Controlled Drug Prescribing Policy

Authors	**Dave Kirby** Associate Director, Clinical Professions
Corporate Lead	**Ruth Burnett** Medical Director
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Executive Summary

The Leeds GP Confederation is committed to the safe, effective and efficient use of Controlled Drugs (CDs) to support the provision of high quality care to patients. The CD Prescribing Policy (CD policy) ensures staff have access to information on the law, best practice and safe systems of working in relation to management of CDs.

The CD Policy is a resource to help staff achieve the safe and secure prescribing,

supply, administration, storage and disposal of controlled drugs in line with current legislative requirements and best practice. It applies to staff employed directly by Leeds GP Confederation as well as staff contracted on a sessional or secondment basis. It should be consulted in conjunction with the Leeds GP Confederations Medicines Policy.

For the safe use and management of controlled drugs in primary care, robust systems and processes are needed. The main key areas relating to controlled drug practice within primary care include:

• Secure prescribing – to reduce controlled drugs related incidents including patient safety incidents
• Obtaining and supplying
• Administering
• Handling (including storing, transporting, possessing, disposing and destroying)
• Monitoring and auditing the management and use of CDs

Contents

1. Introduction

Since the Shipman Enquiry's Fourth Report in 2004 there have been significant legislative changes to the Misuse of Drugs Act 1971 to strengthen the governance arrangements for controlled drugs.

The aims of these legal changes are to encourage good practice in the management of CDs and to help to detect unusual or poor clinical practice systems, criminal activities or risks to patients.

The Leeds GP Confederation has a responsibility to assure the quality of CD management, with external inspection where appropriate as an additional safeguard.

Compliance with appropriate legislation relating to the prescribing, supply, documentation, safe custody and administration of CDs is one of the core standards of the Healthcare Commission's Standards for Better Health.

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 carried forward the main provisions of the 2006 regulations and introduced new provisions to reflect the changes made to the structure of the NHS in England as a result of the Health and Social Care Act 2012.

The responsibility for leading Controlled Drug Local Intelligent Network (LIN) meetings now lies with NHS England CD Accountable Officers.

The Department of Health's information about the Controlled Drugs (Supervision of management and use) Regulations (2013) provides support and additional information about the changes made to the regulations which came into effect on 1 April 2013.

2. Scope

This policy addresses the safe management of Controlled Drugs (CDs) by clinical and non-clinical staff at Leeds GP Confederation; including storage, prescribing, documentation, and disposal of unused CD medicines. Clear processes of monitoring and auditing the use of CDs, appropriate documentation and information sharing regarding incidents related to CDs will be embedded in all CD protocols.

The policy applies to all staff directly employed or contracted by Leeds GP Confederation, or those subject to its policies and procedures under the terms of service level agreements as part of their statutory obligations. It should be read in conjunction with the Leeds GP Confederation's medicines policy, and other related policies.

3. Responsibilities

The **Chief Executive** has overall responsibility for the strategic and operational management of Leeds GP Confed including ensuring that all policies comply with all legal, statutory and good practice guidelines.

The **Medical Director** has Board level responsibility for the management of medicines, and ensuring their safe and secure handling, within the Trust's service delivery

The Controlled Drug Governance Lead is responsible for the monitoring, safe use and management of controlled drugs in the organisation. A CD Accountable Officer of a commissioner/ provider body must establish and operate appropriate arrangements for securing the safe management and use of CDs and to review them as appropriate. However, there is no need for an accountable officer within the Leeds GP Confederation structure due to the nature of not storing or supplying controlled drugs. Should this situation changes as part of the Leeds GP Confederation's structural evolvement, one will be nominated.

The **Safeguarding Lead** is responsible for providing support, supervision and advice for any staff member with a safeguarding or child protection concern.

The **Head of Operations** is responsible for the implementation and adherence to the Controlled Drug Prescribing Policy by staff within their service, paying particular attention to new staff and locums. They are also responsible for the implementation of local procedures and guidelines to support the safe and secure handling of medicines within their service as outlined within the Medicines Policy.

Healthcare professionals are personally responsible for their professional practice and are expected to adhere to professional codes of conduct as specified by their relevant professional bodies'. All staff that are registered with a

professional body must ensure they maintain their professional registration and any associated stipulations or conditions of registration i.e. Continual Professional Development. Each registered professional must take steps to rectify any gaps in their knowledge or competence to ensure that standards of care are safeguarded. Professional staff are also responsible for ensuring that duties are only delegated to those staff with the appropriate knowledge and competence to carry them out.

All staff are responsible for properly discharging their duties and responsibilities in relation to medicines, including storage, handling, prescribing, administration and destruction. All staff employed by Leeds GP Confederation who are in any way involved with the handling or use of medicines and controlled drugs must familiarise themselves with the correct principles of the Medicines Policy and any associated service specific guidelines and protocols. Standard Operating Procedure (SOPs) must be available to every team and base in which they work. Further advice and information on the safe and secure handling of medicines is available from the Confederation's Professional Lead for Pharmacy.

4. Principles and Purpose

The key principles which govern the safe management and use of CDs are:

- Compliance with current legislations
- Adherence to guidance and actions issued by government bodies: MHRA, National Patient Safety Alerts
- Assurance of the safe and effective use and management of CDs within Leeds GP Confederation team
- The opportunities for CDs to be abused or diverted are minimised
- Promotion of transparent and open culture of sharing learning about good practice of CD management and well-founded concerns.

- Established process of monitor and audit of the management and use of CDs to pick up near-misses and poor performance promptly.

5. Definitions

- *Controlled Drug* (CD) - is a drug identified by the Misuse of Drugs Act 1971 and related Regulations as having potential for diversion and misuse. The

Regulations divide the CDs into five Schedules with differing levels of control, depending on therapeutic benefit balanced against harm when misused.

- *Standard Operating Procedure* (SOP) - an SOP is an unambiguous document, describing the responsibilities and procedures, including audit, necessary to safely and accountably manage any set of processes, in this case around the total management of CDs. An SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of CDs in an individual setting.
- *Local intelligence network* (LIN) – Group of AOs and relevant persons from health, social care and police organisations meeting to share information on the assessment and investigation of local CD concerns as required in the Controlled Drugs (Supervision of Management and Use) Regulations 2006. All organisations involved work together to use the intelligence gathered to improve patient and public safety with regards to the safe and secure handling, management and use of controlled drugs.

6. Handling of Controlled Drugs

Stocks of controlled drugs are not, and should not be handled, i.e. stored, transported, possessed, disposed and destroyed as part of the Leeds GP Confederation's services.

Standard operating procedures (SOPs) for the use and management of controlled drugs is one of the measures introduced in new regulations made under the Health Act 2006 to help ensure good practice throughout the health and social care system.

All clinical and non-clinical staff at Leeds GP Confederation whose duties may involve aspects of work involving controlled drugs should be familiar with SOPs which relate to processes in which they are involved.

7. Standard Operating Procedures (SOPs)

There are 4 SOPs detailed within this CD Policy:

- A - Prescription of Controlled Drugs

- B - Monitoring and Auditing the management and use of CDs

- C - Management of Discrepancies/Concerns

- D - Controlled Drugs Governance

STANDARD OPERATING PROCEDURES

A- Prescription of CDs

Practitioners responsibilities:

• Must act within the legislation and professional responsibilities relating to controlled drugs
• Must ensure that having read the policy they consider themselves competent to act in accordance with it. Any CPD requirements must be addressed immediately.
• Registered practitioners are expected to be familiar with, and follow at all times, their own professional code of practice in relation to medicines. These include
    • Medical: GMC guidance on good medical practice
    • Nursing: NMC guidelines for the administration of medicines
    • Pharmacist: GPhC Standards of Conduct, Ethics and Performance

All practitioners are accountable for their actions and omissions. In all actions involving CDs they must exercise their professional judgment and apply their knowledge and skill in a given situation.

When a clinician makes a decision that controlled drugs are required for the treatment of a patient's condition, the preferred option is for the required drugs to be prescribed on an NHS FP10 (or electronically authorised) prescription and then dispensed via a community pharmacy

The quantity of medication prescribed or supplied must consider both the needs of the patient and any risks associated with the particular medication or patient.

Quantities of opioids should normally be limited to 28 days supply as good practice

Before prescribing opioid medication; the clinician should*:

- ✓ Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed to the patient.
- ✓ Ensure where a dose increase is intended, that the calculated dose is safe for the patient
- ✓ Ensure familiarity with the following characteristics of the formulation you are supplying or administering
    - o therapeutic starting dose as per indication

- frequency of administration
- standard dosing increments
- symptoms of overdose
- common side effects

Accurate recording of drugs prescribed is the responsibility of the clinician.

All medication should be recorded in the patient record

A Non-Medical Prescriber must only prescribe controlled drugs if they are legally entitled to do so. They must not prescribe beyond their limits of competence and experience. Legally the prescription must include the dosage to avoid uncertainty on administration. Please refer to Controlled drugs: safe use and management (NG46) published by the National Institute for Health and Care Excellence (NICE), April 2016 which can be found at: https://www.nice.org.uk/guidance/ng46 for further advice

- ***Prescribing Controlled Drugs***

- *Step 1* – clinical decision-making process

    - Specialist advice or literature may be necessary to guide drug selection. It is particularly important to double-check any calculations when converting from an oral to a parenteral preparation or from one opioid to another.
    - Carefully consider cautions, contra-indications and drug interactions

- *Step 2* – Writing the prescription

    - Electronic prescription writing should be used wherever possible. Additional care is required when writing a prescription for a controlled drug to ensure that all legal requirements are met; prescriptions which do not fulfil all legal requirements will be refused by community pharmacies.
    - Please ensure, the following: - Drug name, form & strength are included in full, i.e. no abbreviations
    - The quantity to be supplied is written in both words & figures
    - Clear dose directions are included (‘as required’ or ‘as directed’ are not acceptable)
    - Signature (electronic via smartcard/EPS or handwritten in the event of business continuity issues) & date evidenced
    - Free text electronic prescriptions should not be used for CDs

- *Step 3* – Final check of prescription details

    - All details should be double-checked before handing/sending the prescription to the patient/carer or community pharmacist.
    - When using electronic prescribing, particular care is required to ensure the correct preparation has been selected.

- *Step 4* – Record keeping

    - Details of all medication prescribed must be added to the patient's electronic medical record promptly and accurately.

- *Step 5* – Controlled Drugs in Patients' Homes

    - Individual doses of CDs that have been prescribed for a patient and are no longer required are the patient's property (even after death). Clinicians and Leeds GP Confederation staff should advise patients or carers to return these to a community pharmacy.
    - Compliance with these action points is mandatory as per the National Patient Safety Agency (NPSA) Rapid Response Report on 'Reducing Dosing Errors with Opioid Medicines': July 2008

Prescriptions for Schedules 2 and 3 CDs can now be sent electronically via the Electronic Prescription Service (EPS) and signed with an Advanced Electronic Signature (AES) as well as handwritten. This follows changes to Home Office legislation on 1 June 2015 and to NHS and Human Medicines Regulations on 1 July 2015.

Resources

- The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015
- The National Health Service (Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service) Regulations 2015
- The Human Medicines (Amendment) (No. 2) Regulations 2015

B- **Monitoring and Auditing the management and use of CDs**

Twelve monthly audits on controlled drug prescribing within Leeds GP Confederation should take place.

This audit aims to cover CD prescriptions within 4 analyses:

- Group 1 (multiple drugs, same patient) analysis
- Group 2 (>1/12 supply) analysis
- Group 3 (ratio of shifts: prescriptions) analysis
- Group 4 (high dose CDs) analysis

Results will be reported to the Leeds GP Confederation's Quality Committee.

C- **Management of discrepancies/concerns**

Due to the potential dangers associated with the misuse, abuse or diversion of controlled drugs, it is essential that any discrepancies, suspicions or incidents relating to controlled drugs are taken seriously and reported. This could involve any of the following but not exclusive to:

• Missing CDs

• Suspicions of attempt by patient to obtain CDs by deception/theft

• Suspicions of attempts by clinician/staff to obtain CDs by deception/theft

• Prescribing/Supply of CDs outside of Policy

• Handling of CDs outside of Policy

• Significant events/errors/complaints relating to CDs

The following procedure should be followed:

Step 1 and 2 need to be performed within 24 hours of the rise of concern

Step 1: The concern should be reported immediately to the senior manager on call

***Step 2**:* The controlled drug governance lead and on-call manager must seek to obtain further details of the event. The reporting manager needs to make an assessment of whether there is any suspicion of criminality and whether any immediate danger remains. Further advice can be sought from the controlled drug governance lead.

Step 3 and onwards can be performed on the following working day unless there is reason to suspect criminality or any immediate danger to person or property

***Step 3**:* In the event of suspicion of theft of CDs or other criminality, the police needs to be contacted. If an immediate danger is identified (e.g. suspicion that an overdose has been taken) then this needs to be handled in the same way as t any other medical emergency Please consult the Medicine Safety Officer and/or Governance and Medicine Safety team for further advice as appropriate.

***Step 4**:* The incident needs to be reported as a significant event/incident' on DATIX

***Step 5**:* The incident will be dealt with as detailed in the Incidents Policy.

***Step 6**:* Where a suspicion exists about a clinician, but is not proven, it is the duty of Leeds GP Confederation to share this suspicion with other agencies via the Local Intelligence Network for CDs.

D- Controlled Drugs Governance

The Care Quality Commission (CQC) reports in The safer management of controlled drugs: Annual update 2020:

1. Providers need to include controlled drugs governance as part of their COVID-19 recovery plans
2. Providers should enable all health and care staff to freely engage and participate in activities that support reflection and learning
3. Those leading and working in local health and care systems need to collaborate to reduce risks of avoidable harm associated with controlled drugs
4. All health and care professionals need to prioritise personalised patient care in the context of controlled drugs

The GP Confederation aims to embed these recommendations within its scope of routine practice associated with the management of use of controlled drugs.

Policy Consultation Process

Title of Document	Leeds GP Confederation Controlled Drug Prescribing Policy
Author	Dave Kirby
New / Revised Document	Revised
Lists of persons involved in developing the policy	Dave Kirby Heather Edmonds Simon Boycott Phuong Nguyen

List of persons involved in the consultation process	