accordance with local SOPs.

Controlled drugs are supplied to wards and dispensed to in-patients via the main UHNM pharmacy dispensaries at both the RSUH and County sites by authorised and competent staff according to local SOPs and acting under the authorisation of a pharmacist.

Naloxone injection 400 micrograms in 1ml must be available on all wards/clinical areas where opiates are administered.
Flumazenil 100 micrograms in 1ml must be available on all wards / clinical areas where midazolam is administered.

3. SCOPE

All staff involved in aspects of controlled drug management should be familiar with this policy and associated standard operating procedures and comply with them at all times.

This Policy is an adjunct to the UHNM Policy MM03 Prescription, Supply, Storage and Administration of Medicines and describes in detail the processes, roles and responsibilities in relation to the management of controlled drugs (CDs), including:

- Stocks, storage and security of CDs at ward / department level
- Ordering and receipt of CDs
- Administration of CDs
- Record keeping in the ward controlled drug record book
- Controlled drug stock checking at ward level

- Disposal and / or return to the Pharmacy Department
- Patient's own CDs
- Clinical trials
- Prescribing of CDs
- Management of CDs in operating theatres and maternity

This policy applies to all schedule 2 and 3 controlled drugs. At UHNM schedule 3 CDs (excluding Gabapentinoids) and preparations containing cocaine are subject to the same restrictions and procedures as schedule 2.

Gabapentinoids Pregabalin and Gabapentin were reclassified as Schedule 3 Controlled Drugs on 1st April 2019. Legislation does not require them to be stored in safe custody. They are however subject to prescription handwriting requirements. UHNM assessed the change in legislation against the widespread usage of the medicines across the hospital and health economy and a decision was made not to keep them in safe custody. This decision will be reviewed annually.

In addition all schedule 5 preparations containing morphine and concentrated injectable potassium preparations are subject to ordering, storage and register restrictions.

All staff working within the Trust who are involved in some way with the use of medicines, must familiarise themselves with and comply with, other relevant medicines related policies. **This will include:**

MM03 Policy for the Storage, Prescription, Supply and Administration of Medicines
MM04 Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines
MM05 Use of PGDs for supply and administration of medicines by registered non-medical health care professionals
MM10 Adult Sedation Policy

The scope of this policy does not cover people found to possess a Schedule 1 illicit substance. This is covered by a separate Trust Policy RM11 Management of Illicit Substances.

4. DEFINITIONS

Controlled Drug is defined as a preparation, which is subject to the requirements of the Misuse of Drugs Regulations 2001. Controlled Drugs are classified in the Misuse of Drugs Regulations 2001 into five schedules according to different levels of control (e.g. possession, supply, record keeping). These are summarised in the table below:

Schedule	Examples	UHNM Comments
Schedule 1 (CD Lic)	Hallucinogenic drugs (e.g. LSD, ecstasy-type substances, cannabis)	Production, possession and supply of drugs in this schedule are limited to research and other special purposes and a licence from the Home Office is required for lawful possession.
Schedule 2 (CD POM)	Opiates (e.g. diamorphine), major stimulants (e.g. amfetamine, ketamine	Safe custody applies to all schedule drugs
Schedule 3 (CD No Register)	Minor stimulants (e.g. benzfetamine), other drugs not thought so likely to be misused as those in schedule 2 (e.g. temazepam, midazolam, tramadol, phenobarbital)	Safe custody and prescribing applies as per schedule 2 (excluding Gabapentinoids). Safe custody does not apply to Gabapentinoids. Prescription handwriting requirements do apply.
Schedule 4 Part I (CD Benz)	Most of the benzodiazepines	Safe custody does not apply.
Schedule 4 Part II (CD Anab)	Most of the adrogenic and anabolic steroids, clenbuterol and growth hormones (5 polypeptide hormones)	Safe custody does not apply.

Schedule 5 (CD Inv.)	Includes preparations of certain controlled drugs such as codeine, pholcodine, cocaine and morphine at a sufficiently low strength to be exempt from full control	Safe custody does not apply to codeine and pholcodine but low strength morphine sulphate and cocaine solutions are treated as full Schedule 2 CDs at UHNM - with exception of handwriting requirements for morphine sulphate 10mg/5ml.

Preparations specified in Schedule 2 and 3 of this regulation are distinguished in the British National Formulary (BNF) by the symbol CD. The current BNF includes a summary of the Misuse of Drugs Act together with drugs included in each schedule.

Glossary

Accountable Officer: is a fit, proper and suitably experienced person appointed or nominated by a designated body to ensure the effective management and use of Controlled Drugs within the Trust. The role and responsibilities of the Accountable Officer are defined in the Health Act 2006 and under The Controlled Drugs (Supervision of Management and Use) Regulations 2006.
Midwife: a midwife registered with the Nursing and Midwifery Council.
Nurse: a nurse registered with the Nursing and Midwifery Council
Medical Practitioner: a registered medical practitioner including pre-registration House Officers but excluding medical students.
Pharmacist: a pharmacist registered with the General Pharmaceutical Council (GPhC).
Pharmacy Technician is registered with the GPhC and works under the supervision of a Pharmacist.
A registered operating department practitioner (ODP) has achieved the relevant competencies and whose name is on the register of Health Care Professions Council.
A Theatre Co-ordinator is the person in charge of the theatre suite who may be a Registered Nurse or ODP.
Messenger is the person who conveys or carries the sealed or locked container containing the CDs and acts as a 'messenger' e.g. porters (UHNM and Sodexo), drivers, registered nurses.
Controlled Drugs Record Book / Register is a book containing records of all the controlled drugs transactions on the ward, theatre or department, including the CDs that have been received, administered or supplied to patients, destroyed by or stored on the ward or department.
Controlled Drugs Order / Requisition Book is a book consisting of consecutively numbered orders, which can be completed by authorised ward signatories in order to present written orders for CDs to Pharmacy Services to make a supply against.
Local Intelligence Network (LIN) - there is a statutory duty of collaboration requiring organisations to share information and intelligence regarding the management and use of controlled drugs via LINs.
Prescriber applies to any practitioner legally authorised to prescribe under the Medicines Act 1968 or any subsequent amendments. Thus, this policy applies equally to both medical and non-medical practitioner prescribing. Authorised prescribers include registered medical staff and Trust approved non-medical prescribers.
Appointed Practitioner in Charge is the senior practitioner appointed in overall charge of the ward or department (Ward Sister, Charge Nurse, Ward Manager) or where appropriate a senior professional (i.e. Radiographer, ODP, Physiotherapist, Chiropodist).

5. ROLES AND RESPONSIBILITIES

The responsibilities outlined in this Policy and Appendices are additional responsibilities to those outlined in Trust Policy MM03 and relate specifically to Controlled Drugs.

5.1 **Chief Executive** has overall responsibility for the safe and secure handling of medicines. He / she is responsible for ensuring that the Trust has a nominated Accountable Officer for Controlled Drugs and that a specific job description exists for that role.

5.2 **Medical Director – Executive Lead for Medicines Optimisation** is responsible through membership of the Executive Team and Trust Executive Committee that adequate resources and corporate performance management arrangements are in place regarding the implementation of the UHNM Medicines Optimisation Strategy. This includes the implementation of this policy. The

Medical Director is supported in this role by the **Chief Nurse**, the **Clinical Director of Pharmacy and Medicines Optimisation** and the **Head of Quality, Safety and Compliance**.

5.3 **Lead NHS England Controlled Drugs Accountable Officer (CDAO)** is responsible for the establishment and management of the Shropshire and Staffordshire CD Local Intelligence Network (LIN).

5.4 **The UHNM Accountable Officer for Controlled Drugs** is responsible for:

- Ensuring the safe and effective use and management of controlled drugs within the Trust.
- Safeguarding patient safety by monitoring the use of CDs within the Trust and taking remedial action where necessary.
- Completing the quarterly Controlled Drug Occurrence report for UHNM and submitting it to the CDAO for sharing via the LIN.
- Sharing of information, intelligence and good practice both internally at UHNM and with the Shropshire and Staffordshire LIN.
- Liaising with Accountable Officers from other local Trusts, charities, private and commercial organisations within the LIN regarding controlled drug management.
- Signing off any local standard operating procedures relating to CDs.

5.5 **Clinical Director of Pharmacy** is responsible for:

- The production and review of this policy and associated SOPs.
- Establishing, monitoring and reporting on a system for assuring the safe and secure handling of medicines including controlled drugs.
- Ensuring the safe and effective management of CDs within the Pharmacy Directorate. This includes ensuring that adequate and up-to-date departmental standard operating procedures are in place for all relevant pharmaceutical activities involving CDs.
- Delegation of day-to-day management of controlled drugs to suitably trained and competent pharmacists and pharmacy technicians.
- Ensuring the organisation and dissemination of the pharmacy-lead audit programme for CD management for all relevant wards and departments (including pharmacy) a minimum of every six months.
- Noting all unresolved discrepancies within the Pharmacy Directorate initiating appropriate investigations as Accountable Officer.

5.6 The **Professional Head / Associate Chief Nurses / Directorate Manager / Clinical Director** are responsible for:

- Ensuring that all practices involving CDs within their division/directorate comply with the SOPs included in this policy.
- Identifying any CD practices that may not be able to follow the procedures outlined in this policy and escalating to the CD Accountable Officer
- Ensuring that matrons and ward managers have made staff aware of the policy and associated SOPs
- Ensuring appropriate support and resource for any investigations related to controlled drug management and serious unresolved discrepancies on wards / clinical areas within Department / Directorate / Division. This is in line with UHNM Policy RM07.
- Informing the Accountable Officer of any concerns and / or suspicions regarding CD management
- Informing the Accountable Officer of any concerns that have been raised regarding staff that may affect their ability to prescribe/administer controlled drugs.

5.7 The **Matron / Senior Clinical Nurse** is responsible for:

- Ensuring all wards / departments / theatres within their area of responsibility fully comply with this policy and associated SOPs including: ordering, receipt and secure storage of CDs and controlled stationery;
- Ensuring that staff have completed the Trust online training for CD SOPS (via VCTMS) and mandatory training in medicines optimisation;

- Ensuring appropriate arrangements are in place when wards / theatres / departments are closed.
- Ensuring that Divisional Clinical Governance and Quality Managers, Associate Chief Nurse or Professional Head of Department are informed of any serious incidents relating to CDs.
- Ensuring any concerns and / or suspicions regarding CD management are escalated to Associate Chief Nurse and Accountable Officer in a timely manner.
- Ensuring that the Appointed Practitioner in Charge takes action to resolve any deficiencies identified through the CD audit programme or adverse incident investigations in a timely manner.

5.8 The **Appointed Practitioner in Charge (e.g. Sister / Charge Nurse / Ward Manager / Theatre Co-ordinator)** of a ward, department or theatre is responsible for:

- Ensuring that all staff comply with this policy at all times, receive training on this Policy and complete mandatory medicines optimisation training and staff have completed the Trust online training for CD SOPS (via VCTMS);
- All aspects of ordering, receipt, security (e.g. keys), safe storage of controlled drugs and accurate records are maintained on their wards / departments / theatres.
- Reports and investigates adverse incidents ensuring that all relevant information and actions are documented on Datix®. This includes implementing recommendations from investigations and audits in a timely manner.
- Escalating any concerns and / or suspicions regarding unaccountable discrepancies to their Matron, Associate Chief Nurse and / or the Accountable Officer.

5.9 The **Operating Department Practitioner / Nurse** is responsible for:

- The safe custody of the controlled drug keys whilst working in a particular theatre. The keys must be returned to the central key cupboard as soon as possible once the theatre list is finished.
- The ordering, receipt and safe storage of CDs.
- Accurate records are maintained.
- Reports and investigates adverse incidents.

5.10 **UHNM Safe Medication Group and Divisional Safe Medication Groups and relevant Divisional Governance and Quality Managers** are responsible for ensuring that adverse incidents relating to controlled drugs are adequately reported, investigated, findings documented and any lessons learnt are identified and cascaded through Divisions and the wider Trust.

5.11 **UHNM Quality and Safety Oversight Group#** will receive an annual report from the Accountable Officer for Controlled Drugs on all matters of controlled drug management and the appropriate risk management control measures to eliminate or reduce identified risks.

5.12 **Individual prescribers and healthcare practitioners** carry their own responsibility and are professionally accountable for their judgement in doing so. They must only undertake tasks which they are responsible for, competent to do and authorised to undertake, as outlined in all of the UHNM medicines related policies and standard operating procedures. They should ensure that when **prescribing, dispensing, supplying medicine via a PGD and / or administering opioids** they:

- Ensure that all CD prescriptions comply with legal requirements.
- PGDs used are up to date. Practitioner has completed associated training package and signed off to use the PGD.
- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient.
- Ensure where a dose increase is intended, that the calculated dose is safe for the patient.
- Check the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, and common side effects of that medicine and formulation. This is in accordance with NPSA Safety Alert 2008/RRR005.

5.13 **Messengers** are responsible for the safe delivery of the intact 'container' containing CDs in accordance with SOPs.

5.14 The UHNM **Local Security Management Specialist** is authorised by the Accountable Officer as being responsible for witnessing the destruction of CDs in Pharmacy in accordance with local SOPs. He / she will support and provide advice to the Accountable Officer on the investigation of any security concerns or unaccountable stock discrepancies regarding controlled drugs. He / she is responsible for UHNM Policy RM11 on Illicit Substances.

5.15 The **Waste Manager** is responsible for providing specialist advice on the destruction of CDs in accordance with national guidance.

6. EDUCATION, TRAINING AND PLAN OF IMPLEMENTATION

6.1 Education and Training

Individual Divisions and Directorates are responsible for ensuring that all staff involved in the prescription, ordering, dispensing, distribution, supply via Patient Group Directions, administration, storage and disposal of CDs are familiar with the relevant sections of the policy and SOPs which apply to them and that they receive education and training appropriate to their involvement. This includes permanent, temporary and locum staff including:

- Medical and Dental practitioners
- Registered Pharmacists, Registered Pharmacy Technicians & pharmacy support workers.
- Registered Nurses and Midwives
- Registered Allied Health Professionals
- Operating Department Practitioners
- Hotel services (portering) staff

All registered practitioners involved with any aspect of controlled drugs must complete the Trust online training package on CD SOPs – package 3 of the Medicines Optimisation training.

All staff involved in any aspect of handling medicines must complete the Trust online training package on storage of medicines – package 1 of the Medicines Optimisation training

All practitioners responsible for ordering and administering Controlled Drugs on a ward / department / theatre and all prescribers should familiarise themselves with the Misuse of Drugs Act (summarised in the BNF) before handling or prescribing Controlled Drugs. Individual prescribers will keep their competencies and knowledge up-to-date.

Medicines related training is part of the Trust mandatory training programme. The Pharmacy Directorate is able to provide additional local training to support implementation of this policy if requested by ward managers / Matrons. Training records should be held in the staff personal record, ideally within ESR.

Links with Keele Medical School, Keele Schools of Nursing and Pharmacy and the Foundation Medical School exist to ensure that adequate medicines related training is provided.

6.2 Implementation

It is essential that Divisions and Directorates are able to demonstrate implementation and compliance with the Policy to support compliance with the CQC Essential Standards of Quality and Safety Outcome 9 – Management of medicines and NHS LA medicines management standards.

Divisions and Directorates need to identify any additional standard operating procedures or risk assessments that need to be developed or updated in light of this policy.

Ward based pharmacists and pharmacy technicians will work with ward managers and their teams to ensure that non-compliance issues identified in the quarterly CD audits are actively addressed in a timely manner.

The Clinical Director of Pharmacy will liaise with the UHNM Local Security Management Specialist and Waste Manager to ensure that the destruction of CDs within the Pharmacy and on wards is in line with national guidance.

7. MONITORING AND REVIEW ARRANGEMENTS

7.1 Internal Monitoring

There should be on-going monitoring of compliance with this Policy in relation to the prescribing, dispensing, supply, transport, storage and / or administration (via prescription or patient group direction) of controlled drugs by the Accountable Officer, relevant Heads of Profession, Associate Chief Nurses, Matrons and ward managers in their respective areas of responsibility. Audits of the policy and management of Controlled drugs will be conducted a minimum of 6 monthly. Wards and departments where there are concerns from audits or incidents may be audited 3 monthly.

When significant changes are made to ward locations / specialities / facilities the bi-annual Controlled Drug audits may be completed from a point prevalence perspective.

Areas of non-compliance should be identified and action plans put in place to rectify them in a timely manner. It may be appropriate to audit compliance across a Directorate if major problems are identified or a number of adverse incidents occur in one particular area.

At the UHNM and Divisional Safe Medication Groups controlled drug management should be a standing agenda item so that review of audits undertaken by pharmacy on ward / departmental CD management can be reviewed; standard operating procedures approved for sign off by appropriate UHNM Group and / or Accountable Officer; review of adverse incidents on Datix® regarding controlled drugs to identify any trends and learn lessons.

Controlled drug stock balances and registers in wards and departments must be checked and signed as accurate every three months by a designated pharmacist, pharmacy technician or Pharmacy nurse, assisted and witnessed by a senior nurse on the ward or department.

An audit report form will be completed and retained by the pharmacy for a minimum of 2 years. This report will also include a check on security, a check on the quantity and range of controlled drugs stocked, and a random check on requisition and register details. When checking stock balances pharmacists must record that the balance has been checked under each drug entry.

The Pharmacy Directorate will maintain an up-to-date database of ward audits so that improvements in compliance can be monitored and any areas for further review identified. This information will be shared with Divisions (via Associate Chief Nurse and Divisional Governance and Quality Managers) and Professional Advisory Group.

An annual controlled drugs report will be submitted to UHNM Quality and Safety Oversight Group.

Controlled drug incidents reported on Datix should be reviewed and actions agreed immediately by the ward or department manager with the support of the Medicines Safety Officer, Deputy Medication Safety Officer or the Controlled Drugs Accountable Officer. The incidents will be reviewed a minimum of monthly by the Medicines Safety Officer or Deputy to ensure that appropriate actions have been undertaken. The data will be used to produce the quarterly report for the controlled drugs local intelligence network.

7.2 External Monitoring

The Health Bill 2006 contains powers of entry and inspection to facilitate the inspection of CDs. In secondary care the Care Quality Commission will report specifically on any points of concern about CDs, including hospital pharmacy. They will do this as part of their routine assessment of whether a Trust is meeting core standards.

The CDAO and Shropshire and Staffordshire Local Intelligence Network will provide a forum for sharing information, intelligence and good practice with other Accountable Officers. A quarterly occurrence report will be submitted by the UHNM AO to the CDAO.

7.3 Policy Review

The policy will be reviewed in three years unless national guidance or legislation indicates an earlier review is required.

8. PANDEMIC AND MAJOR INCIDENT CONTINGENCY PLANS

Working practices during a pandemic or other significant incident may be disrupted and require urgent changes to be made to Controlled Drugs policies and procedures. If needed a local decision will be made by the Controlled Drugs Accountable Officer, UHNM Safe Medication Group and Pharmacy Department in collaboration with the relevant senior nursing or medical teams. A risk assessment will be completed if necessary, decisions can be made at pace as required and local SOPs will be provided to support staff. The group will be as flexible as possible within legislation to optimise safe and efficient working practices for patients and staff according to the situation. Advice will be sought from other professional bodies if required e.g. The Local Intelligence Network (LIN).

9. REFERENCES

- Misuse of Drugs Act, 1971
- Misuse of Drugs (safe custody) Regulations, 1973
- Misuse of Drugs Regulations, 1985
- Misuse of Drugs Regulations, 2001
- The Safe and Secure Handling of Medicines: A Team Approach. A revision of the Duthie Report (1988) led by the Hospital Pharmacists Group of the Royal Pharmaceutical Society of Great Britain March 2005
- Safer practice Notice 12, Ensuring Safer Practice with High Dose ampoules of Diamorphine and Morphine, National Patient Safety Agency (NPSA), May 2006
- Safer practice Notice 21, Ensuring Safer Practice with epidural injections and infusions, National Patient Safety Agency, March 2007
- Safer practice Notice 19, Promoting safer measurement and administration of oral medicines via oral and other enteral routes, National Patient Safety Agency, March 2007
- Rapid Response Report (NPSA/2008/RRR005), Reducing Errors with Opioid Medicines, National Patient Safety Agency 2008.
- Safer Management of CDs: Guidance on the Destruction and Disposal of CDs new role for accountable officers, Dept of Health, August 2007
- Safer Management of CDs: A guide to good practice in secondary care (England) Dept of Health/Royal Pharmaceutical Society of Great Britain October 2007
- Department of Health. Safer Management of Controlled Drugs: (1) Guidance on strengthened governance arrangements. Gateway reference: 6077. 9th March 2006.
- Department of Health. Safer Management of Controlled Drugs: Guidance on standard operating procedures for controlled drugs. Gateway reference: 7585. January 2007.
- Department of Health. Safer Management of Controlled Drugs: Changes to requirements for requisitions for the supply of Schedule 1, 2 and 3 Controlled Drugs (Final Guidance). Gateway reference: 8713. October 2007.

- Safer Management of CDs: changes to requirements for requisitions for the supply of Schedule 1, 2 and 3 CDs (Interim Guidance) Dept of Health 2007
- Safer Management of CDs: changes to record keeping requirements (Interim Guidance Dept of Health 2007
- Statutory Instrument 2006 No. 3148, The CDs (Supervision of Management and Use) Regulations 2006, HMSO
- Medicines Ethics and Practice. A Guide for Pharmacists. Royal Pharmaceutical Society of Great Britain. Issue 35. July 2011
- A Guide to good practice in the management of CDs in Primary Care (England). National Prescribing Centre (2004)
- Guidelines for administration of Medicines 2008, Nursing and Midwifery Council.
- Records Management: NHS Code of Practice, Department of Health 2006.
- Healthcare Commission. The best medicine – The management of medicines in acute and specialist trusts. January 2007.
- Care Quality Commission, The safer management of controlled drugs – 5th Annual Report (Aug 2012)
- Nursing and Midwifery Council, Standards for Medicines Management 2010.
- NICE Guideline 12th April 2016
- Human Medicines Regulations 2012
- Controlled Drugs (Supervision of Management and Use) Regulations 2013

Appendix 1: Storage and Safe Custody of Controlled Drugs – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-1 The Storage And Safe Custody Of Controlled Drugs

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all Controlled Drugs that are required for patients on a ward or department are stored in accordance with:

- The Misuse of Drugs Act (Safe Custody) Regulations 1971,
- The Safer Management of Controlled Drugs, A guide to good practice in secondary care (England) (DH2007)
- The Nursing and Midwifery Council Standards for Medicines management (2010)

Scope:

- This SOP applies to the storage of all schedule 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage regulations for specific schedule 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to the storage of controlled drugs on all wards and departments at UHNM
- Any ward, theatre or department that requires controlled drugs to be stored for administration to patients must have an appropriately appointed qualified person in charge responsible for their storage and use
- This SOP applies to all registered practitioners involved in the management of Controlled Drugs at UHNM.
- Appointed and Assigned Practitioners in charge of each ward or department have additional responsibilities as outlined in this SOP. Such practitioners must ensure that all staff working on the ward are aware of this SOP and have training records to support this.

Related Documents:

- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM06–SOP-2 Ordering of Controlled Drugs and Associated Stationary
- MM06–SOP-3 SOP Delivery and Receipt of Controlled Drugs from Pharmacy
- MM06–SOP-4 Administration of Controlled Drugs
- MM06–SOP-5 Management of Patients Own Controlled Drugs.
- MM06–SOP–6 Stock checking controlled drugs on wards and departments and the Management of Stock Discrepancies
- Trust SOP for the Storage of Medicines
- PHA 68 Pharmacy Procedure for returning controlled drugs from wards/departments to the Pharmacy Department.

No.	Instruction	Photograph / Diagram / Explanation
1	**CD Cupboards** CDs and associated stationary in wards/clinical areas must be stored in a locked controlled drugs cupboard which is firmly fixed to the wall at all times. The CD cupboard and associated locks and keys must conform to the specification of the Misuse of Drugs (Safe Custody) regulations 1971. Ward CD cupboards should conform to the British Standard reference BS2881 and must be approved by the Pharmacy Department. This is a minimum security standard and may not be sufficient for some areas: • Where large amounts of CDs are required to	 *If new cupboards are required it is essential that the correct type of cupboard is ordered to meet the needs of the ward. This is the responsibility of the ward manager. If in doubt advice should be sought from the Clinical Director of Pharmacy or the Trust Medication Safety Officer*

No.	Instruction	Photograph / Diagram / Explanation
	be stocked. • There is not a 24-hour staff presence • The CD cupboard is within easy access of non-clinical staff. In these circumstances a local risk assessment should be undertaken and consideration given to using a security cabinet that has been evaluated against the SOLD SECURE standard SS304 (Healthcare Commission. The best medicine – The management of medicines in acute and specialist trusts. January 2007).	
2	**Contents of CD Cupboards** Only controlled drugs and associated stationary may be stored in the controlled drugs cupboard. No other medicines, valuables or items except CDs and other medicines deemed 'controlled' by Trust Policy (e.g. concentrated potassium injection) should be stored in this cupboard. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.	*The NMC Standards for Medicines Management 2010 states "The cupboard must be dedicated to the storage of CDs. No other medicines or items may be stored in the CD cupboard"* *Schedule 2 and 3 Controlled Drugs must be stored in the Controlled Drugs cupboard excluding Gabapentin and Pregabalin.*
3	**Keys** The lock to the CD cupboard must not be common to any other lock. Controlled drugs cupboards must be kept locked at all times when not in use. Controlled drug cupboard keys must be kept separately to all other keys i.e. must not be kept on the same key ring as any other keys. The registered practitioner in charge must be responsible for the key(s) at all times. The registered practitioner in charge must be aware of every time the CD cupboard is opened and must be informed of the reasons when the keys are used and approve of their use. Ideally the registered practitioner in charge would be present every time the CD cupboard is opened but if this is not practical then there must be two registered practitioners present at all times the cupboard is open – one to carry out the required activity and one to check / witness the activity. If the registered practitioner in charge leaves the ward area then the CD keys should be handed over to the designated person in charge who	 *The NMC Standards for Medicines Management 2010 states that "The registrant in charge is responsible for the CD key and should know where it is at all times.* 1. *Key holding may be delegated to other suitable trained members of staff but the legal responsibility rests with the registrant in charge* 2. *The CD key should be returned to the registrant in charge immediately after use by another registrant member of staff* 3. *On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff* 

No.	Instruction	Photograph / Diagram / Explanation
	ideally would not be the same registered practitioner who holds the ward keys. The key(s) should not be handed over to medical staff except in an emergency. It may be handed to a registered pharmacist or pharmacy technician for the purpose of stock checking but there should always be a registered member of the ward/department staff present if they open the cupboard.	
4	**Wards and Departments not open 24 hours** The person in charge of a ward or department has responsibility to ensure that there is accountability for CD keys at all times. When a ward or department is closed overnight there must be a secure process in place for storage of the keys. This must include a record of registered staff who would have access to the keys overnight.	If a ward or department is closed overnight the matron for the area must agree with the LSMS and Accountable Officer for CDs that the arrangements for key security is appropriate.
5	**Storage Containers** All controlled drugs must be stored in the correct original outer packaging carrying the dispensing label from Pharmacy. Where possible ampoules will be issued in sealed containers. Where there are multiple containers of the same strength of drug only break the seal on one container at a time and use the contents of that box first to facilitate stock checks. It is not safe to have loose tablets/capsule/ampoules in the CD cupboard. Where a container may be damaged loose tablets/capsules/ampoules must be secured in a suitable container so that they are not accidentally lost or discarded and returned to Pharmacy as soon as possible – ideally within 24 hours.	• For return of CDs - see MM06 – SOP – 6 Stock checking controlled drugs on wards and departments and the Management of Stock Discrepancies
6	**High Strength Opiates** All higher strengths of injectable morphine, diamorphine and oxycodone (20mg and above) must be stored away from the lower strengths. All morphine, diamorphine and oxycodone injectable products over 20mg will be labelled with a red additional label stating 'CAUTION - high dose opioid'. (Safer Practice Notice Number 12 (May 2006)).	The (NPSA) issued a Safer Practice Notice in 2006 highlighting that the packaging of different strengths of diamorphine and morphine ampoules frequently look the same and that the outer carton and ampoule labelling are poorly differentiated. There is a high risk of selecting the wrong strength of opiate resulting in accidental overdose and potentially very serious consequences.
7	**Antidotes / reversal agents** The Appointed Practitioner in Charge (e.g. sister / Charge Nurse / Theatre Co-ordinator) must ensure that naloxone injection 400 micrograms in 1ml is available on all wards/clinical areas where	

No.	Instruction	Photograph / Diagram / Explanation
	opiates are administered and flumazenil injection 100micrograms in 1ml is available on all wards where midazolam is administered.	
8	**Fridges** Controlled drugs which require refrigeration must be stored in a Controlled Drugs refrigerator that conforms to the regulations in point 1 above. The same restrictions on access and keys apply. This must be a separate fridge to the ward fridge where non-controlled drugs are stored and temperatures must be monitored as for standard medicine fridges – See Trust SOP for Monitoring of Fridge Temperatures.	
9	**Epidurals** If any wards / departments stock ready-to-administer epidural injections or infusions containing opioids these must be stored in a separate CD cabinet which is used solely for epidural infusions. This is in line with NPSA recommendations. Patient Safety Alert 21, Safer practice with epidural injections and infusions. (March 2007)	
10	**Missing controlled drugs keys** If the CD keys are missing then urgent efforts should be made to retrieve the keys as speedily as possible, for example, by contacting staff who have just gone off duty. The matron should be informed if the keys cannot be found. A Datix adverse incident record must always be completed where CD keys cannot be accounted for. If, after extensive searching the keys cannot be found the registered practitioner in charge along with the matron must risk assess the security of the CDs: • They must consider if there is any possibility that the CD keys have been taken by a non-authorised person. If this is the case contact security and a senior pharmacist immediately and agree if locks are to be changed • The keys have accidentally gone home with a member of staff. If this has happened the ward/department manager should be contacted so that the spare keys can be used temporarily. If the spare keys are not available the ward will have to borrow doses of CDs from another ward or department until the keys are returned – see MM06 – SOP - 2 Ordering of Controlled Drugs and Associated Stationary	 *Contacting a senior pharmacist – ideally any breach in security with CDs should be escalated to the Accountable Officer for Controlled Drugs or a nominated deputy. In working hours the Pharmacy can be contacted on ext. 74501. Ask to speak with the Accountable Officer for Controlled Drugs, The Medication Safety Officer / Deputy or a member of the Pharmacy Senior Management team.* *Out of hours the on-call pharmacist can be contacted via switchboard and they will be able to escalate to a senior pharmacist as required.*

No.	Instruction	Photograph / Diagram / Explanation
	Do not break into cupboards without contacting Pharmacy for advice.	
11	**Defective CD Cupboards** If the ward or department's CD cupboard is found to be defective, this should be reported immediately to Estates for retained estate or Sodexo Helpdesk for the PFI build. The security of CDs should be maintained at all times. Contact the ward pharmacist for advice during pharmacy working hours or the on-call pharmacist outside of working hours. If it is necessary to re-locate CDs to alternative storage, this should be done on the advice of a pharmacist. On the arrival of Estates or Sodexo personnel, they should be escorted to the CD cupboard by a registered nurse/ midwife or ODP. He / she should remain with the Estates / Sodexo personnel whilst the CD cupboard is fixed. Immediately after the CD cupboard is fixed a stock check of all CDs should be performed. See SOP MM06 - 06 for stock checking controlled drugs on wards and departments. If the lock is replaced then this must be reported via Datix® and the Clinical Director of Pharmacy, Trust Medication Safety Officer or divisional lead pharmacist informed. Out of Hours the Site Manager and the on-call pharmacist should be informed. If the cupboard has been altered in any way during the repairs it may no longer conform to the regulations as specified in point 1 above. The cupboard must be risk assessed by a senior pharmacist in discussion with the Accountable Officer to establish if a new cupboard is required.	

Appendix 2: Ordering of Controlled Drugs and Associated Stationary – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-2 Ordering of Controlled Drugs and Associated Controlled Stationary

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all Controlled Drugs that are required for patients on a ward or department are stored in accordance with:

- The Misuse of Drugs Act (Safe Custody) Regulations 1971,
- The Safer Management of Controlled Drugs, A guide to good practice in secondary care (England) (DH2007)
- The Nursing and Midwifery Council Standards for Medicines management (2010)

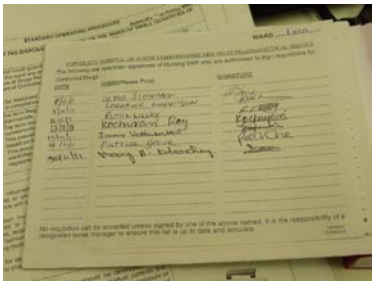
Scope:

- Controlled Drugs and associated stationary can only be obtained by ordering from the Pharmacy Department.
- This SOP applies to the ordering of all schedules 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage and ordering regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to the ordering of controlled drugs and associated stationary for all wards and departments at UHNM.
- Controlled stationary is used to describe CD order books and CD registers
- This SOP applies to all registered practitioners involved in the management of Controlled Drugs at UHNS.
- Appointed and Assigned Practitioners in charge of each ward or department have additional responsibilities as outlined in this SOP. Such practitioners must ensure that all staff working on the ward are aware of this SOP and have signed Appendix 1.
- Overall Responsibility for Controlled Drugs remains with the appointed practitioner in charge of a ward or department.
- Signatory lists must be held at ward level for the purposes of audit and / or inspection.

Related Documents:

- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM06–SOP-1 Storage and Safe Custody of Controlled Drugs
- MM06–SOP-3 Delivery and Receipt of Controlled Drugs from Pharmacy
- MM06–SOP-4 Administration of Controlled Drugs
- MM06–SOP-5 Management of Patients Own Controlled Drugs.
- MM06–SOP–6 Stock checking controlled drugs on wards and departments and the Management of Stock Discrepancies
- Trust SOP for the Storage of Medicines

No.	Instruction	Photograph / Diagram / Explanation
1	**Controlled Drug Stationary** • A controlled drug order book must be used for all requests for controlled drugs and associated stationary required for treatment of patients in wards and departments. • One controlled drug order book is issued to each ward or department authorised to order controlled drugs. • The controlled drug register is a legal document used to record all transactions involving CDs. Each ward or department will be issued with one for stock controlled drugs and one for patients' own CDs if applicable.	 Loss or theft of any controlled order or register must be reported immediately to the Accountable Officer or their nominated deputy.

No.	Instruction	Photograph / Diagram / Explanation
	• The CD Order book is used to order a replacement CD Order book or CD register. A new CD order book will only be issued as the old book finishes i.e. above requisition number 95 • When the CD order book/register is completed the ward/department manager must keep them in a locked cupboard on the ward for a minimum of two years from the date of the last recorded entry. They should be labelled with the time period covered to facilitate accessing records if required.	
2	**Staff approved to Order Controlled Drugs** • Controlled drugs may only be ordered by registered practitioners, specifically named and approved by the appointed practitioner in charge of a ward or department. Approved registered practitioners include registered nurses/midwives/ODPs and approved radiographers who have received local training. Locum and/or agency staff are **not** authorised to order controlled drugs • The approved list of registered practitioners must be attached to the front cover of the controlled drug order book. All staff authorised to order controlled drugs must provide a sample signature on the sheet in the order book to enable Pharmacy staff to verify their authority to make the request. • The appointed practitioner in charge must ensure that the list of staff authorised to order controlled drugs is accurate and up-to-date. In addition he / she must ensure that all staff signing the sheet are authorised to do so. The practitioner in charge must check the list of names and signatures and sign and date the list at the bottom of the page at least every 3 months	
3	**Completing the Controlled Drug Order** • Each order request must be on a separate, duplicated, numbered page. Consecutive order numbers should be used. • The order book uses carbon paper to duplicate the order. Staff must ensure that it is in the correct place before writing out the order so that the order is clear on both the top copy and the bottom copy. • Ensure that all details are completed on the order. The order should state: o specific ward or department o drug name and form o strength of the preparation and ampoule size where relevant o quantity required	Quantity: • The quantity for stock items (see point 4) should be as stated on the stock list. • For non-stock items the quantity ordered should be sufficient for the anticipated requirements of the patient during their stay. Generally the quantity should be in original packs or whole strips of tablets to avoid loose tablets/injections in containers. • For non- stock controlled drugs, no more than one week's supply should be requested or supplied.

No.	Instruction	Photograph / Diagram / Explanation
	• The order must be signed and dated by the authorised, registered practitioner making the order. • Failure to enter all details will result in the CD not being dispensed	
4	**Controlled Drug Stock Lists** • The registered practitioner in charge must ensure that adequate controlled drugs are available on the ward / department area for their patients' anticipated requirements. This includes ensuring that adequate supplies are available on the ward to cover weekends and /or Bank Holidays when CDs cannot be routinely ordered. • Each ward or department will have an agreed list of controlled drugs that are routinely used on the ward/department. This list will be attached to the back cover of the controlled drug order book or the inside of the cover for the ward CD box. Controlled drugs included in this list will have agreed order quantities. • Any controlled drugs included in the stock list can be ordered without any further clinical checks of individual prescriptions by a pharmacist. • If controlled drugs are not on the agreed stock list the prescription will need a clinical check by a pharmacist prior to issue of the controlled drug. This is to ensure that the prescribed controlled drug is safe and appropriate for the patient. o Ideally the order for a non-stock controlled drug should be clinically checked by the ward pharmacist before sending the controlled drug order to Pharmacy. The pharmacist will check the prescription chart and sign the CD order if the request is considered clinically appropriate. o If the pharmacist is not available on the ward, the prescription chart must be sent to the dispensary so that the pharmacist in the dispensary can clinically check the prescription o The pharmacist must check that the quantity ordered is sufficient for no more than one week. They should ensure that the quantity ordered can be dispensed as an original pack or a single strip of tablets/capsules or individual patches whichever is the lowest quantity. o Each ward will have allocated days when they can order stock CDs. It is essential that if staff are aware that there is a high level of use of a particular CD that more than the minimum stock level is requested.	The controlled drug stock list for a ward or department will be agreed between the ward/department registered practitioner in charge and the ward pharmacist. The agreed list of controlled drugs will include those drugs that are routinely used in a ward or department and the staff have knowledge and experience with administration and monitoring of these drugs.

No.	Instruction	Photograph / Diagram / Explanation
5	**Send the Order to Pharmacy** • Controlled drugs can only be ordered from Pharmacy during Pharmacy opening hours unless there is a clinical situation that cannot be avoided. • Once the controlled drug order is accurately completed, the book must be placed inside the ward controlled drug box and sent to Pharmacy. This can be collected from the ward by the Pharmacy porter at allocated times or sent with a member of the ward staff.	Occasionally, it may be necessary for Pharmacy staff to alter the quantity ordered to that of a whole pack or blister strip (e.g. if limited stocks available; part packs are routinely ordered). If this happens, the quantity will be altered, signed and dated by designated pharmacy staff on both the white and pink copies of the order book.
6	**Transfer of Stock Controlled Drugs** Stock controlled drugs can only be obtained from Pharmacy. It is not permitted to transfer stock controlled drugs from one ward or department to another. • If a controlled drug is ordered exclusively for administration to one patient and the patient is subsequently transferred to another ward the controlled drug must be returned to Pharmacy as per MM06 - 06 SOP for Stock Checking Controlled Drugs on Wards and Departments. The receiving ward must order the controlled drug from Pharmacy for use on that ward. • Outside Pharmacy opening hours if a patient is prescribed a controlled drug but it is not stocked on the ward the nurse in charge should bleep the on-call pharmacist for advice. The pharmacist will establish if the patient may come to harm as a result of a missed dose of the controlled drug and what the options are for obtaining the drug e.g. if patient has their own supply. • In an emergency, outside Pharmacy opening hours, the pharmacist may authorise the administration of a dose of a CD from another ward. If this needs to happen the following process must take place: o A member of authorised, registered staff should take the prescription to the ward that has the CD in stock. o The registered staff on the ward with the stock should remove the required dose only from the cupboard and sign it out of the register to the patient – NOT the receiving ward. The registrant from the requesting ward and the registrant from the issuing ward should both sign the CD register. o Both registrants – one from the issuing ward and one from the receiving ward should attend the patient and witness the administration of the CD. o Both registrants should sign the	. Stock CDs must never be transferred from one ward register to another wards' register as this would constitute supply and this is illegal for nurses/midwives/ODPs to supply. If signing a CD out of the register to administer a dose to a patient on another ward the patient's name should be recorded and noted what ward they are on.

No.	Instruction	Photograph / Diagram / Explanation
	prescription chart to witness the administration of the CD. o It is good practice to record in the patients notes that the dose of CD needed to be obtained from another ward and a note left to prompt the ordering of the CD from Pharmacy when it is open.	

Appendix 3: Record Keeping and Entries in Controlled Drug Record Books / Registers

Within the Pharmacy Directorate records must be kept of all controlled drugs received (e.g. from wholesalers, manufacturers, wards) or issued (e.g. to wards, departments, external hospitals). This is in accordance with local SOPs.

On wards and departments details of each controlled drug product obtained and administered must be recorded in the CD record book / register. Entries in the register must be made at the time of receipt or administration of controlled drugs - see SOPs for receipt/administration of CDs. It is essential that all order books and CD registers are in good condition and that there are no loose or missing pages. If a register is in a poor state of repair a new register must be ordered.

All entries (including balance transfers) in the CD record book / register must be signed by two registered nurses / midwifes / ODPs . Exceptionally, the second entry can be by another practitioner (e.g. doctor or pharmacist) provided that they have witnessed the administration of the drug. Radiographers are also permitted to sign / countersign receipt and balance check entries in CD registers according to local SOPs.

In CD record book / register a separate page should be used for each controlled drug and each page must be clearly headed to indicate the drug, form, strength and ampoule size to which it refers.

All entries should be made in indelible black or blue ink and must be clear and unambiguous.

<u>Management of errors in the Controlled Drugs register</u>
If an error is made in the CD record book it should not be corrected or defaced. Correction fluid is not permitted. The entry and error should be clear and transparent to an auditor and be managed in one of the following ways:

- If an error is made it may be, **crossed out - one** clear **line** through it, signed and dated with an explanation in the form of a footnote.
- Enclose the error with brackets. A note should be made in the margin at the bottom of the page acknowledging the error and this should be signed and dated. The correct entry if appropriate for that page should be made on the line below.

When a page in the CD register is full and a continued record is needed, use consecutive pages where possible.

- At the bottom of the old page, write the new page number in the “carried over to page…” section.
- On the first line of the new page, write ‘Balanced transferred from page ……..’ and sign and date the entry. Enter the balance after it has been confirmed as correct against the actual stock. As with any register entries, this entry and the balance check should be signed by a witness.

When selecting a new page in the register, it is good practice to leave a reasonably sized sections for preparations frequently used so that where possible the records for a particular preparation run on consecutive pages.

When a new page is started, the index at the front of the register should be updated.

When a new CD record book / register has to be started the balance of the CDs in stock on the ward should be transferred from the old CD record book / register and written into the new record Book / register promptly by a registered nurse / midwife or authorised member of staff e.g. pharmacist or pharmacy technician.

- The controlled drug stock should be signed out of the old register as ‘Transferred to page …. of new register’ and signed, dated and signed as witnessed by a second practitioner.
- The stock should be signed into the new register as ‘Transferred from old register page ……,’ the balance checked against the actual stock recorded and signed, dated and witnessed by a second practitioner.

It is good practice to transfer all balances when a new controlled drugs register is started on a ward/clinical area.

When checking ward CD stock balances pharmacists must record that the balance has been checked under each drug entry.

Appendix 4: Delivery and Receipt of Controlled Drugs

Standard Operating Procedure (SOP)

MM06-SOP-3 The Delivery And Receipt Of Controlled Drugs From Pharmacy

V4 December 2020

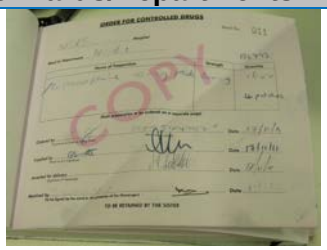
University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all Controlled Drugs that are required for patients on wards and departments are delivered and received from pharmacy in accordance with the Misuse of Drugs Act (Safe Custody) Regulations 1973, the Safer Management of Controlled Drugs, a guide to good practice in secondary care (England) (DH2007), and the Nursing and Midwifery Council Standards for Medicines management (2010)

Scope:
- This SOP applies to the delivery and receipt of all schedule 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage, ordering and delivery regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to the delivery of controlled drugs from Pharmacy to all wards and departments at UHNM.
- This SOP applies to all registered practitioners involved in the management of Controlled Drugs at UHNM.
- Appointed and Assigned Practitioners in charge of each ward or department have additional responsibilities as outlined in this SOP. Such practitioners must ensure that all staff working on the ward are aware of this SOP and have signed Appendix 1.
- Overall Responsibility for Controlled Drugs remains with the appointed practitioner in charge of a ward or department.
- Signatory lists must be held at ward level for the purposes of audit and / or inspection.
- Controlled drugs must not be delivered to patients or other units by commercial taxi. Any exception to this should be considered to be an adverse incident and a Datix completed accordingly with a documented risk assessment.

Related Documents:
- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM06-SOP-6 Stock Checking Controlled Drugs on Wards and Departments
- MM06–SOP-1 Storage and Safe Custody of Controlled Drugs

No.	Instruction	Photograph / Diagram / Explanation
	Delivery general principles	
1	Controlled drugs can be transferred or conveyed in a number of ways within and outside the hospital and are likely to involve the following situations: • Collection by ward staff or porters from the pharmacy • Delivery by pharmacy staff to wards, departments and theatres • Collection by patient or representative for out-patient items only • Delivery by non-pharmacy porter/driver	Note it is **NOT** permitted to send controlled drugs in the UHNM Pneumatic Tube system.
2	Any appropriate UHNM or Sodexo member of staff may undertake the role of 'messenger' to collect and deliver controlled drugs. Messengers must always wear current UHNS/Sodexo identification name badge according to Trust Policy.	

No.	Instruction	Photograph / Diagram / Explanation
3	The general principles of delivery and transfer are: • CDs should be transferred in a secure, locked or sealed, tamper-evident container • The system must be fully auditable and explicit to who has custody of the CDs at any point in time. At each point where a CD moves from the authorised possession of one person to another, a signature for receipt should be obtained. • Pneumatic tubes cannot be used to transport CDs.	
4	In most cases the messenger will be the Sodexo or Pharmacy porters but the procedure will be the same whoever the messenger is.	
5	Controlled drugs should NOT be delivered by commercial taxi out-of-hours. Any exception to this should be considered to be an adverse incident and a Datix completed accordingly. Documented risk assessment undertaken.	
Delivery of Stock CDs from Pharmacy Department to Wards/Departments		
6	**Collection from Pharmacy:** • The messenger must check that the bag or box containing the CDs is sealed and that the seal number corresponds to the number recorded on the CD order book and Pharmacy CD Delivery Receipt Form. (see appendix 1) • The messenger must check that the quantity on the order book corresponds with the quantity stated on the Pharmacy CD Delivery Receipt Form. • The messenger must sign and date the 'accepted for delivery' section in the CDs order book and the Pharmacy CD Delivery Receipt Form. • The yellow copy of the form remains in pharmacy and the white copy accompanies the CD with the porter and will be returned to Pharmacy to be reconciled with the yellow copy once the ward have signed for receipt. • If the messenger is a member of ward staff the Pharmacy CD Delivery Receipt Form will be retained in Pharmacy and reconciled with the corresponding yellow copy. • The white copy of the CD order must then be retained by the pharmacy for 2 years	
7	**Delivery to Wards and Departments** The messenger will deliver CDs in a sealed box or bag to the ward. When the messenger arrives the following MUST be carried out immediately. NB it is not appropriate to make the porter wait or come back later as they have other deliveries to complete and it would significantly delay prescriptions going to patients.	

No.	Instruction	Photograph / Diagram / Explanation
	• A registered nurse/midwife/ODP/radiographer must receive the CDs from the messenger. • The registered nurse/midwife/ODP/radiographer must check the box/bag is sealed and that the seal number on the box/bag is the same as the number stated on the top of the page of the numbered order in the ward CD order book and Pharmacy CD Delivery Receipt Form. • When satisfied the registered person must sign the numbered order page (pink sheet) and the Pharmacy CD Delivery Receipt Form in the "received by" section. This must be done in the presence of the messenger. In some cases the messenger and the person accepting delivery may be the same person (e.g. a registered nurse collects the CDs from pharmacy and transports to ward). • The Pharmacy porter will return the Pharmacy CD Delivery Receipt Form back to Pharmacy where it will be reconciled with its corresponding yellow copy	
8	**Receipt on Ward/Department** • The registered person receiving the CDs is responsible for their safe custody until the CDs are securely stored in the locked CD cupboard. • Immediately after delivery, two registered people must check the contents of the sealed box or bag against the order – **this includes checking the number ordered & received.** Both nurses/midwives/ODPs/radiographers must sign the pink copy of the CD Order Book**.** • The CDs must be entered into the ward CD register by the same two registered people. Both must sign the number received as part of the entry and both sign their names in the register. It is good practice to enter receipt of controlled drugs in red ink to differentiate from administration entries. • the CD register entry should show the: o Words 'received from pharmacy' o Date of receipt o Quantity received in words and figures o Order / Requisition number o Signatures of the practitioner making the entry and the witness o New balance - the quantity received should be added to the balance already recorded • The new balance should be checked against the contents of the cupboard by both	***When entering CDs into the register take care to select the correct page for the drug form and strength, particularly when there is more than one strength available.***

No.	Instruction	Photograph / Diagram / Explanation
	registered nurses/midwives/ODPs/radiographers to ensure the balance in the record book/register matches that in the cupboard. • When completed the CD cupboard must be locked. NB – if there is only one registered nurse or midwife available on the ward to accept CDs then a student nurse/midwife may be the second signature.	
9	**Discrepancy with an Order** Any discrepancies in the order must be reported immediately to the Senior Pharmacy Technician on duty in the Pharmacy dispensary on ext 74500 (Royal Stoke) or 4463 (County) and the discrepancy must be investigated. In the event that the Pharmacy is closed at the time of receipt the on-call pharmacist must be contacted immediately to investigate. The procedure for investigating discrepancies with controlled drugs outlined in MM06 - 06 must be followed.	
Receipt and Delivery of Discharge Prescriptions (TTOs) from Pharmacy to Wards/Departments		
10	Discharge prescriptions containing CDs are delivered in a sealed Pharmacy bag. It is accompanied by the Pharmacy Delivery Receipt Form. • When CDs on TTOs are dispensed in Pharmacy the checking Pharmacist will seal the bag, record the seal number and sign the form to confirm the contents of the bag. • The Pharmacy porters or person collecting will check that the number on the seal corresponds to the one recorded on the form and sign for collection. The top white copy is removed and goes with the bag. The yellow copy remains in the file to ensure it can be reconciled once the process is complete. • When the porter/messenger arrives on the ward the registered person will check the seal number on the bag corresponds to the seal number on the delivery form and sign the form • If the patient is not leaving the hospital immediately the CDs must be stored in the CD cupboard. The TTOs should be segregated from the ward CD stock, clearly marked and remain in a TTO bag. The CD TTOs should be recorded in the 'Patient's Own Drugs' section of the controlled drugs record book/register by two registered nurses/midwives.	 *Refer to SOP for the Management of Patients Own Controlled Drugs Including TTOs*

No.	Instruction	Photograph / Diagram / Explanation
Collection of CD prescriptions from Pharmacy by patients/relatives		
11	• Outpatient prescriptions for controlled drugs may be presented to the Pharmacy at County Hospital. • When issuing the CD to an outpatient the Pharmacy team will use the Pharmacy CD receipt form but will not place it in a sealed bag so will not record the seal number – they will record N/A for not applicable. • When handing out the prescription to the patient or their representative the Pharmacy staff will ask them if they have any identification (e.g. driving licence/bank card) and record this on the bottom of the delivery receipt form. The patient or their representative will be asked to sign the delivery receipt form to confirm that they have received the controlled drug.	*It is a legal requirement for Pharmacy staff to record in the CD register who has collected a controlled drug. This is facilitated by recording the details of the patient or their representative on the delivery receipt form which unique number is recorded in the register. The delivery receipt form is retained in pharmacy for 2 years.*

Appendix 1 - Pharmacy CD Delivery Receipt Form

Pharmacy Department

RSUH ☐

County ☐

Ref no:	Ward:/Outpatient clinic

Controlled drug delivery receipt form

Section 1: Content of CD Bag/Box:
Patient unit number if TTO:/Outpatient
Section 2: n/a if outpatient **Seal No:**
Section 3 **Content of bag checked and sealed by:** **Name:** **Signature:** **Date:** **Time:**
Section 4 **Porter, Healthcare worker or patient/patient representative collected by:** **Name:** **Signature:** **Date:** **Time:** *(CDs can be collected by Registered Nurse, Healthcare Assistant, Theatre Porter)*
Section 5 **For CD bags delivered to ward by pharmacy porter** ***(Qualified nurses and Operating Department Practitioners only to receive controlled drugs)*** "I accept this bag of controlled drugs and undertake and ensure that the contents are entered into the ward controlled drugs register and stored according to Trust policy" **Name:** **Signature:** **Date:** **Time:**
Section 6 **For all CDs collected from pharmacy by a healthcare worker or patient:** Evidence of ID (i.e. Trust ID badge) (please tick) ☐ Signature of member of pharmacy staff:

Appendix 5: Prescription of Controlled Drugs

Extra legal requirements apply for the prescribing of controlled drugs. These requirements apply in hospital for the writing of discharge medication / TTOs and out-patient prescriptions.

Controlled Drugs may only be prescribed by legally authorised practitioners. Non-medical prescribers must be authorised by the Trust before they can prescribe.

From 23rd April 2012 new legislation introduced a number of changes to the professional use of controlled drugs by pharmacists and nurses came into force. Independent pharmacist prescribers and independent nurse prescribers are now enabled to prescribe, administer and give directions for the administration of schedule 2, 3, 4 and 5 controlled drugs. Neither independent pharmacist or nurse prescribers will be able to prescribe diamorphine, dipipanone or cocaine for treating addiction but may prescribe these items for treating organic disease or injury.
In addition, the changes will mean that any person acting in accordance with the written directions of a pharmacist independent prescriber, nurse independent prescribers, doctor, dentist, or supplementary prescriber (working in accordance with a clinical management plan), will be able to compound (mix) schedule 2, 3, 4 or 5 controlled drugs.

All prescriptions for controlled drugs should be written in indelible ink. A computer-written prescription is acceptable (i.e. prescriptions generated by MedOncology® and electronic prescription and administration, however, the prescriber's signature **must** be handwritten. Currently the MediSec® electronic discharge summary **cannot** be used as a valid prescription for Schedule 2 and 3 controlled drugs.

Pharmacists must be confident that the prescriber is genuine and should ensure as far as is reasonably practical that the prescription is valid and the items are not being prescribed for the purpose of misuse. In order to support the Pharmacy department in this role it is essential that prescribers print their surname and bleep number alongside their signature.

Prescriptions for controlled drugs are valid for 28 days after the date the prescription was signed or the indicated start date by the prescriber. This also applies to schedule 4 controlled drugs e.g. diazepam/zopiclone. Up to a maximum 30 days' supply should be issued at any one time for schedule 2, 3, and 4 controlled drugs.

Prescribers cannot prescribe or administer schedule 2, 3, or 4 controlled drugs for themselves, their family or their friends unless the relative or friend is a registered patient under their professional care.

Clinical considerations for prescribing Controlled Drugs

- When prescribing controlled drugs prescribers must give consideration to:
  - ✓ The benefits of the controlled drug for the patient
  - ✓ The risks of prescribing the controlled drug including overdose/respiratory depression and dependency and whether monitoring is required.
  - ✓ Patient's current clinical needs and, if appropriate, adjust the dose to balance effect versus potential side effects.
  - ✓ Suitability of the drug in opioid naïve patients and consider lower starting dose to balance the effect versus potential side effects.
  - ✓ Potential interactions with other medication that may potentiate the effect of the opiate e.g. gabapentin, benzodiazepines and amitriptyline. Consider whether further monitoring is required .
  - ✓ Check the UHNM guidelines for prescribing opiates in the relevant condition
  - ✓ Dose conversions when switching between formulations or different opiates. If in doubt consult your ward pharmacist, check the BNF or contact Medicines Information on extension 74538. Out of hours advice can be obtained from the on-call pharmacist.
- When Initiating Controlled Drugs:
  - ✓ Document clearly the indication and regimen for the CDs in the patient's medical record.

- ✓ Discuss with the patient and/or their family and explain if this is a short term treatment (e.g. analgesia after surgery) or if it is likely to be continued (e.g. chronic pain/end of life). Provide clear information to patients and caregivers regarding potential side effects, how to identify opioid toxicity and when to seek medical attention.

In-patient Prescriptions

- Controlled Drugs must be prescribed in the same way as any other medicine on the UHNM in-patient medicines chart (see Policy MM03). The anaesthetic record sheet can also be used for patients being administered controlled drugs during a surgical procedure in theatres and / or recovery.
- The written requirements for controlled drugs on these charts are the same as for other medicines i.e. drug name and form; route; dose and frequency; start date; finish date (where appropriate); signature of the prescriber (plus name in block capitals for identification purposes). In addition the patient's name, unit number and allergy status should clearly be written on the prescription chart.
- If prescribing when required opiates document clear instructions on when to take, dosage and maximum dose.
- If prescribing the same opiate by different routes each must be prescribed separately with clear instruction on when each should be used. Never write PO/IV (oral or IV) as the dose for oral is likely to be different than the dose for IV.

Discharge and Out-Patient Prescriptions

- Prescriptions for CDs for patients who are going home (i.e. discharge medicines) should be written either on the pre-printed CD proforma on the back of 'Drugs to take home' section of the UHNM In-patient prescription chart or other UHNM approved discharge prescription forms. Out-patient prescriptions should be prescribed on the UHNM Out-patient prescription form. Discharge prescriptions are dispensed at the UHNM dispensaries at both the RSUH and County sites. Out-patient prescriptions are dispensed at the County Hospital dispensary or at the dedicated out-patient Lloydspharmacy® dispensary.
- When prescribing controlled drugs for discharge the prescriber should establish if the patient has an existing supply of suitable CDs either at home or stored on the ward CD cupboard. It is not safe to stockpile CDs in a patient's home and the prescribers and pharmacists have a duty of care to ensure that the patient does not receive excessive quantities.
- It is against the law for pharmacy to dispense a prescription that does not comply with handwriting regulations. Currently UHNM does not have an approved electronic prescribing system for discharge prescriptions. The Medisec system is set up as a letter and not a prescribing system. Discharge prescriptions for CDs must be handwritten in the prescriber's handwriting. Current legislation states that the following information is required for CD prescriptions:
  - ✓ Name and address of the patient (or ward and unit number if they are an in-patient)
  - ✓ Age and weight of patient (if under 12 years)
  - ✓ Generic name of the controlled drug (or brand if appropriate)
  - ✓ The form of the preparation (e.g. oral solution, modified release tablets, patch) **must** be included irrespective of whether it is implicit in the proprietary name or of whether only one form is available
  - ✓ The strength of the preparation
  - ✓ Dose, route and frequency
  - ✓ Total quantity in words and figures of the volume or the number of dose units to be supplied
  - ✓ The words 'For Dental Treatment Only' if issued by a dentist
  - ✓ Signature of the prescriber including name in block capitals and bleep number
  - ✓ Date

An example of an acceptable complete CD prescription:

John Smith WX36792V
11 Hospital Lane
Stoke-on-Trent ST4 9AZ DOB: 16/08/1958
Morphine Sulphate Tablets M/R 50mg 12 hourly for 30 days
Please supply
30mg x 60 (sixty) tablets
10mg x 120 (one hundred and twenty) tablets
John D Jones Dr J Jones (SHO) – Bleep 999
20 January 2014

The prescription requirements for dose, form, strength and total quantity in both words and figures do not apply to Schedule 4 and 5 CDs. Morphine sulphate 10mg/5ml solution is a schedule 5 CD and is not subject to handwriting restrictions

Outpatient prescriptions are retained for a minimum of 2 years.

Pharmacist amendments to prescriptions
All the above requirements for discharge and out-patient prescriptions must be fulfilled for a prescription for a controlled drug(s) to be dispensed. However, pharmacists may supply against and amend prescriptions (in accordance with Pharmacy SOPs) with minor typographical errors e.g. spelling mistakes or where only the total quantity in either words or figures (but not both) is specified. Any amendments must be signed, dated and made in indelible black or blue ink.

Appendix 6: Administration of Controlled Drugs – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-4 Administration of Controlled Drugs

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all schedule 2 and 3 Controlled Drugs, required for treatment of patients on wards or departments at UHNS, are administered in accordance with the Misuse of Drugs Act (Safe Custody) Regulations 1971, the Safer Management of Controlled Drugs, a guide to good practice in secondary care (England) (DH2007), and the Nursing and Midwifery Council Standards for Medicines management (2010)

Scope:
- This SOP applies to the administration of all schedule 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage, ordering and delivery regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to all registered practitioners involved in administration of controlled drugs.
- This SOP provides a framework for the additional legal requirements for administration of controlled drugs. This SOP should be used in conjunction with the procedure outlined for administration of medicines in the SOP for Administration of Medicines – see MM03
- The Trust has adopted the Royal Marsden Manual of Clinical Nursing Procedures (9th edition) (access via Trust Intranet) for procedures involved in administration of medicines. All staff who administers medicines are responsible for ensuring knowledge and compliance with these procedures.
- UHNM Bedside Clinical Partnership Guidelines must be followed where in place.
- For administration of an epidural or patient controlled analgesia (PCA) local standard operating procedures are in place. Only registered practitioners who have been trained and deemed competent in these specific SOPs may administer an epidural or PCA.

Related Documents:
- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM06 – SOP - 1 Storage and Safe Custody of Controlled Drugs
- MM06 – SOP - 2 Ordering of Controlled Drugs and Associated Stationary
- MM06 – SOP - 3 SOP Delivery and Receipt of Controlled Drugs from Pharmacy
- MM06 – SOP - 5 Management of Patients Own Controlled Drugs.
- MM06 – SOP – 6 Stock checking controlled drugs on wards and departments and the Management of Stock Discrepancies
- MM03 - SOP for the Administration of Medicines
- MM03 - SOP for Prescription of Medicines to Inpatients where electronic prescribing is not used.

No.	Instruction	Photograph / Diagram / Explanation
1	**Required Checks before Administration of any Medication to a Patient -** See MM03 - SOP for the Administration of Medicines and MM03 - SOP for Prescription of Medicines to Inpatients where electronic prescribing is not used **Check the Prescription is Clear and Legal** • Confirm that the prescription is for the correct patient • Check that allergy section has been completed. Confirm that the patient does not have an allergy to prescribed medication. • Confirm that the age and weight of any patient younger than 16 years is documented. • Check that the weight is documented if the dose	Medication must not be administered to a patient if a prescription is illegible, ambiguous, incorrect, incomplete or there is any doubt about its clinical appropriateness and safety. **Use common sense** – does the dose seem high or unusual e.g. If it is a high strength opiate that is prescribed but the patient is opiate naïve. If in any doubt challenge the prescription with the prescriber. • Inpatients – if a medicine is needed via more than one route the two routes must

No.	Instruction	Photograph / Diagram / Explanation
	of any prescribed medicine is calculated on weight. • The prescription must specify the drug to be administered using its generic or brand name where appropriate, the form, strength, dose, route and times for administration. • Ensure that each prescription is signed and dated by a prescriber. **Check the prescription is Safe for the patient** • Confirm that the dosage, method of administration, route and timing of administration is appropriate to the patient's condition. • The administering practitioner must have knowledge of the medicine to be administered and be familiar with its actions and potential side effects. • Ensure that any dose calculations are checked by a second qualified person e.g. nurse, pharmacist, doctor, ODP. • Check all sections of the prescription chart, including the once only section, regular, PRN, patient controlled analgesia (PCA) section, parenteral infusion pages and separate epidural prescription to ensure that the dose has not been duplicated.	be prescribed with clear instructions regarding which route should be used, dose and the times. Prescriptions written as "PO / IV" are not permitted and should be referred back to the prescriber because the dose required for oral is likely to be different than the dose for IV.
2	**Checking Administration** UHNM requires a full second check for the administration of Controlled Drugs from preparation to bedside as follows: • Two practitioners must check the administration of Controlled Drugs. One of the practitioners must be a registered nurse / midwife / ODP. The second practitioner may be a 3rd year student nurse who has been assessed as competent**.*** • One practitioner will take the lead and administer the medicine and the other must act as a witness to the procedure. The witness must be present at all stages of the process and must independently check: o The identity of the patient, o The prescription as per stage 1 above. o The medicine being administered. o The expiry date. • Both practitioners must observe: o The patient taking an oral formulation, the patch being applied or the injection being administered. o For infusions, the witness must see the infusion set up and administration commence ensuring that the rate is correct according to the prescription chart. o Any surplus drug or used patches being	The Standards for Medicines Management NMC 2010 – Section 10 controlled drugs states: "All entries must be signed by two registrants, or one registrant and one student nurse or midwife (for administration only). Exceptionally, the second signature can be by another practitioner (for example, doctor or pharmacist) provided that they have witnessed the administration of the drug" ***Note – for paediatrics two registered nurses must witness and sign for administration. If a student nurse is involved they can be a 3rd checker.***

No.	Instruction	Photograph / Diagram / Explanation
	discarded appropriately. o The entry in the CD record book / register.	
3	**Obtaining and preparing the Controlled Drug** • Obtain keys to controlled drugs cupboard, open the cupboard and remove the required drug. The cupboard must be closed and locked immediately afterwards. The CDs must be supervised at all times. • Check the formulation, strength, route and expiry date of the selected preparation and confirm it corresponds with the prescription. • Remove the exact quantity of medication required to fulfil the prescription: • **Tablets, Capsules and Patches** Place the exact number of tablets, capsules or patches into a medicine tot or a cardboard injection tray to transport to the patient. • **Liquids** Liquid preparations intended for oral or enteral administration must be measured using an appropriately sized purple oral syringe for the dose required. The correct purple bottle adapters must be used in the bottle to facilitate accurate measurement using oral syringes. The bung will be supplied by pharmacy with each new bottle. • **Intravenous, intramuscular and sub-cutaneous injections/infusions** The exact dose to be administered should be drawn up into an appropriate size syringe for parenteral administration to take to the patient. Any surplus drug should be destroyed by expelling into a yellow sharps bin for incineration. e.g. If 5mg is required from a 10mg ampoule only 5mg should be drawn up to administer the dose and the remainder should be destroyed.	Do **not** leave the CD cupboard open and unattended. Do **not** leave CDs unattended after removing from cupboard. *Good practice: It is good practice to count medication inside a tray to minimise the risk of small losses of single tablets / capsules.* **Measuring Oral Liquids**: Each bottle MUST have a purple bottle adaptor inserted into the neck of the bottle when first opened (The purple syringes for oral administration are compatible with the purple bottle adaptors). The same purple adaptor MUST stay in the bottle until empty. The lid of the bottle MUST be replaced when not in use (the lid will still fit even with the purple bottle adaptor in). 
4	**Administer the correct dose to the Patient** • The controlled drug should be administered to the patient in accordance with the specific procedure stated in the Royal Marsden Manual of Clinical Procedures 9th Edition for the prescribed route.	

No.	Instruction	Photograph / Diagram / Explanation
5	**Documentation in the administration section of the prescription and register** • Record the exact time and dose administered in the relevant section of the patient's prescription. Both registrants must sign the record. Records / entries must be legible and in black ink. • Record the administration in the ward Controlled Drug register: o Select the correct page for the drug, formulation and strength and document in the appropriate column: ▪ Date and time of administration ▪ Name of the patient ▪ Dose administered and the amount discarded where relevant. ▪ Deduct the quantity used from the balance in the register and enter the new balance in the running balance column. Reconcile the stated balance with the remaining stock. ▪ If the balance is zero or nil it should be documented as 'zero' or 'nil' rather than 0. ▪ Signature of both practitioners once the drug has actually been administered to the patient.	 *The entry in the CD register must state both the dose given and the amount wasted in the 'amount given' column. Both registrants must sign the whole entry.* *When reaching the end of a bottle of liquid the actual stock balance must be fully checked against the register balance. Any discrepancies must be managed according to Appendix 8 – MSOP for stock checking.*
6	**Incorrect Balance in the register** • If the balance remaining in the cupboard does not correspond exactly to the balance stated in the register the registered practitioners involved must investigate immediately in accordance with MM06 – SOP – 6 Stock checking Controlled Drugs on Wards and Departments.	
7	**Incorrect Entries in the Register** o If an error is made during the entry in the Controlled Drug register, corrections must be managed in one of the following two ways: o Enclose the error with brackets and write a note at the foot of the page acknowledging the error, signed and dated by both practitioners. o The incorrect entry may be, **crossed out - one** clear **line** through it, signed and dated with an explanation in the footnote. The correct entry should be made on the line below the original entry.	
8	**Monitoring of Patient** o When strong opioids are given to opiate-naïve patients, i.e. patients who have not previously been taking opiates, additional observations must be made for the first hour to monitor for	Monitor patient using NEWS chart Guidance for monitoring of patients on

No.	Instruction	Photograph / Diagram / Explanation
	respiratory depression. This should be in accordance with clinical advice or treatment guidelines specified in the UHNM Bedside Clinical Partnership Clinical Guidelines. o When patients' medication is changed to a strong opiate or their existing dosage is being increased they must be monitored as above. o Care with patches is required as opiate strength may be higher than expected, check in BNF. For example Fentanyl Patch '25' is equivalent to 90 mg morphine. It may take several hours to take full effect which will require extra monitoring.	controlled drugs can be found in the Surgical Guidelines under Opioids Monitoring and Adjustment.
9	**Administration of Naloxone** Patients administered opiates must be monitored for: • Depressed level of consciousness • Respiratory Rate If a patient is noted to have respiratory depression and naloxone is indicated check the UHNM Surgical Guidelines for naloxone. **Caution to ensure the correct dose is administered.**	*In October 2015 a NHS Patient Safety Alert highlighted:* *"Use of naloxone in patients where it is not indicated, or in larger than recommended doses, can cause a rapid reversal of the physiological effects for pain control, leading to intense pain and distress, and an increase in sympathetic nervous stimulation and cytokine release precipitating an acute withdrawal syndrome. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest may result from inappropriate doses of naloxone being used for these types of patients".*
10	**Administration of Flumazenil.** Flumazenil injection 500micrograms/5ml is licensed in the UK for the complete or partial reversal of the central sedative effects of benzodiazepines and must be held as stock on departments that hold benzodiazepines. This is particularly important in areas that use midazolam for conscious sedation.	*Refer to MM10 Intravenous Sedation Policy for adults where appropriate.*
11	**Controlled Drugs Not Administered/No Longer Required** **N.B. this refers to individual doses only.** • If an individual dose of a controlled drug has been prepared for a patient, but not administered e.g. patient refused/patient condition changed. or • If the controlled drug is no longer required e.g. removal of a fentanyl/buprenorphine patch, discontinuation of an infusion Then the doses should be disposed of as follows: o Solid dosage forms (e.g. tablets/capsules) should be placed directly in a yellow sharps bin for incineration. o Patches should be folded so that the adhesive sides stick together and placed directly in a yellow sharps bin for incineration.	

No.	Instruction	Photograph / Diagram / Explanation
	o Liquid doses and infusions should be expelled from the container (e.g. syringe) directly into a yellow sharps bin and the empty container also placed into the yellow sharps bin. All doses of controlled drugs not administered must be witnessed by two registered practitioners and recorded in the controlled drugs register and the patient's prescription. Discontinued doses must be witnessed by two registered practitioners and recorded in the patient's prescription.	
12	**Interruptions in Administration** o If there is an interruption in the process of preparing a controlled drug prior to administration to the patient, for example in the event of an emergency situation, it must be secured in the controlled drug cupboard until the registered practitioners are able to return to continue the administration as soon as possible. o The key to the controlled drugs cupboard must remain solely in the possession of the registered practitioner or the nurse in charge throughout this time.	*Any delay in administering pain relief to patients should be documented in the patient's care plan and apologies given to the patient explaining the reason for the delay.*
13	**Patient Self Administration** • The Trust does not currently have provision for safe storage of CDs in the patients' locker and self-administration by the patient. The Trust does not currently allow patient self-administration of CDs. • If a patient insists on self-administering controlled drugs this must be escalated to the Associate Chief Nurse and Accountable Officer for Controlled Drugs, Medicine Safety Team or nominated deputies.	
Nurses/Midwives working in a Community Setting		
14	There may be circumstances when a midwife or specialist nurse employed by UHNM but working in a community setting has to prepare and administer prescribed controlled drugs without a second checker being present. A local risk assessment should be undertaken and where appropriate a separate standard operating procedure should be developed and approved by the Trust Safe Medicines Committee and the Accountable Officer for Controlled Drugs.	

Appendix 7: Management of Patients Own Controlled Drugs – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-5 The Management Of Patients Own Controlled Drugs (Including TTOs)

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all Patients Own Controlled Drugs (POD CDs) brought into hospital by patients / relatives or Discharge CDs supplied by the hospital pharmacy for the patient to take home are managed in accordance with:

- The Misuse of Drugs Act (Safe Custody) Regulations 1971,
- The Safer Management of Controlled Drugs, A guide to good practice in secondary care (England) (DH2007)
- The Nursing and Midwifery Council Standards for Medicines management (2010)

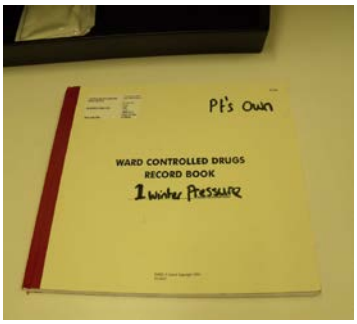
Scope:

- This SOP applies to any schedule 2 and 3 controlled drugs and all preparations containing morphine and cocaine that patients may bring with them on admission or that may be dispensed for an individual patient to take home at discharge. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to patients own controlled drugs on all wards and departments at UHNM.
- This SOP applies to all registered practitioners involved in the management of Controlled Drugs at UHNM.
- Appointed and Assigned Practitioners in charge of each ward or department have additional responsibilities as outlined in this SOP. Such practitioners must ensure that all staff working on the ward are aware of this SOP and have signed Appendix 1.
- Signatory lists must be held at ward level for the purposes of audit and / or inspection.
- Controlled drugs that have been dispensed for an individual patient in accordance with a legal and valid prescription are the legal property of the patient for who they have been dispensed.
- This SOP does not cover illicit substances or CDs acquired illegally brought into hospital by patients. This is covered in the Illicit Substances Policy RM11

Related Documents:

- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM03 Policy for the Storage, Prescription, Supply and Administration of Medicines
- MM01 Trust Policy for Medicines Reconciliation
- MM06 – SOP - 4 Administration of Controlled Drugs
- MM06 – SOP – 1 Storage and Safe Custody of Controlled Drugs
- MM06 – SOP - 3 Delivery and Receipt of Controlled Drugs from Pharmacy
- MM06 - SOP - 6 Stock Checking controlled drugs on wards and departments
- PHA 68 Pharmacy Procedure for returning controlled drugs from wards/departments to the Pharmacy Department.

No.	Instruction	Photograph / Diagram / Explanation
	Patients Own Controlled drugs brought into UHNM Trust	
1	**Sending Patient's Own CDs home** • Where possible registered practitioners must request that relatives take patients own CDs home. Registered practitioners must take into consideration: i. Whether an accurate medicines reconciliation has been undertaken / recorded as per Trust Policy MM01 (Medicines Reconciliation). This must be recorded before the CDs are sent home. ii. If there are sufficient quantities of CDs available on the ward to administer doses until a supply can be arranged from	

No.	Instruction	Photograph / Diagram / Explanation
	Pharmacy. It is not appropriate to send CDs home if the patient will miss a dose of medication. iii. If the relative or carer with the patient is suitable and reliable to take responsibility for the patient's controlled drugs. Registered practitioners may need to use own judgement regarding the suitability of relatives to receive CDs. • If it is appropriate to send the controlled drugs home, the registered practitioner must document the following in the patient's medical notes: i. That patients own controlled drugs have been sent home including the time and date ii. The name of the person that they were given to and their relation to the patient iii. The drug name and strength iv. Drug quantity v. Signature of registered practitioner, printed name and designation. vi. Signature of an appropriate witness – usually a second registered practitioner but may be a 3rd year student nurse. • If it is not appropriate to send patient's own controlled drugs home with relatives follow procedure below.	
2	**Patient's Own CDs kept at UHNM** i. There must be a separate 'Patient's Own' CD register i.e the ward stock CD register must not be used for patient's own. ii. A record of receipt must be entered into the department 'Patients Own' CD register by two registered practitioners. See 1.3. below for register entries. iii. Patient's own controlled drugs must be stored according to safe custody principles in the CD cupboard on the ward or department – see MM06 - 01 SOP for Storage and Safe Custody of Controlled Drugs iv. Patients own CDs must be checked at least every 24 hours as per MM06 -06 SOP for Stock Checking controlled drugs on wards and departments	
3	**Entries in the CD register** • Two registered practitioners must witness the receipt and storage of patients own controlled drugs. • A new page must be started for every patient. It	

No.	Instruction	Photograph / Diagram / Explanation
	is sensible to use chronological order when allocating pages. • The name of the patient must be entered at the top of the page and in the contents page the patient name must be recorded with the page number that has been allocated. • More than one controlled drug for a specific patient can be entered on the same page but at least 6 lines must be left in between each drug to allow for entries relating to: o Drug administration in the event of insufficient stock on the ward. o Returning CDs to patient on discharge o Sending CDs to pharmacy for disposal • The entry in the register must state: o The date CDs received o The Origin of the CDs – see guidance in adjacent column. o Name of the drug o Form and strength of the preparation o The quantity received must be written in the quantity received column and must be written in the running balance column. o The signatures of the two registered practitioners. • If the patient has a large quantity of controlled drugs then a second page may be used. The page number of any additional pages must be documented in the contents page.	Register entry options for origin of controlled drugs: o "patients own CDs received from patient on admission" Or o "patients own CDs received from ward … on transfer of patient" Or o "patients own CD TTOs received from Pharmacy"
4	**Patient's Own CDs not stored in original packaging / outer container** CDs brought into hospital that are not stored in their original packaging (e.g. loose tablets / capsules or blister strips) must be placed in an envelope labelled with the following details where possible: • Patient's name and unit number • Drug name, strength, form and quantity. The envelope must be sealed and two registrants must sign over the top of the seal. The envelope must then be placed in the CD cupboard. The details must be recorded in the register as in 1.3 above.	Where possible, the CDs must be returned to the relative as described in section 1.1. Where verbal permission is granted by the patient / relative to dispose of the CD it must be handed over to the ward pharmacist as soon as possible to arrange return to pharmacy and disposal.
5	**Re-issuing Patients' Own Controlled Drugs Back to the Patient** Patient's Own CDs are the personal property of the patient and should, where possible and / or appropriate be returned to the patient on discharge. Registered practitioners must give consideration as to whether or not the CD prescription has been changed during the patient's stay in hospital as below. The Patient's Own CDs can be re-issued back to	

No.	Instruction	Photograph / Diagram / Explanation
	patients by the discharging registered practitioner when the following has taken place: • The discharge prescription must have been clinically screened by a pharmacist. • The CDs must have been assessed for suitability for continued use and accuracy against the discharge prescription by the relevant pharmacy / nursing staff. This includes a product check as well as a dispensing label check. • An entry must be made in the patients own CD register stating that the CD has been returned to the patient. Two registered practitioners must witness that this has taken place and document and sign in the patients notes in the section where discharge arrangements have been recorded. NB. If the Patient's Own CDs are reissued then the discharge prescription is not subject to CD handwriting requirements as it is assumed that the CD has already been dispensed against a legally valid prescription.	
6	**Transfer of Patients Own CDs between wards/departments** • When patients are transferred from one ward to another then all the patients medicines must be transferred with them. • One registered practitioner from the original ward must remove the patient's own CDs from the CD cupboard and transport these, along with the Patients' Own CD register, to the new ward/department. • On arrival at the new ward/department two registered practioners (one from the original and one from the new ward/department) must check that the actual quantity of the patient's own CDs match the quantity recorded in the original CD register. • If satisfied that all is correct, both registered practitioners must sign the CDs out of the original register and into the new ward/departments Patients' Own CD register. Ensure that the ward where the CDs were transferred from is recorded as per 1.3 above. Both registered practioners must signed the entry. • The CDs must be secured in the patients' own section of the CD cupboard of the new ward/department. • The registered practitioner from the original ward must ensure that they return their register to it's original secure place.	

No.	Instruction	Photograph / Diagram / Explanation
7	**Patient's Own CDs not suitable for use on discharge** • If the patient is not prescribed the CDs on discharge or if the Patient's Own CDs are otherwise not suitable for use the medicines still remain the patient's property and the patient has the right not to agree to the removal or destruction of their medicine. • If the Patient's Own CDs are not suitable for returning to the patient the registered practitioner must obtain permission from the patient or carer where possible to send the CDs to pharmacy for disposal. This must be documented in the CD register. • The patients own CDs must remain in the ward CD cupboard until the ward pharmacist or pharmacy technician is able to return to pharmacy as per MM06 - 06 SOP for Stock Checking controlled drugs on wards and departments. • If the patient does request to keep their CDs against advice from the registrant then refer to medical staff or a Senior Pharmacist for further discussion with the patient or carer. • If the patient insists that their property be returned to them the registered practitioner must return the CD. It must be clearly documented in the medical notes that this was done against the advice of the prescriber.	
	Patients Own Discharge (TTO) CDs	
8	**Receipt of Discharge CDs from Pharmacy** • Discharge CDs are delivered from pharmacy in a sealed pharmacy bag – see MM06 – 03 SOP for Delivery and Receipt of Controlled Drugs. The CD Pharmacy Delivery Receipt form must be signed by the registrant receiving the CD and the sheet must be returned to the pharmacy porter who will return this to Pharmacy. • If the patient is leaving the ward or department immediately it is not necessary to record the TTO in the Patient's Own CD register. The issue of the controlled drugs to the patient must be recorded in the patient's notes in the section where discharge arrangements are recorded. Two members of staff must witness and sign the record one of which must be a registered practitioner. • If the patient is not leaving imminently the Discharge CDs must be stored in the controlled drug cupboard and entered into the Patient's Own CD register as in 1.3 above.	

Appendix 8: Stock Checks of Controlled Drugs on Wards / Departments – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-6 Stock Checking Controlled Drugs On Wards / Departments And The Management Of Stock Discrepancies

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all Controlled Drugs (CDs) requiring safe custody at UHNS and that are stored at ward / department level are stock checked in accordance with:

- The Misuse of Drugs Act (Safe Custody) Regulations 1971,
- The Safer Management of Controlled Drugs, A guide to good practice in secondary care (England) (DH2007)
- The Nursing and Midwifery Council Standards for Medicines management (2010)

Scope:

- This SOP applies to the storage and stock checking of all schedule 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to the stock checking of controlled drugs on all wards and departments at UHNM.
- This SOP applies to all registered practitioners involved in the management of Controlled Drugs at UHNM
- Appointed and Assigned Practitioners in charge of each ward or department have additional responsibilities as outlined in this SOP. Such practitioners must ensure that all staff working on the ward are aware of this SOP and have signed Appendix 1.
- Signatory lists must be held at ward level for the purposes of audit and / or inspection.

Related Documents:

- MM06 Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs.
- MM06 – SOP - 4 Administration of Controlled Drugs
- MM06 – SOP – 1 Storage and Safe Custody of Controlled Drugs
- MM06 – SOP - 3 Delivery and Receipt of Controlled Drugs from Pharmacy
- MM06 – SOP - 5 Management of Patients Own Controlled Drugs.
- PHA 68 Pharmacy Procedure for returning controlled drugs from wards/departments to the Pharmacy Department.

No.	Instruction	Photograph / Diagram / Explanation
1	**Personnel permitted to undertake stock checks** • The Appointed Practitioner in Charge of the ward or department is responsible for ensuring that the 24 hourly stock check of controlled drugs is carried out and recorded by staff on the ward / department. • Two registered practitioners, one of whom must be the Assigned Practitioner in charge of the ward or department, must perform this check. Where possible the staff undertaking this check will be rotated. • A student nurse or midwife (2nd or 3rd year pre-registration only) may be the second checker / witness provided they have the necessary knowledge and competency to carry this out.	
2	**Frequency of CD stock checks** • The stock balance for <u>every</u> controlled drug (including patients own controlled drugs) recorded	**Special measures** The Practitioner in Charge may decide to

No.	Instruction	Photograph / Diagram / Explanation
	in the CD register and stored within the controlled drug cupboard on a ward or department must be checked a minimum of once every 24 hours. • The Appointed Practitioner in charge must designate a time for the 24 hourly CD stock checks to take place. • A rolling stock balance must be maintained for each individual drug every time the individual item is received from Pharmacy, or receipt of a patient's own controlled drug. • A rolling stock balance must be maintained for each individual drug every time the individual item is removed from the cupboard for administration to a patient, returning controlled drugs to Pharmacy or returning patient's own controlled drugs to the patient.	implement more frequent checks in their area. This would usually be decided after undertaking a local risk assessment or in liaison / after advice from the Associate Divisional Nurse and/or Clinical Director of Pharmacy (Accountable Officer).
3	**How to carry out the stock check** • Select the page in the controlled drugs register for the individual drug/form/strength. • Check that the running balance for the item is recorded accurately. The registered practitioner must be satisfied that the entries in the controlled drug register are accurate and that there are no ambiguities or discrepancies in the recording / legibility of the entries. • Count the actual quantity of the item within the controlled drug cupboard and reconcile to the recorded stock level in the register. N.B. There is no requirement to open packs with intact tamper evident seals for stock checking purposes • Check the expiry date on every container of the individual controlled drug. • Repeat the procedure for every controlled drug recorded in the controlled drug register and patients own controlled drug register	Checking of CDs involves the checking of entries in the record book/ register against the contents of the CD cupboard and **NOT** the reverse. i.e.Do NOT check the CDs present in the cupboard and then confirm with the register as this could inadvertently lead to a CD recorded in the register, missing from the cupboard and not identified on the CD stock check. This is to ensure that all entries in the ward CD record book are checked.  Unopened containers, complete with intact tamper evident seals are assumed to contain the quantity / volume recorded on the manufacturers packaging.
4	**Stock checking liquid volumes** • Stock balances of opened / unsealed liquid medicines may be estimated by visual inspection. This is to minimise liquid lost by repeated measuring of volumes and ensures that excessive handling does not compromise the integrity of the liquid. • The actual balance MUST be confirmed to be correct when the bottle has been finished. Note – the running balance for the bottle should be documented as 'zero' or 'nil' when the bottle is empty rather than 0. If the bottle is empty but the running balance states a positive balance this must be investigated as a stock discrepancy – see point 8 below.	 *At the end of each bottle ensure the actual stock balance corresponds with the register balance. Escalate discrepancies to ward manager & report via Datix.*

No.	Instruction	Photograph / Diagram / Explanation
5	**Stock check record keeping** • Wards and departments must keep a record of all controlled drug stock checks. The Appointed Practitioner in charge must designate where the information is to be recorded. The record may be kept at the back of the CD register or in a designated log book. • The record must show the date and time of each stock check, that all stocks are present and correct, and must be signed and dated by the two registered practitioners undertaking the stock check.	
6	**Infrequently used Controlled Drugs** • During the stock check preparations and strengths of controlled drugs that are not routinely used on the ward/department may be identified. • Preparations and strengths of controlled drugs not routinely used on the ward / department and no patient currently prescribed the CD must be returned to Pharmacy for re-use / disposal – see point 7 below	
7	***Returning Controlled Drugs to Pharmacy*** • *Unnecessary high quantities, expired stock or controlled drugs no longer required (including patients own) should be returned to Pharmacy at the earliest practical opportunity.* ***(i) Returning Controlled Drugs via Ward Pharmacy Team*** • *Ideally the stock should be returned via the registered pharmacist or pharmacy technician routinely based on the ward. The ward Pharmacy team should be alerted that there are controlled drugs to be returned to Pharmacy and a mutually agreed time should be arranged to remove the controlled drugs and return to Pharmacy.* • *The registered practitioner in charge of the ward and the approved pharmacy practitioner must select items to be returned to Pharmacy and the corresponding page in the controlled drug register. The following process should be followed:* o *Count the quantity of drug to be returned to Pharmacy. – SEE NEXT COLUMN* o *On the next available line in the register record the date, state "returned to Pharmacy", state the quantity returned in the "quantity used" column and the remaining balance in the running balance column. Check that the remaining balance (if any) corresponds exactly with the quantity of drug to be left on the ward/department.* o *Both the registered practitioner in charge of the ward/department and the pharmacist/pharmacy*	*Controlled Drugs (including patients own) must always be returned to Pharmacy in the secure process described in this SOP. They must NEVER be put into the green Pharmacy boxes or Pharmacy bags and left for collection by a porter.* *Persons Authorised to return Controlled Drugs:* • *The designated practitioner in charge of a ward or department must sign the register to authorise the removal of a controlled drug from the ward/department.* • *The removal must be witnessed by a registered pharmacist, registered pharmacy technician, registered Pharmacy nurse or registered pre-registration pharmacist.* ***Confirming Quantity to be returned:*** *For liquid preparations it is not always practical to measure the volume accurately. In the first instance the Pharmacy practitioner must visually assess the container to estimate the volume of liquid. If the estimated volume corresponds to the volume recorded in the register this can be accepted for return. If the estimated volume appears to be less than the recorded volume the volume must be measured accurately using a measuring cylinder or*

No.	Instruction	Photograph / Diagram / Explanation
	technician must sign the register to witness the removal of the individual drug from the ward. • *The pharmacist/pharmacy technician will put the controlled drugs into a Pharmacy bag and complete the Controlled Drugs return note (appendix 1). The registered practitioner in charge of the ward must sign the Controlled Drugs return note to confirm the quantity of controlled drugs returned.* • *The Pharmacist/Pharmacy Technician will return the controlled drugs to Pharmacy according to SOP PHA 068.* ***(ii) Returning Controlled Drugs to Pharmacy when there is no registered Pharmacist/Pharmacy Technician Available*** • *Call the Pharmacy Dispensary to arrange a suitable time to bring the controlled drugs to the Pharmacy.* • *The registered practitioner in charge of the ward and a second registered practitioner must select items to be returned to Pharmacy and the corresponding page in the controlled drug register. The following process should be followed:* o *Count the quantity of drug to be returned to Pharmacy.* o *On the next available line in the register record the date, state "returned to Pharmacy", state the quantity returned in the "quantity used" column and the remaining balance in the running balance column. Check that the remaining balance (if any) corresponds exactly with the quantity of drug to be left on the ward/department.* o *Both the registered practitioners must sign the register to witness the removal of the individual drug from the ward.* o *Place the controlled drugs into the blue controlled drug box and seal with the red seal that is inside the box.* • *The box, along with the controlled drug register must be brought to the In-patient Pharmacy Dispensary by the registered practitioner. They must be handed directly to a registered pharmacist or pharmacy technician – confirm that this is the case.* • *The Pharmacy staff will handle the returned controlled drugs in accordance with Pharmacy SOP PHA068.*	*syringe. If the volume is more than 5% less than the recorded volume this must be investigated as a discrepancy as in point 8 below.* *Controlled drugs should be returned to the Pharmacy at a time when there is appropriate Pharmacy staff available to receive them into the Pharmacy. They will not be accepted into Pharmacy during weekends or bank holidays unless in exceptional circumstances e.g. ward closing.*
8	**Controlled Drug Stock Discrepancies – see guidance flow chart in appendix 2.** • If a stock discrepancy is found between the quantity of the controlled drug present in the	The UHNM Accountable Officer for Controlled Drugs is the Clinical Director of Pharmacy. Contact number 01782 674505/ 674501.

No.	Instruction	Photograph / Diagram / Explanation
	cupboard and the balance recorded in the register it must be investigated immediately. The Appointed Practitioner in charge must immediately carry out an initial investigation to attempt to resolve the discrepancy. - see attached flow chart (appendix 1). • Discrepancy checklist o Two registered practitioners must re-count the quantity in the cupboard, ensuring that all possible locations have been searched and all possible containers of the specific drug/form/strength have been checked. o Check that arithmetic is correct when comparing CD receipt and removal from the CD cupboard with the rolling stock balance. o Check that all requisitions received have been entered into the correct page of the register. o Check that a receipt entry e.g. Patients Own CDs has not been entered twice on multiple pages. o Check that all CDs removed from the cupboard for administration / return / disposal have been entered into the correct page of the CD record book o Check that items have not been accidentally stored in a different area of the cupboard. o Check that all controlled drug doses administered on the ward/department have been entered into the register. o Check if patients own controlled drugs have been returned to the patient but not recorded accurately in the register **(i) When a stock discrepancy is resolved on initial investigation** o If an error or omission is identified the Assigned Practitioner in charge must make an entry in the CD register to explain the discrepancy. The balance must be correct. This entry should be witnessed by a second registered practitioner. o An adverse incident report (Datix®) must be completed with full details of the incident including: • Date and time when the discrepancy was identified • Date and time of the last stock check • Name, strength, form and quantity of the drug • Remedial action where appropriate • A note under the investigation that the stock discrepancy has been resolved **(ii) When a stock discrepancy is not resolved on initial investigation** **During Pharmacy Opening Hours**	The Trust Medication Safety Officer can be contacted on 674510/674501 The on-call pharmacist can be contacted via switchboard.

No.	Instruction	Photograph / Diagram / Explanation
	• If the above actions fail to resolve the discrepancy the discrepancy must be reported immediately to the Matron / Divisional Nurse on duty who must ensure all possible sources of the error have been investigated and that an adverse incident report has been completed. • The senior investigating nurse must inform the ward pharmacist, the Medication Safety Officer or Deputy to confirm that all possible sources of error have been investigated including any returns to Pharmacy through unapproved routes (e.g. check Pharmacy green boxes returned from ward). • The senior investigating nurse must ensure the **Accountable Officer** is informed immediately who will advise on further action after consideration of the facts. **Outside Pharmacy Opening Hours** • The discrepancy must be reported immediately to the Clinical Site Manager who must ensure that all possible sources of the error have been investigated and that an adverse incident report has been completed. • If there is suspicion of criminal activity or that the incident compromises patient safety, the Site Manager must contact the on-call pharmacist immediately who will contact an appropriate Senior Pharmacist for advice. If there is no suspicion of criminal activity the Divisional Lead Pharmacist must be informed when Pharmacy is open. If this is a weekend the senior pharmacist on duty must be contacted • The Investigating Nurse must inform the **Accountable Officer** the next working day. **(iii) Further investigation and root cause analysis (RCA)** • An investigation and root cause analysis must be conducted when the discrepancy cannot be satisfactorily resolved. This must be conducted jointly between: o The clinician o The matron o The divisional clinical governance manager o Accountable Officer (Clinical Director of Pharmacy) or designated deputy o The Trust Security Manager where appropriate. • Support is available from the Divisional Lead Pharmacist and the Trust Medication Safety Officer. • The results of the RCA must be fed back to the Accountable Officer via the Controlled Drug	

No.	Instruction	Photograph / Diagram / Explanation
	Discrepancy RCA Panel who report to the Trust Safe Medications Group. They will advise if further investigation is required or any remedial measures that may need to be taken such as changes in procedure. • In some cases, if the Accountable Officer or the Trust Security Manager are not satisfied with the outcome of the investigation they may decide to escalate to the local police/external auditors for the Trust for further advice and support.	

UHNM PHARMACY DEPARTMENT CONTROLLED DRUGS RETURNS NOTE / RISK ASSESSMENT

This form must be completed by Pharmacists / Pharmacy Technicians before returning CDs from wards / departments to the Pharmacy CD Room.

WARD / DEPARTMENT: _____ PHARMACIST / TECHNICIAN: _____ DATE: _____ TIME: _____ SEAL NUMBER: _____

SECTION 1: CDS FOR RETURN VIA THE PHARMACY CD ROOM								
PATIENTS NAME & UNIT NO. (IF POD CD)	**DRUG NAME**	**STRENGTH**	**FORM**	**QUANTITY**	**PHARMACIST / TECH**	**WITNESS (Practitioner in charge of the ward / nominated practitioner)**	**TICK (√) IF FOR DESTRUCTION**	**TICK (√) IF FOR RE-USE**
e.g. John Smith A12345	Morphine sulphate MR	10mg	Capsules	60	J.Jones	T.Bloggs	√	

SECTION 2: RISK ASSESSMENT FOR COMPLETION FOR ALL CDS RETURNED FOR RE-USE (NOT FOR CDS BEING RETURNED FOR DESTRUCTION).		
CRITERIA FOR RE-USE	**DOES THE CD MEET THE CRITERIA? (√)**	**ADDITIONAL COMMENTS**
Has the product been supplied by UHNM as ward stock or during the current inpatient admission?		
Has the product got an expiry date of at least 6 months?		
Has the product been stored appropriately?		
Is the product in good condition? I.e. not damaged, sticky, cracked, defaced.		
N.B. Part packs may be re-used at the discretion of the CD room staff only.		

SECTION 3: TO BE INITIALLED AND DATED BY THE PHARMACY CD ROOM			
3A: All returned CDS have been recorded in the Pharmacy CD register / destruction register – initial and date.		**3B: All CDs returned for re-use have been returned on Ascribe – initial and date.**	

Signature of pharmacist / technician in receipt of the CDs in Pharmacy:_____ Date:_____ Time: _____ Seal number: _____

Guidance Flowchart Regarding Controlled Drug Stock Discrepancies

Preliminary Investigation

- Inform Appointed Practitioner in Charge of ward / department / theatre of discrepancy.
- Perform initial review of the CD record book for cause of discrepancy.
  - Re-check daily count of CD cupboard stocks against record book balances.
  - Check prescriptions record charts for omitted records of administration.
  - Question other members of staff who held CD keys during shift.
  - Check CD Order Book to ensure deliveries were entered correctly.
- Initiate an adverse incident report on Datix®, classifying as a medication incident and noting names of staff consulted and actions taken.
- Bring incident to the attention of the Matron / Senior Clinical Nurse at the earliest opportunity.

Record Keeping error identified?

Yes

Record-Keeping Error

- Do not cross out or attempt to alter any entry in the CD record book
- If incorrect entry has been made, draw brackets around the mistake and write a concise explanation in the margin at the foot of the page (e.g. "entered in error").
- Make correct entry in an adjacent space of on the next line
- Datix reviewer for ward / department records details of resolution and any further actions necessary on adverse incident report.

No

Is discrepancy small liquid difference of Oramorph 10mg in 5mL? (i.e. 5% or less of total volume)

Yes

Adjusting Balance of Oramorph 10mg in 5ml

- Discuss with Appointed Practitioner in Charge and amend CD record book accordingly, documenting discrepancy clearly and reset balance.
- Report to ward pharmacist in hours.
- If any trends in discrepancy are noted, treat as 'Major' or 'suspicious' CD incident.

No

Report discrepancy to:

- Appointed Practitioner in Charge / Matron (in hours) or Site Manager (out of hours).
- Ward or Lead Pharmacist (in hours) or on-call pharmacist (out of hours).

The above will determine whether the discrepancy is to be treated as 'Major' or Suspicious'.

- Inform Matron and Accountable Officer for Controlled Drugs /Medication Safety Officer or on-call pharmacist out of hours for suspicious discrepancy

'Major' or 'Suspicious' discrepancy?

No

Yes

Actions by Appointed Practitioner in Charge / Matron (in hours) Or Site Manager (out of hours)

- Repeat preliminary investigation actions above.
- Carry out thorough search of stock cupboards, drug trolleys, pharmacy returns box and POM waste bin (in case of breakage or unintentional disposal).
- Question staff who carried out last correct stock check and all staff since then who had access to the CD cupboard and obtain statements.
- Record details of the discrepancy on the next line in the CD record book noting the Datix® reference number and amending the stock balance to the quantity present.
- Inform the Divisional Lead Pharmacist and the Accountable Officer CDs of discrepancy.
- Add details of actions completed to adverse incident report.
- Closure of the adverse incident report should be authorised by the Accountable Officer CDs

Actions by Appointed Practitioner in Charge / Matron (in hours) Or Site Manager (out of hours)

Retain and secure any evidence / documentation.

- Take statements from all staff with access to CDs during period of loss.
- If foul play is suspected the Security manager (or site manager out of hours) should be informed who will consider if Police to be informed.
- Report to Associate Chief Nurse and Accountable Officer CDs and discuss next course of action.
- Accountable Officer or relevant Associate Chief Nurse to contact UHNM Local Security Management Specialist and / or Local Counter Fraud Liaison Police Officer for advice where necessary.
- Add details of actions completed to adverse incident report.
- RCAs must be presented to the CD Discrepancy Panel by the practitioner in charge or deputy.
- Closure of the adverse incident report should be authorised by the Accountable Officer CDs.

N.B Accountable Officer CDs – Director of Pharmacy and Medicines Optimisation

Appendix 9: Administration of Controlled Drugs in Theatres – Trust SOP

Standard Operating Procedure (SOP)

MM06-SOP-7 Administration Of Controlled Drugs by Anaesthetists/Clinicians within Theatres

V4 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
To ensure that all schedule 2 and 3 Controlled Drugs, required for treatment of patients in Theatres at UHNM, are administered in accordance with the Misuse of Drugs Act (Safe Custody) Regulations 1971, the Safer Management of Controlled Drugs, a guide to good practice in secondary care (England) (DH2007), and the Nursing and Midwifery Council Standards for Medicines management (2010). This SOP complements the principles outlined in MM06.

Scope:
- This SOP applies to the administration of all schedule 2 and 3 controlled drugs, all preparations containing morphine and cocaine, and potassium concentrate solution. The Trust Accountable Officer for Controlled Drugs may deem it appropriate to stipulate safe storage, ordering and delivery regulations for specific 4 or 5 Controlled Drugs that are not legally subject to safe custody regulations. This would be in line with local risk assessments and must be strictly adhered to.
- This SOP applies to all registered practitioners involved in the administration of controlled drugs within the operating Theatres and other areas where anaesthetists administer controlled drugs e.g. Imaging department in MRI but excludes Recovery who will follow the standard MM06 – 04 SOP for the administration of controlled drugs.
- This SOP provides a framework for the additional legal requirements for administration of controlled drugs. This SOP should be used in conjunction with the procedure outlined for administration of medicines in MM06 – 04 SOP for administration of controlled drugs.
- The Trust has adopted the Royal Marsden Manual of Clinical Nursing Procedures 9th Edition (see Trust Intranet) for procedures involved in administration of medicines. All staff who administer medicines are responsible for ensuring knowledge and compliance with these procedures.
- UHNM Bedside Clinical Partnership Guidelines should be followed where possible.
- For administration of an epidural or patient controlled analgesia (PCA) local standard operating procedures are in place. Only registered practitioners who have been trained and deemed competent in these specific SOPs may administer an epidural or PCA.

Roles and Responsibilities:
The Registered Anaesthetic Assistant who is either an ODP (Operating Department Practitioner) or registered nurse is responsible for:
- The keys to the Controlled Drug cupboard for their particular theatre at all times when the theatre is in use. Controlled drug cupboard keys must be kept separately to all other keys i.e. must not be kept on the same key ring as any other keys. The registered practitioner in charge must be responsible for the key(s) at all times and hold them on their person. When not in use the keys should be returned to the key cupboard as soon as possible
- Ensuring that the balance in the controlled drug register is reconciled with the cupboard following every issue of Controlled drug to the Anaesthetist/Clinician
- Ensuring that the CD register is fully completed (including two signatures) before the patient leaves the operating theatre
- Ensuring that controlled drugs are never left unsupervised
- Ensuring that a full check of all controlled drugs is undertaken at the beginning and end of each theatre list according to the method stated in MM06 – 06 – SOP for stock checks of controlled drugs

The Anaesthetist/Clinician is responsible for:
- Ensuring controlled drugs are administered safely in accordance with the AAGBI guidelines Controlled Drugs in Perioperative Care and the principles for administration of medicines outlined in MM03 and MM06.
- Ensuring that they sign for the supply, administration and waste in each section of the CD register at the appropriate time.
- Documenting the administration on the anaesthetic chart
- Ensuring that controlled drugs are never left unsupervised
- Ensuring that prepared drugs are labelled in accordance with MSOP 13 – Procedure for the Administration of

Medicines.

Equipment:
- A Theatre Controlled Drug Record Book must be used in all areas within theatres.
- A traditional Controlled Drug Record book must be used in recovery areas.

Glossary:
- AAGBI – Association of Anaesthetists of Great Britain and Ireland

No.	Instruction	Photograph / Diagram / Explanation
1	**Required Checks before Administration of any Medication to a Patient –** see MM03 SOP for Administration of Medicines • Confirm that the patient does not have an allergy to prescribed medication. • Confirm that the dose is appropriate for the weight and age of the patient • Confirm that the dosage, method of administration, route and timing of administration is appropriate to the patient's condition.	
2	**Keys to CD Cupboards** • The appointed practitioner in charge is responsible for ensuring that keys to the CD cupboards are secure at all times and that there is a full record available of who has been accountable for keys at all times. • While the theatre is in use the key(s) for the CD cupboards must be kept separately and on the person of the registered practitioner in charge. • Under no circumstances can the key to the CD cupboard be handed to a doctor. If a doctor requires a CD they should obtain it via an ODP/Nurse as point 3 below. • If the theatre is closed overnight or over the weekend there must be a safe system in place to ensure accountability for controlled drugs keys. This must be risk assessed and approved by the Trust security manager and the Accountable Officer for Controlled drugs	
3	**Obtaining the controlled drug** • The ODP/ nurse will be responsible for obtaining the CD in response to the request from the Anaesthetist/Clinician. • Open the cupboard and remove the required drug. The cupboard must be closed and locked immediately afterwards. The CDs must be supervised at all times. • The ODP/Nurse and Anaesthetist/Clinician must check the name, formulation, strength, route and expiry date of the selected preparation and confirm it corresponds with the dose required. • Remove the exact quantity of medication required by the Anaesthetist/Clinician • Record the supply in the Theatre Controlled Drug register in legible black ink:	*Do **not** leave the CD cupboard open and unattended. Do **not** leave CDs unattended after removing from cupboard.* *If, in exceptional circumstances during the procedure, extra controlled drug is requested, the ODP will bring the drug and the register for the Anaesthetist/Clinician to sign within theatre. Extra vigilance is required to ensure the correct drug has been selected as some preparations may look similar.* *See Appendix 1 for example of entry in register.*

No.	Instruction	Photograph / Diagram / Explanation
	o Select the correct page for the drug, formulation and strength using the index. Document in the appropriate column: ▪ Date ▪ Name of the patient and unit number ▪ Quantity issued on the supply section (S). The register will be signed by both the Anaesthetist/Clinician and ODP/Nurse at this point, the Anaesthetist/Clinician being the responsible person and the ODP the witness. ▪ Document the time. ▪ Deduct the quantity issued from the balance in the register and enter the new balance in the running balance column. Reconcile the stated balance with the remaining stock. Use 'zero' or 'nil' rather than 0 where applicable.	*Please be aware that the ODP/Nurse is also legally responsible for the controlled drugs within their theatre* *Only the ODP/Nurse will reconcile the balance with the remaining stock on issue to the Anaesthetist/Clinician*
4	**Preparing the Controlled Drug and Administration** The Anaesthetist/Clinician is responsible for the preparation and administration of the controlled drug • The required dose is drawn up in a suitable dilution and labelled with the approved labels writing the concentration • The Anaesthetist/Clinician will administer the intended dose to the patient including setting pump infusion rates. The Anaesthetist/Clinician will decide on the dose and time of administration. • The Anaesthetist/Clinician will titrate the dose to patient response throughout the perioperative period. • Where infusions are continued into recovery or onto the ward, a Trust infusion label (or yellow epidural label if appropriate) must be accurately completed by the Anaesthetist/Clinician and checked by the witness. • The dose administered will be documented on the patient's anaesthetic chart at the appropriate time. • The Anaesthetist/Clinician will document in the Theatre Controlled Drug register next to "A" against the patients name, the amount administered followed by their signature under responsible person whilst the patient is still in theatre	*The Controlled drug must remain in the sight of the Anaesthetist/Clinician at all times.* *Unless used immediately the syringe should remain capped off and identified with an initialled label* *Do not use a drug that has not been under direct supervision of attending Anaesthetist/Clinician to guard against tampering and sterility* *Batch drawing up of drugs for more than one case is not permitted* *Sharing of any drug vials between patients is not permitted* *No syringes should leave theatres unless set up as an infusion*
5	**Wastage** • All empty and part used vials/syringes must be placed into a tray and brought out of the theatre so that the ODP/Nurse can witness any destruction. • Any surplus drug should be destroyed by expelling into a yellow sharps bin for incineration. e.g. If 5mg is required from a 10mg ampoule only 5mg should be drawn up to administer the dose and the remainder should be destroyed. This MUST be witnessed by the ODP/nurse in theatre at that time. Note this may be a different ODP/nurse from	*See Appendix 1 for example of entry in register.* *If the whole dose has been given the ODP/Nurse should see the empty syringe/ ampoule before witnessing the entry*

No.	Instruction	Photograph / Diagram / Explanation
	the person issuing the original CD if there has been a changeover of staff during the procedure. • The Anaesthetist/Clinician will document the amount destroyed in the Theatre Controlled Drug Register next to "D" against the patients name and witnessed by the ODP/Nurse. If the whole dose has been administered the wastage must be recorded as " NIL". The ODP/nurse must witness the empty vial/syringe and sign to say they have witnessed that there is nothing to waste or destroy.	
6	**Interruptions in Administration** o If there is an interruption in the process of preparing a controlled drug prior to administration to the patient, for example in the event of an emergency situation, it must be secured in the controlled drug cupboard until the registered practitioners are able to return to continue the administration as soon as possible. o The key to the controlled drugs cupboard must remain solely in the possession of the ODP/Nurse in charge of the theatre	*Any delay in administering pain relief to patients should be documented in the patient's care plan and apologies given to the patient explaining the reason for the delay.*
7	**Incorrect Entries in the Register** o If an error is made during the entry in the Controlled Drug register, corrections must be managed in one of the following two ways: o Enclose the error with brackets and write a note at the foot of the page acknowledging the error, signed and dated by both practitioners. o The incorrect entry may be, **crossed out - one** clear **line** through it, signed and dated. The correct entry should be made on the line below the original entry.	
8	**Controlled Drugs Not Administered/No Longer Required** **N.B. this refers to individual doses only.** o If an individual dose of a controlled drug has been prepared for a patient, but not administered e.g. patient condition changed. or o If the controlled drug is no longer required o Liquid doses and infusions should be expelled from the container (e.g. syringe) directly into a yellow sharps bin and the empty container also placed into the yellow sharps bin. All doses of controlled drugs not administered must be witnessed by two registered practitioners and recorded in the controlled drugs register.	*Documentation in the CD register should state "Nil" next to A followed by the Anaesthetist/Clinician's signature and the amount destroyed next to D with a double signature for that particular patient*

No.	Instruction	Photograph / Diagram / Explanation
9	**Stock Checks** o The balance in the controlled drugs register must be checked against the contents in the controlled drugs cupboard by two registered practitioners (registered ODP or nurse) at the beginning and end of each theatre session and whenever another ODP takes over control of the keys to that theatre. o The daily check of controlled drugs must occur in accordance with MM06 -06. o If the balance remaining in the cupboard does not correspond exactly to the balance stated in the register the registered practitioners involved must investigate immediately in accordance with MM06 - 06 SOP for Stock checking Controlled Drugs on Wards and Departments.	
10	**Inaccurate Records of Controlled Drugs** If there are any sections of the register not correctly completed, a datix must be completed and the incident investigated by the Matron	*Note, the Anaesthetist/Clinician must sign separately for each stage of the process for every individual patient*

Appendix 10: Controlled Drugs and Patient Group Directions (PGD)

Note: Please refer to MM05 Use of PGDs for supply and administration of medicines by registered non-medical health care professionals

Registered nurses, pharmacists, midwives, ophthalmic opticians, chiropodists, physiotherapists, radiographers, occupational therapists and orthoptists can give Schedule 4 and 5 CDs under Trust approved PGDs. Exceptions are: anabolic steroids and injectable formulations for the purpose of treating a person who is addicted to a drug.
Legislation came into force on the 23rd April 2012 which introduced a number of changes to the professional use of controlled drugs by pharmacists and nurses. This included circumstances in which certain CDs may be administered or supplied under a patient group direction (PGD). The circumstances are outlined below:

- All registered pharmacists and nurses will be able to supply diamorphine or morphine under a patient group direction (PGD) for the immediate, necessary treatment of sick or injured persons.
- Diamorphine for the treatment of cardiac pain by nurses working in Coronary Care Unit and Accident and Emergency department of a hospital.
- Midazolam, which is part of Schedule 3 of the 2001 Regulations
- All drugs listed in Schedule 4 of the 2001 Regulations (mostly benzodiazepines), except anabolic steroids and any drug or preparation which is designed for administration by injection and which is to be used for the purpose of treating a person who is a substance misuser.
- All drugs listed in Schedule 5 of the 2001 Regulations (i.e. low strength opiates such as codeine).

Appendix 11: Clinical Trials

Any controlled drug which is an investigational medicinal product (IMP) or a non-investigational product (NIMP) used in a clinical trial must comply with both clinical trials legislation and the Misuse of Drugs regulations. **Please also refer to UHNM Policy G02 Research Governance.**

Discussions between the Research and Development Department, the Pharmacy Clinical Trials team and the Chief Investigator should take place at an early stage so that all safe and secure storage requirements including documentation are addressed in a timely manner.

A separate controlled drugs record book / register in Pharmacy must be used for controlled drugs which are IMPs or NIMPs. A separate page must be used in the ward / departmental controlled drugs register for controlled drugs which are IMPs and NIMPs.

If the trial involves schedule 1 controlled drugs (e.g. cannabinoids) a licence from the Home Office will be required for the Pharmacy Directorate to receive the controlled drugs into stock. This should be held by the Clinical Director of Pharmacy.

Appendix 12: Destruction of Controlled Drugs

CDs must be destroyed in accordance with the requirements of the Misuse of Drugs Regulations 2001 and in compliance with the UHNM EF05 Waste Disposal Policy.

Destruction must occur in such a way that the drug is denatured or dissipated so that it is incapable of being retrieved, reconstituted or used. Destruction must occur in a timely fashion so that excessive quantities are not stored awaiting destruction.

Items for destruction should under no circumstances be sent back to pharmacy in a ward bag or box.

All CDs returned to pharmacy for disposal (via ward pharmacist or pharmacy technician) will be disposed of in accordance with local SOPs.

Expired/Unwanted Stock

Expired or unwanted controlled drugs must be signed out of the ward CD record book / register by a registered nurse and the Pharmacist or Pharmacy Technician. A transit form must also be completed. – see SOP for stock checking

If the stock is unsuitable for reuse, it should be entered into the Pharmacy CD destruction register and stored in the Pharmacy CD room/cupboard for later destruction by an 'authorised witness'. The frequency of destruction will depend on the quantity of material for destruction and the storage area available. The controlled drugs will be destroyed in accordance with Pharmacy SOP for destruction.

The 'Authorised witness' for the Trust currently includes the UHNM Local Security Management Specialist and nominated deputy

If the stock is suitable for reuse, it should be returned to Pharmacy stock in the CD cupboard/room and re-entered into Pharmacy CD registers according to local SOPs.

Permitted Disposal on Wards/Clinical Areas

This includes: part doses for individual patients, discontinued infusions, used patches and lozenges, doses drawn up but not given and unused dose units (e.g. dropped tablets).

An 'Authorised Witness' is not required for controlled drugs destruction in ward/clinical areas.

Full details must be recorded in the CD record book / register by a registered nurse and witnessed by another registered nurse, or a doctor or pharmacist if a second nurse is unavailable.

In theatres, the anaesthetist must destroy any unused controlled drugs, which have been issued to him/her for individual patient administration and have this witnessed by a registered nurse / ODP. Details must be entered into the CD record book / register. – see theatre SOP

The CDs must be destroyed as follows:-

- Solid dosage forms (e.g. tablets, capsules, lozenges) should be placed directly in a yellow sharps bin for incineration.
- Patches (e.g. fentanyl) should be folded so the adhesive sides stick to each other and placed directly in a yellow sharps bin for incineration
- Volumes of less than 10ml should be expelled into a yellow sharps bin together with the empty vial/ampoule/syringe for incineration
- Larger volumes of liquid should be expelled from their container into a yellow sharps bin

Dropped/broken ampoules/vials must be carefully cleaned up according to ward/clinical area procedures. The action must be witnessed and recorded in the controlled drugs register by a registered nurse and second registered nurse/doctor.

Liquid preparations (e.g. Oramorph®) often contain ‘overage’ in the bottle such that there will be more than the nominal bottle volume. If the total contents of the bottle have been correctly administered according to the nominal bottle volume and the controlled drugs register and there is a volume remaining in the bottle, it should be destroyed and witnessed as above by registered nurses. The CD register should be annotated to indicate that destruction of an overage has occurred. – this is not current practice – see sop for stock checks

Appendix 13: Midwives and Controlled Drugs

Registered midwives may possess, and administer parenterally, a number of specified CDs in the course of their professional practice. This is covered by The Prescription Only Medicines (Human Use) Order 1997 (SI 1997 No. 1830) and The Misuse of Drugs Regulations 2001 (SI 2001 No. 3998). The specified CDs are diamorphine, morphine, pentazocine lactate and pethidine hydrochloride. Midwives rules and standards (NMC 2012) state that a practising midwife should only supply and administer those medicines in respect of which she / he has received the appropriate training as to use, dosage and methods of administration and for which they are exempt.

Supplies may only be made to a midwife on the authority of a Midwife's Supply Order signed by the 'appropriate medical officer' who is a doctor authorised in writing by the local supervising authority or the person appointed by the local supervising authority to exercise supervision over midwives.

The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

The midwife must keep a record of supplies received and administered in a book used solely for that purpose.

Midwives may administer doses of morphine, diamorphine and pethidine during labour according to local guidelines using the midwives exemption. The 'doses administered without prescription' section of the prescribing and administration chart must be completed. Ward stock should be used for this administration.

Practising in the Community
Midwives practising in the community must comply with the local clinical protocol for the administration of pethidine within the Obstetric Directorate.

All community-based midwives should follow the locally agreed guidelines (August 2000 COMM2 OBS/GYNAE) for the supply, storage, return and disposal of controlled drugs, and prescription only and other medicines, by a community midwife.

Community midwives should advise a woman to destroy any unused controlled drugs which have been prescribed by her GP, and suggest she does so in the midwives presence. Alternatively community midwives can advise the woman to return the unused controlled drug to the pharmacist from where it was obtained. Community midwives must not return unused controlled drugs themselves (NMC 2004 Midwives Rules and Standards, Rule 7).

When a woman is cared for in, or transferred to, the Obstetric Directorate, the community midwife must use drugs and medicines supplied in the Directorate and comply with the local protocols, policies and procedures in respect of drug administration.

Appendix 14: Ward or Department Closure

When wards or departments close for a period of time, a decision must be made as to whether or not the controlled drug storage remains safe and controlled within the vacated area. The Matron still has overall responsibility for the stock of CDs within a vacated area.

If necessary CDs can be stored in Pharmacy Directorate whilst a ward or department is closed if this is more appropriate from a security point of view.

If the CDs are left on the ward or department, there must be very specific arrangements in place for the security of, and access to, the controlled drug cupboard keys.

When a ward or department closes permanently, the controlled drugs will be destroyed or returned to Pharmacy Services for re-use.

The ward or department Controlled Drug Register and Requisition Book must be retained by the relevant matron for a minimum of two years from the date of the last entry.

Permanent Ward Closure or Re-designation
If a ward is to close or be re-designated on a permanent basis such that ward stocks of CDs are no longer required a pharmacist should remove stocks from the ward in accordance with local SOPs and return them to the pharmacy. If suitable for re-use the CDs should be "returned" on the pharmacy computer system and value credited to the ward and placed within pharmacy stock. If the drugs are unlikely to be used before their expiry date they should be written off as expired stock and not credited to the ward.

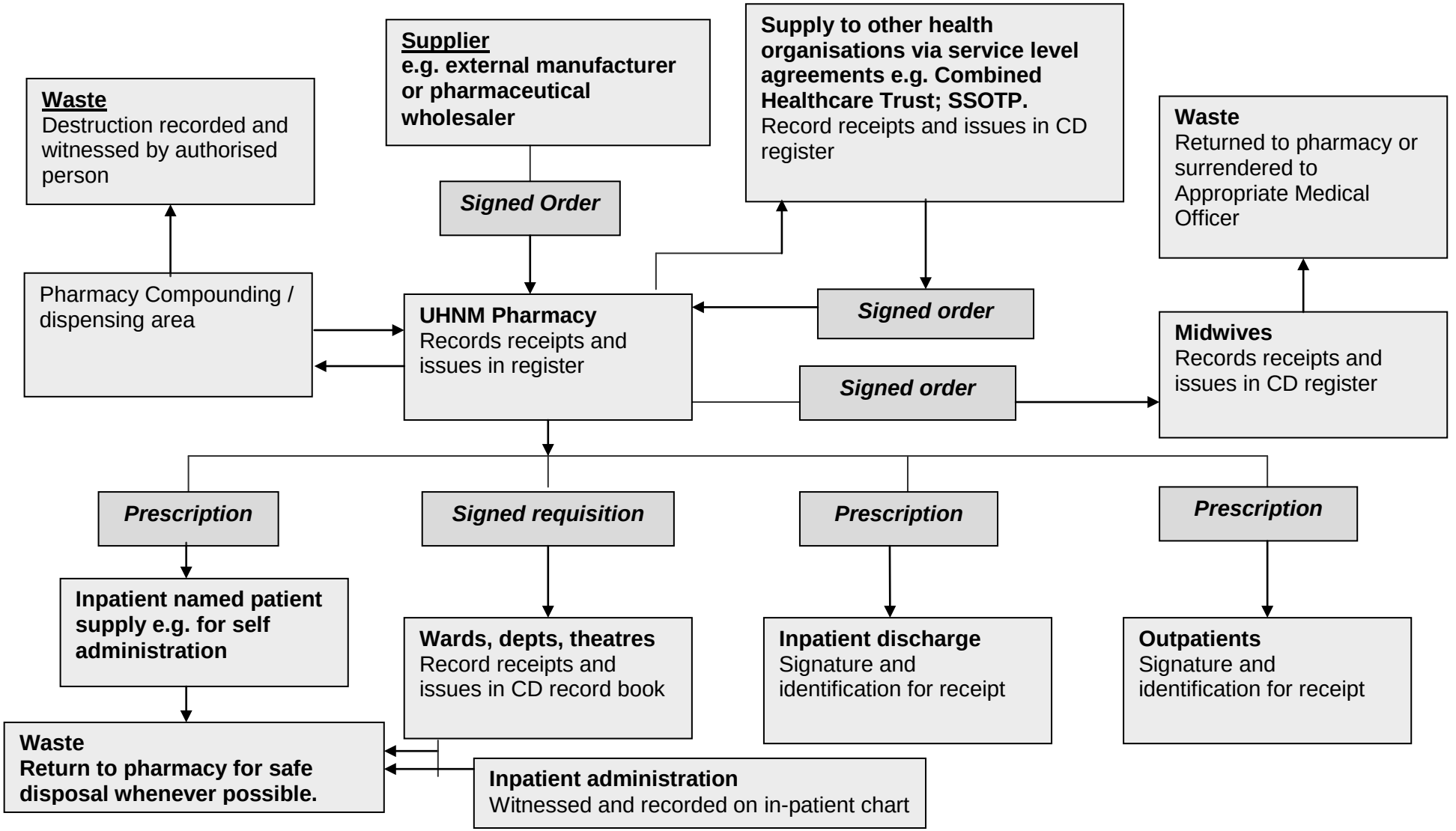
Temporary Ward Closure and Ward Relocation
In the case of a temporary closure stocks may need to be returned to pharmacy. For relocation of a ward the pharmacist and nurse in charge may elect to personally and physically remove the stock from one controlled drug cupboard, check the stock and move to the new CD cupboard. Alternatively, if there is likely to be a delay in the move or security is likely to be compromised by the presence of contractors or non-Trust personnel, stock should be removed from the ward CD cupboard and returned to the pharmacy for secure storage. These controlled drugs will be stored within the pharmacy CD cupboard separated from existing pharmacy stock. They may then be returned to the relocated ward when the move is complete and security is ensured.

Entries in the Ward Controlled Drugs Record Book
The pharmacist and nurse/midwife in charge or their authorised deputy should check the CD stock against the quantities in the Ward Controlled Drugs Record Book.

For each item the record should be:

- Annotated with the date and time of the stock check
- Signed out, "check of stock level and X (number of dose units) returned to pharmacy prior to the move."
- The new stock level should be recorded as zero and signed by the pharmacist and nurse or midwife in charge.

Appendix 15: Controlled Drug Journey at UHNM



Appendix 16

Standard Operating Procedure (SOP)

MM06-SOP-8 Disposing Of Patient's Own Controlled Drugs At Ward Level During The Covid-19 Pandemic

V1 December 2020

University Hospitals of North Midlands NHS Trust

Purpose:
This document has been prepared to support the disposal of Patient's Own Controlled Drugs at ward level during the Covid 19 pandemic and aims to:

i. Provide formal standards, safe systems of work and consistency of approach for actions to be taken regarding the denaturing and disposal of Controlled Drugs.
ii. To ensure that the denaturing and disposing of Controlled Drugs is carried out in accordance with legislation applicable to Controlled Drugs and Waste.
iii. Support registered practitioners in their practice

Scope:
This SOP strictly applies to:
- Patient's Own Controlled Drugs that are stored on wards / departments undertaking aerosol generating procedures e.g. critical care and wards with patients using CPAP.
- Patient's Own Controlled Drugs that belong to Covid positive patients that require disposal.
- This does not apply to ward stock CDs in these areas or POD CDs on any other ward.
- Trust employed NMC registered nursing staff and other registered practitioners who may be involved in the disposal of Patient's Own Controlled Drugs at ward level.

Roles and Responsibilities:
Trust Accountable Officer for Controlled drugs :
The Trust Accountable Officer for Controlled Drugs is responsible for:
- Authorisation of this SOP
- Ensuring that the Trust has an up to date T28 exemption certificate in place to allow for the denaturing and disposal of CDs.

Associate Chief Nurse / Matrons:
The Associate chief nurses are responsible for:
- Investigating any incidents relating to the process described in this SOP, liaising with the lead pharmacist.

Sister / Charge Nurse
Ward/departmental managers are responsible for:
- Ensuring that all staff are trained to an appropriate level of competence according to this SOP as part of the induction process/on-going training mechanisms.
- Ensuring that there is appropriate and sufficient stock of pre-packs are available.
- Must report and investigate any controlled drug balance discrepancies immediately as per Trust policy MM06.
- Ensuring that registered nursing staff and registered practitioners have completed the Mandatory Medicines Management Training packages 1, 2 &3 which are available on ESR.

All registered nurses / practitioners:
All registered nursing staff are responsible for:
- Ensuring safe management & accountability for Controlled Drugs
- Meeting minimum standards in their own practice.
- Ensuring compliance with the SOP
- Alerting the sisters/ charge nurses to non-compliance with the standards & recording via Datix.
- Ensuring that Mandatory Medicines Management Training has been undertaken.
- Reporting any controlled drug balance discrepancies immediately as per Trust policy MM06.

Related Documents:
- Trust Policy MM03: Medicines Management Policy
- Trust Policy MM06: Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs

- NMC Standards of conduct, performance and ethics for nurses and midwives (latest version)
- EF05: Trust Waste Management Policy

Training:
1. Read the SOP
2. Conduct the process with a member of pharmacy staff experienced in denaturing Controlled Drugs the first time the process is completed.

No.	Instruction	Photograph / Diagram
1	**Safety requirements:** • Personal protective equipment (PPE) is required. • Firstly observe current UHNM Covid 19 PPE guidance. <u>CD disposal specific guidance:</u> • Gloves must be worn at all times when directly handling any medication. • If there is a risk of powder escaping into the air a mask should be worn. • If there is a risk of splashes goggles should be worn.	
2	**Staff authorised to undertake the process:** o Two registered practitioners must complete the whole process, one as a witness. o Ideally one practitioner will be a nurse / ODP / midwife from the ward / department where the POD CD waste is generated. o A pharmacist / pharmacy technician can act as witness if needed.	
3	**POD Controlled Drugs that need to be denatured at ward level:** Any CD stored in the ward CD cupboard(s) in any form as per Trust CD Policy MM06 needs to be denatured. This includes Morphine Sulphate 10mg / 5ml oral solution (Oramorph) & concentrated potassium / Addiphos.	
4	**Preparation & denaturing:** Assemble the required equipment: o CD denaturing kit (also known as DOOP kit – see photo) o POD CD register o Measuring equipment if required for liquids o Gloves and any other personal protective equipment required See Appendix 1 for instructions on how to denature each form of Controlled Drug safely and effectively. Ensure that PPE guidance is observed at all times.	
5	**CD Register entry requirements:** • The denaturing / disposal of all Schedule 1, 2 & 3 CDs must be entered into the POD CD Register. • Select the item that requires denaturing. Check that it is a Patient's Own CD brought in from home. • Find the relevant entry in the POD CD register. • Compare the product with the entry checking that it corresponds: o Patient's name / unit number o Medicine name	

No.	Instruction	Photograph / Diagram
	o Strength o Form o Quantity. o Note: If the item is a liquid and the tamper evident seal is intact there is no requirement to measure the liquid. If the seal is not in tact the staff must estimate the physical volume against the volume recorded in the CD register. If it looks to be correct then dispose of. If there looks to be a variance then the volume must be physically measured. Discrepancies must be reported and investigated as per CD Policy MM06. • Make a new entry as usual entering: o Date and time o Medicine name o Strength o Form o Quantity o Patient's Name o Destroyed by: o Witnessed by: • The person destroying the CD must sign against 'destroyed by:' and date. The signature must be recognisable. • The witness must sign against 'witnessed by:' and date. The signature must be recognisable. Example entry: 14.4.2020 17:20 30 x Morphine 10mg MR capsules for Dorothy Smith Destroyed by: S.Taylor Witnessed by: P.Lewis	
6	**Prohibited practices** • Controlled Drugs must never be disposed of before being denatured. The only exception to this is part vials wasted during administration as per CD Policy MM06. • Controlled Drugs must never be disposed of into the sewerage / water system.	
7	**Final disposal** • Disposal kits containing denatured controlled drugs must be placed into a Sharpsmart yellow bodied rigid pharmaceutical clinical waste bin (see picture opposite). • Ideally a part used bin will be used as once the disposal kit has been added the bin must be closed and sealed. • Sharpsmart destroy the contents of all yellow bodied yellow lidded bins by incineration in accordance with legislation.	

Appendix 1: How to denature Controlled Drugs

FORM	METHOD OF DENATURING	PICTURE
TABLETS / CAPSULES	• Wear gloves • Remove from outer packaging (e.g. cardboard box) • Remove from blister packaging if present. • Place the whole unit (e.g. capsule) into CD denaturing kit • Place the empty outer blister into the Sharpsmart yellow bodied yellow lidded waste bin.	
LIQUIDS	• Wear gloves and other PPE if required. • After measuring pour from the outer container into CD denaturing kit • Be aware of risks of splashing and spills • Rinse the bottle out with water. Pour the rinsed water into the CD denaturing kit. • Place the empty bottle into the Sharpsmart yellow bodied yellow lidded waste bin.	
SACHETS	• Wear gloves • Open the sachet • Pour the contents into CD denaturing kit • If there is a risk of inhalation wear a face mask / goggles if required. • Put the empty sachet packet itself into the CD denaturing kit.	Example: MST Continus sachets
AMPOULES CONTAINING LIQUID	• Wear gloves • Open ampoule and empty contents into the CD denaturing kit. • Put the empty ampoule into the CD denaturing kit. • Be aware of risks of sharps injuries / splashing / spills.	
AMPOULES CONTAINING POWDER	• Wear gloves. If there is a risk of inhalation wear a face mask / goggles if required. • Open ampoule and empty contents into the CD denaturing kit. • If the powder will not come out of the ampoule add a small amount of water to dissolve the liquid inside. Pour resulting mixture into the CD denaturing kit. • Be aware of risk of sharps injuries. • Put the empty ampoule into the CD denaturing kit.	

PATCHES	• Wear gloves • Remove the backing from the patch • Fold the patch over onto itself. • Place the patch and backing into a CD denaturing kit.	
AEROSOL FORMULATIONS	• Aerosols must be expelled into water to prevent droplets from entering the air. • A facemask must be worn. • Carry this out in a well-ventilated area with no other staff around. • Pour the resulting mixture into the CD denaturing kit. If the aerosol cannot be rinsed out, where denaturing kit. If this is not possible a sticker must be placed on the outside of the aerosol stating 'product denatured' and the item should be placed into the Sharpsmart yellow bodied yellow lidded waste bin.	

ADDITIONAL CONSIDERATIONS

- If a mixture of dosage forms are being denatured in the same CD denaturing kit it would be preferable to denature solid formulations first and liquid formulations at the end where possible.
- If there are no liquid formulations for denaturing then water must be added to the denaturing kit *after* all intended CDs have been added.
- Follow the manufacturer instructions on the side of the CD denaturing kit when finished. Ensure that more destruction kits are ordered via your ward pharmacy team to replace the ones that have been used.
- Once the denaturing process has been completed and lid replaced, place the denaturing kit into the Sharpsmart pharmaceutical waste bin (yellow body with yellow lid).