National Clinical Assessment Service

NHS Clinical Governance Support Team

Royal Pharmaceutical Society of Great Britain

NHS National Patient Safety Agency

Clinical Governance Toolkit for Controlled Drug Management in Primary Care in the NHS

Guidance for Accountable Officers and their staff

1. **Background**

2. This document aims to provide support and information for those such as Accountable Officers who will be involved in implementing the monitoring and inspection of systems for control of controlled drugs (CDs) as part of the overall clinical governance review of practices. The recommendations from the 4th Shipman Inquiry will require that practices submit an annual controlled drug return to their Primary Care Trust (PCT) [***Appendix 1***]. This return will require practices to document their use of controlled drugs (CDs) and issues pertaining to their adherence to the Misuse of Drugs Act 1971 and their associated Regulations. In addition, PCTs will be required to monitor the use of controlled drugs by practitioners and to determine whether further investigations are required when idiosyncratic prescribing or practice is identified. Compliance with Standards for Better Health will also require: **(C4) Health care organisations keep patients, staff and visitors safe by having systems to ensure that……medicines are handled safely and securely.**

3. This toolkit should be used in conjunction with the annual CD return and provides support and information for those such as Accountable Officers and their staff who will be involved in developing and implementing the new governance arrangements for controlled drugs as part of the overall clinical governance arrangements for GP practices, community pharmacies and other primary healthcare providers.

4. The overriding objective of these new processes is to promote a greater understanding of best practice in the prescribing and use of CDs and through this, to improving patient care. As the government said in its response to the Shipman Inquiry's 4th report, strengthened systems of governance will help the vast majority of healthcare professionals who want to provide the best possible care for patients, as well as deterring the small minority who may be tempted to abuse their professional position. The guidance set out in this document should be understood in this light.

5. The guidance outlines processes for investigating apparent anomalies or idiosyncratic prescribing of controlled drugs in primary care and how the less common causes of idiosyncratic prescribing, including poor professional performance, fraud and criminal behaviour might be identified and investigated.

6. This document has been aimed specifically at general practitioners working within the NHS. However, it provides a framework that can equally apply to other professional groups

with prescribing responsibilities, such as Supplementary and Independent prescribers.

7. This is intended to be used in conjunction with the high level guidance available on http://www.dh.gov.uk/Consultations/LiveConsultations/LiveConsultationsArticle/fs/en?CONTENT_ID=4114886&chk=c1v7Dp

8. While enhanced monitoring and inspection has been introduced in response to the Shipman Inquiry, individuals with a responsibility for monitoring and inspecting use of controlled drugs should use this process as an opportunity to promote a greater understanding of best practice in the prescribing and utilisation of controlled drugs and through this, to improving the quality of patient care.

9. The document advocates a standard approach to investigating problems so that:

   - Policies and procedures can be publicised in advance
   - Issues such as the need for confidentiality at some stages of an investigation and how information will be shared and retained can be discussed and agreed in advance
   - The linkage to local clinical governance and risk management processes can be tested.
   - Policies and procedures can be developed that are robust, fit for purpose and able to withstand legal challenge
   - Information on best practice can be shared

The vast majority of practitioners, who purchase, prescribe, dispense, administer and destroy controlled drugs do so in keeping with legislative requirements and their professional code and practise to a high standard.

10. Context

11. Over 2.7 million prescriptions for controlled drugs were issued in the year from April 2002 to March 2003. The number of Schedule 2 and Schedule 3 controlled drug items issued is increasing at an annual rate of 8%.

12. Detailed analysis of this prescribing data has indicated that the vast majority of these prescriptions were entirely appropriate and adhered to national good practice guidelines for the management of opiate addiction, pain and treatment of attention deficit disorders in children. Experience has shown that

most examples of unusual prescribing are explained by exceptional patient-need rather than poor clinical performance, fraud or criminal behaviour. However, Accountable Officers and their staff should always be alert to the possibility, however remote, that apparently anomalous clinical practice really is an indicator of serious underlying problems.

13. The purpose of this guide is to promote the safe and effective use of controlled drugs. The new governance arrangements must be implemented in a way that supports professionals in their clinical practice and does not deter them from prescribing these important medicines when clinically required by patients.

14. **Routine monitoring prescribing of controlled drugs**

15. The role of the Accountable Officer has been introduced and it is anticipated that they will be expected to develop and implement systems for monitoring the management of controlled drugs at PCT (or group of PCTs) level.

16. The Accountable Officer should have appropriate professional standing and be a senior executive officer of the organisation (i.e. they should be an Executive Director or report directly to an Executive Director). They should have credibility with all healthcare professionals and sufficient seniority to be able to take action regardless of how a concern is raised. Wherever possible, they should be independent of the organisation's day-to-day use of controlled drugs. It is unlikely that the Accountable Officer will be directly involved in investigating possible transgressions or problems. Rather, their role will be one of coordination, strategic overview and advising and supporting professionals at local level.

17. As part of the routine monitoring process each PCT should undertake a risk assessment of their local controlled drug and/or substitute prescribing policy/guidelines. Policies/guidelines that are too stringent (such as limits on what can be prescribed) or advising on treatment that falls below national good practice guidelines (such as too low a dose of substitute medication) may have the effect of lowering the threshold for GPs triggering concern.

18. Overview of the new arrangements

19. The key principles of the DH high-level guidance, safer management of controlled drugs - draft guidance on strengthened governance arrangements, as they apply in primary care, are:

Each PCT will be required to appoint an "Accountable Officer", a senior professional executive of the PCT, with responsibility for promoting the safe and effective use of CDs within the PCT;

The Accountable Officer will be responsible for setting up appropriate clinical governance mechanisms, which will include:

i routine monitoring of CD usage patterns, including the occasional use of on-site inspections

ii regular clinical governance reviews of the use of CDs by GP practices and other primary healthcare providers

iii further investigation of apparent anomalies

iv decisions on appropriate action where such investigations indicate performance problems.

20. Following the model developed by the NCAS [give reference] there should be a clear separation between the investigative and decision-making steps. Accountable Officers will therefore normally delegate steps (i) to (iii) but are likely to be personally involved in step (iv). Some PCTs may wish, as recommended in the NCAS guidance, to develop joint units serving several PCTs to carry out the highly specialised activities in steps (i) to (iii).

21. There are three strands in the routine monitoring of CD prescribing all running in parallel:

22. **Monitoring of positive indicators**

- Reviewing the practice annual report for information including:

    i. A special interest in management of substance misusers, pain control (non malignant pain), palliative care, care of patients in hostels for the homeless, care of patients in a secure environment, care of patients in nursing homes or other situation where controlled drugs may be involved. This information is likely to be in the annual controlled drug review.
    ii. Special characteristics of the practice population; for example large numbers of single homeless, or sickle cell patients

iii. Attendance by doctors or other prescribers on training courses or involvement in continuing professional development related to their special interest area
iv. Adherence to good practice guidelines (e.g. supervised consumption schemes, installement and daily dispensing)
v. Practice audit of controlled drugs use and handling
vi. Handwriting dispensation
vii. Evidence of regular reviews of Standard Operating Procedures and Patient Group Directives

- Assessment of how a practice adheres to the Misuse of Drugs Act 1971 and the associated Regulations (recording, returns and storage)

- Involvement in training joint events such that joint care pathways and clinical guidelines are developed across professional groups.

- Community pharmacist delivering local enhanced service to substance misusers with general practitioners

- Compliance with the NPSA National Reporting and Learning System (NRLS). http://www.npsa.nhs.uk/health/reporting/background

- Part of a clinical network such as the Royal College of General Practitioner Substance Misuse Training Programme. http://www.rcgp.org.uk/drug/index.asp

23. Monitoring of negative indicators

- Significant event audits (e.g. patient death, overdose involving controlled drugs) discrepancies between records

- Patient or carer complaints involving the prescribing and use of controlled drugs.

- Concerns expressed by colleagues e.g. doctor's partners or nursing colleagues, local drugs misuse services, local pharmacists.

- Concerns relayed from Police or drugs misuse services about diverted medication.

24. Bench marking information

- Routine monitoring of PACT data including:

    i. Cost of controlled drug prescribing – on an individual prescription or set against a comparator group of practitioners, practices or PCTs
    ii. Quantity of controlled drugs prescribed – apparently excessive amounts on an individual prescription
    iii. Volume of controlled drugs prescribed - set against a comparator group of practitioners, practices or PCTs.
    iv. Choice of drug [See ***Appendix 2***]
    v. Benzodiazepine prescribing rates form the basis of PCO performance markers and are universally monitored by prescribing advisers. Doctors at the extreme top end of prescribing for this group of drugs may well be prescribing to patients with substance misuse (including alcohol) problems.
    vi. Pre-set alert triggers, set by the Prescription Pricing Authority (PPA), for excessive cost and volume of prescribing.

- Local audits and monitoring – e.g. pre-set ePACT audits of controlled drug injectables; the template audit tool on the NPC web-site; or locally developed systems

25. Investigating specific concerns

26. If routine-monitoring reveals concerns or if alerted to specific concerns through other routes, Accountable Officers will need to arrange for more detailed investigations to be carried out. The Accountable Officer will wish to draw on local sources of advice and expertise as well as the wider network of Accountable Officer colleagues. Local GP performance procedures provide information on local procedures for handling concerns about the performance of general practitioners. (http://www.ncas.npsa.nhs.uk/toolkit) The model it recommends separates investigating from decision-making. A Performance Advisory Group provides specialist knowledge and investigative skills. A Decision-making Group makes decisions on action. In this model, the Accountable Officer may be a member of the Decision-making Group and use it for making decisions on the outcome of the investigation. The Performance Advisory Group may be able to provide the necessary analytical and investigative support.

27. Whichever model is adopted, it is important that information is shared appropriately, with the proper safeguards, aimed at

protecting patients without infringing the civil rights of the practitioner.

28. Whilst the above model has been designed for general practitioners the same model can be used for other professionals.

29. The investigation may involve reviewing the appropriateness of individual prescriptions. The following is offered as a general approach to the areas that should be considered:

- **The prescription** – consider the complete pathway from the preparation and signature of the prescription through to the dispenser and the recipient of the drugs. If the dispensing pharmacy is known, it may be possible to retrieve the prescriptions that gave rise to the cause for concern from the PPA but only for prescriptions dispensed in the previous 14 months. Calling up the actual prescription will have cost implications for the PPA and the PCT.

- **The prescriber** – does the local clinical governance lead (or other professional tasked with governance issues) have any other concerns about the individual prescriber or practice?

30. **The quantity of drug prescribed** - at present clinicians can prescribe any amount of a CD on a single prescription, though the National Drug Misuse Clinical Guidelines recommend that no more than two weeks of substitute medication be issued on a single prescription. The National Prescribing Centre Guidelines recommend no more than 28 days on a single prescription. http://www.npc.co.uk/background_for_cd.htm . Prescribing large amounts on a single prescription may place the patient at risk of overusing the medication and of the medication being diverted. However, there maybe a number of valid reasons why large amounts may be prescribed, such as:

    - Patient requires high dose treatment, for example a patient using a diamorphine syringe driver for pain relief.
    - Patient going on holiday and requiring unusually large amounts.
    - Patient has a very high tolerance to opiates and hence requires large dosages.
    - If Patient is transferring to home to die.

- **The drug** – often, it is the choice of drug that will draw attention to the clinician. There are a number of controlled drugs that when used in primary care, may be an indication that the clinician is not following established good practice and that

his/her prescribing needs further investigation. Examples are included in Appendix 3. However, this is not a comprehensive list and the Accountable Officer and others responsible should be alert to any unusual CD or formulation.

31. The patient and his/her condition – exceptionally, it may be necessary to reconcile the indications for the prescription with the patient and their medical record. This will require the PCO to gain access to the patient's medical record and this should be undertaken only after careful consideration by the local Performance Decision-Making Group and with advice and approval of the Caldicott Guardian.

32. It is expected good practice that PCTs should seek the consent of the patient before accessing identifiable information and PCTs should endeavour to obtain the consent of the patient before seeking access to identifiable information. In some circumstances, where it is agreed [that the public interest justifies disclosure without consent, access may still be provided. Where consent has not been obtained, patients should be informed that disclosure has been required.

33. Taking action once the investigation is completed [*Appendix 4*]

34. Once the investigation has been completed the Accountable Officer will review the results and, if appropriate, arrange for discussion in the PCT's local Performance Decision-making Group. Arrangements should be made to discuss the findings of the investigations with the practitioners who have been subject to investigation and offer their support in promoting good practice in the use of controlled drugs. The practitioner should be told that concerns have been raised and investigated and made aware of any information that is retained.

35. The majority of investigations will demonstrate that unusual prescribing or patterns of drug usage are explained by exceptional patient need rather than poor clinical performance, fraud or criminal behaviour.

36. Following the investigation, the local Decision-Making Group will decide on appropriate further management. Possible outcomes are:

- **Concerns are not substantiated** and the practitioner's prescribing of controlled drugs is appropriate. This will be the case in the

majority of cases that are investigated. The local Decision-Making Group will wish to offer an explanation to the practitioner of why and how his/her prescribing was a cause of initial concern and in view of any circumstances identified, may wish to recommend that the PCT offer help and support to the practitioner. It is important to note however, that transcribing errors can occur at PPA level in recording data from the prescription.

37. **Practitioner's prescribing is irresponsible and/or inappropriate**. Physical or mental ill-health of the practitioner should be considered routinely as a cause of poor performance. Secondary consideration should be to the possibility of drug or alcohol addiction. The local Decision-Making Group may wish to review the help and support they can offer the practitioner and consult with the National Clinical Assessment Service or, if the circumstances are sufficiently serious to call into question the practitioner's registration with their professional body, such as the General Medical Council, the Nursing and Midwifery Council, or the Royal Pharmaceutical Society of Great Britain.

38. **There is evidence of fraud or criminal activity**. The Counter-Fraud Service or the Police should be informed as appropriate. The PCT will wish to limit knowledge of the concerns on a 'need to know' basis and seek its own legal advice. A communication strategy will need to be agreed involving the PCT and the practitioner's colleagues to ensure that public concern is kept to a minimum and risk is managed appropriately.

39. In all cases of unfavourable outcome, the PCT will need to consider how the situation arose and what can be done to prevent a recurrence. A multi-professional review of each incident may be helpful to reflect on issues and the learning outcomes and this information should be shared across the PCT to encourage development of best practice in all prescribers.

Appendix 1

ANNUAL DECLARATION FORM FOR CONTROLLED DRUGS

To be used for all health care units [for example general practice, care home] or individuals working outside these units but carrying out responsibilities where controlled drugs are used or stored (for example, out of hours, forensic medical advisor). This form is designed for general practitioner and general practices, however, it is equally suitable for other settings.

General details	**For example**	
Name and contact detail of person filling in form	Jo Bloggs	
Designation of person filling in form	Practice manager Sports doctor	
CD designated lead if different from above	Dr Smack, Practice CG lead	

Type of Health care organisation	For example General practice Prison Out of hours provider	
Name of PCT	White Stuff PCT	
Name of health care unit	The Street Surgery, 1 Heroin Lane	
About your unit		**Describe if the answer is yes and include as much detail as possible**
Are there any special circumstances about your health care unit, which might influence the use and storage of controlled drugs.	For example, involved in palliative care, high number of drug users, supervised ingestion on site, sporting facility. .	
Are you a dispensing practice		

Are there any roles where you, or your colleagues, may be called upon to carry controlled drugs?	For example, forensic medical advisor, sports doctor, involved in out of hours work	
Have any members of your unit any special training relevant to controlled drugs	For example, substance misuse training, palliative care training	

Specific details

	Yes	No	Comments
Do you keep controlled drugs on the premises			
Have there been any significant events relating to controlled drugs in your unit – for example, death of a patient involving CDs, theft of CDs from premises			

Do any of the practitioners keep controlled drugs on their personal possession, for example, in doctors bag for out of hours use			
Do any of the practitioners keep controlled drugs in any other settings, for example in mountaineering club			
Does your organisation/unit comply with the Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001 and Safe Custody Regulations 1974			
If the answer to above is yes how does your unit			

ensure compliance?			
Has any member of your unit been convicted of an offence under the MDA			
Signed			
Date			
Return to CG lead at relevant PCT named person			

Appendix 2

Examples of information gathered from routine monitoring		
	Reassuring	Concerning
The prescription	Small quantities of controlled drugs on single prescription. Using established good practice controlled drugs, such as methadone mixture For treatment of controlled drug misuse; uses Blue FP10s, with instalment dispensing and supervised ingestion.	Prescribing outside of indications in Table 1. Prescribes large quantities of controlled drugs on single prescription Does not prescribe for instalment dispensing No supervised consumption
The practitioner	Has necessary skills, experience and knowledge to practice at level of service delivery Engages in CPD relevant to area Works in a team approach. No complaints or concerns related to controlled drug use	Practicing outside level of competence. Has not attended CPD in relevant area Does not practice in shared care system Complaints or concerns related to controlled drug use
The practice	Able to demonstrate that they adhere to MDA and Regulations, in terms of storage, recording and dealing with returns. Not an outlier for controlled drugs Significant events: recorded, investigated and acted on. No complaints or concerns relevant to controlled drug use INCLUDE EPACT DATA	Not able to demonstrate that they adhere to MDA regs in terms of storage, recording and dealing with returns. Extreme outlier for controlled drugs – with no reason to expect that this should be the case. Significant events: not recorded, not

		investigated and not acted on. Complaints and concerns relevant to controlled drug use
The PCO	Minimal amount of diverted prescribed medication identified on illicit market. Inline with the UK Drug Strategy, at least 30% of general practitioners involved in the care of substance misusers. General practitioners trained and working under good shared care schemes with drug users	Several areas where diverted prescribed drugs are being sold. Small number of general practitioners involved in care of drug users – these GPs providing care to large number of patients. No shared care schemes for management of drug users
The pharmacist/ general practice interface	Joint meetings to discuss problem patients Pharmacist aware of patient deaths Pharmacist aware of patients receiving palliative care and high dose controlled drugs.	No joint meetings No sharing of information regarding patient deaths, patients receiving palliative care and on high dose controlled drugs.

Appendix 3

Summary of the use and potential misuse of controlled drugs	
Class of controlled drugs	Examples
Drugs that are used by primary care practitioners as part of generalist work	Morphine Diamorphine 30mg or less used for the treatment of acute or severe pain. The NPSA are currently looking at issuing guidance for the removal of 30mg Diamorphine from all out of hours 'doctors bags' as the need for this strength is limited. Oxycodone Pethidine
Drugs that are used by generalist practitioners under shared care arrangements	Methadone Mixture 1mg/ml Buprenorphine- in the form of high dose Subutex (*this is not the same as Temgesic) shared care only*
Drugs that should be initiated only after consultation with a specialist or special interest practitioner	Fentanyl patches
Drugs that should only be used after initiation or consultation with a specialist practitioner and in the context of on-going shared care	Methadone tablets 5mg Methylphenidate Diamorphine 30mg, 100mg, 500mg
Drugs that should rarely be prescribed in primary care	Dipipanone (and cyclizine) Diamorphine reefers Dexedrine for purpose of addiction Dextromoramide for the treatment of addiction Methamphetamine Any Barbiturate for the treatment of addiction Methadone Concentrate (10mg, 20mg, 50mg/ml) for the purpose of addiction Methadone ampoules Cyclimorph preparations

Summary of the use and potential misuse of controlled drugs	
Class of controlled drugs	Examples
Drugs that have a limited place in primary care	All barbiturates
Drugs that may act as markers for inappropriate prescribing	Addicts may request large quantities of Benzodiazepines or dihydrocodeine tablets to potentiate the effect of their illicit drugs, minimise the effect of withdrawal or for diversion to the illicit market. High volume prescribing may indicate a problem with substance misusing patients.

Appendix 4

INVESTIGATING IDIOSYNCRATIC PRESCRIBING OF CDs IN PRIMARY CARE

IDENTIFY

Prescribing Adviser (PA) alerted to idiosyncratic prescribing of CD

INFORM

Inform PCT's Performance Decision-Making Group

Are there immediate concerns for patient safety?
If fraud suspected at this stage, is there a need to secure information?

INVESTIGATE

A. reviewing the appropriateness of individual prescriptions

If possible, obtain individual prescriptions from PPA and review:

The prescription

- Consider the complete pathway from the preparation and signature of the prescription through to the dispenser and the recipient of the CD

The prescriber

- Does the local Performance Decision-Making Group have any other concerns about the individual prescriber or practice?

The quantity

- Patient requires high dose treatment, for example a patient using a diamorphine syringe driver for pain relief.
- Patient going on holiday and requiring unusually large amounts.
- Patient has a very high tolerance to opiates and hence requires large dosages.
- Patient is travelling home to die.

The drug

- The PA should be alert for to any unusual CD or formulation

The patient and his/her condition

- Do the prescriptions relate to repeats for the same patients or many different prescriptions for different patients?

B. reviewing comparative prescribing patterns

Undertake CD prescribing audit and consider:

- **Practice populations** – is the Practice or doctor prescribing for a population that is broadly similar to the comparison population? Have ethnographic issues been considered e.g. large numbers of single homeless or sickle cell patients?

- **Doctors' behaviour, skills and knowledge** e.g. is the general practitioner a GPWSI, drug misuse, palliative care, child and adolescent mental health? A GP lead for hospice, homeless hostel, and care home? GP lead for addiction service? GP lead for patients in secure environments such as prisons.

- Is the need for the prescription supported by the patient's case records?

REVIEW

Report to PCT's Performance Decision-Making Group
Except in cases of fraud or the investigation of criminal acts, the practitioner should be informed that concerns have been raised and investigated.

ACT

Poorly performing clinician?
Discuss with NCAS

Fraud?
Contact CFS

Criminal act?
Inform Police

Appropriate prescribing?

Offer help and support

Consider involvement of Professional Regulatory Bodies

In all cases of unfavourable outcome, the PCT will need to consider how the situation arose and what can be done to prevent a recurrence.