

Community Pharmacy Controlled Drug Audit 2009/10

AUDIT PACK

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INTRODUCTION

Over the last two years there have been a number of changes around the Prescribing and dispensing of controlled drugs. Many of these have been made as a result of the Shipman enquiry and the following are particularly relevant to community pharmacy:

- Prescriptions for controlled drugs are valid for 28 days (previously 13 weeks), this also includes any owings on the prescription;
- Prescriptions for controlled drugs can be computer generated;
- Pharmacists may correct typographical errors and spelling mistakes;
- The back of the prescription is signed by the person collecting;
- The entry in the CD register must include the name of the person collecting the medication and, if it is a health care professional, the entry must include their address (work or home);
- Record whether proof of identity was requested and whether this was provided;
- Pharmacists may elect to keep their controlled drugs register electronically;
- Private prescriptions for schedule 2 and 3 controlled drugs must be on a standardised form (FP10PCD) with the prescribers identification number;
- Up to date Standard Operating Procedures to cover the following:
 - ❖ Who has access to the controlled drugs;
 - ❖ Where the controlled drugs are stored;
 - ❖ Security in relation to the storage and transportation of controlled drugs as required by the misuse of drug legislation;
 - ❖ Disposal and destruction of controlled drugs which includes the requirement to record patient returns;
 - ❖ Who is to be alerted when complications arise;
 - ❖ Record keeping.
- Pharmacists must consider the clinical appropriateness of the Controlled Drug prescribed in line with the NPSA Rapid Response Report issued July 2008:-

<http://www.npsa.nhs.uk/nrls/alerts-and-directives/rapidrr/>

The Royal Pharmaceutical Society of Great Britain has also issued further guidance and recommendations around controlled drugs which although are not legal requirements, they are deemed as best practice:

- Requisitions for controlled drugs are on NHS approved forms;
- Supply of schedule 2, 3 and 4 drugs do not exceed 30 days, prescribers need to justify on the basis of clinical need if a supply greater than 30 days is needed;
- Controlled drug registers contain a running balance;
- A record of schedule 2 patient returned controlled drugs is kept;
- There must be systems in place to report untoward incidents involving the management and use of controlled drugs to the Controlled Drugs Accountable Officer (Dr Peter Magirr).

Aim of the Audit

To assess whether Standard Operating Procedures reflect the recent changes in the management of Controlled Drugs. This audit is intended to compare current practice against legal requirements, the NPSA rapid response report and best practice guidelines as stated in the Medicines, Ethics and Practice (MEP) Guide.

The audit will be partly based on a short questionnaire covering systems and procedures in your pharmacy.

The audit will also seek to assess whether all prescriptions meet the legal requirements for schedule 2 and schedule 3 controlled drugs via a two week data collection exercise.

Criteria and Standards

Criteria	Standard
An SOP is in place to cover the receipt of Controlled drugs	100%
An SOP is in place to cover the safe custody of controlled drugs	100%
An SOP is in place to cover the supply / dispensing of controlled drugs	100%
An SOP is in place to cover the handing out / delivery of controlled drugs	100%
An SOP is in place to cover the destruction of controlled drugs	100%
An SOP is in place to alert the accountable officer when complications arise	100%
All SOPs relating to controlled drugs are up to date and signed by all relevant staff	100%
All prescriptions for controlled drugs are dispensed in line with the NPSA rapid response alert	100%

Method

- Complete the questionnaire provided (Appendix A). The questions relate to pharmacy practice in the pharmacy to which the audit was sent.
- Controlled Drug prescriptions should be reviewed over a two week period. Prescriptions for a schedule 2 or 3 drug written incorrectly should be recorded in the chart provided (Appendix B). To obtain the percentage of prescriptions (forms) that are not written correctly the total number of schedule 2 or 3 controlled drug prescriptions (forms) dispensed in the two week period must be recorded. This information can be recorded by using the tally section on the form for each CD prescription dispensed.
To avoid risk of double counting and the duplication on the recording of the prescriptions, each prescription, once entered on the record, should be marked appropriately.

The success of the audit will depend on the participation of all relevant staff thus all staff should be made aware of the audit.

Timescales

October 2009	Audit pack distributed to Community Pharmacies
Friday 27 November 2009	Deadline for returning data to NHS Sheffield
January 2010	Data analysis and production of report
March 2010	Dissemination of report to community pharmacies

Preparation

Take time to read the audit and appendices thoroughly, then decide what needs to happen and who needs to be involved. Someone in the pharmacy team should take the lead on the audit. They should make sure all relevant staff have been briefed so they are aware of their involvement. The team need to agree a two week period as to when the data collection exercise should take place. The audit lead should be responsible for posting the completed forms back to NHS Sheffield before the deadline. (Friday 27 November 2009). Please return the completed questionnaire, data collection sheet and a copy of your reflective action plan to;

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References

1. NPSA Rapid Response Report dated 4th July 2008. Reducing dosing errors with opioid medicines.
2. RPSGB, Medicines, Ethics and Practice, Edition 33.
3. RPSGB. Legal and Ethical Advisory Service Fact Sheet One; Controlled Drugs and Community Pharmacy.

Questionnaire

1. A SOP is in place to cover the receipt of controlled drugs. (Standard 100%)

Question	Y/N
Is there a SOP in place to cover the receipt of controlled drugs into the pharmacy?	
Does an authorised person take receipt of incoming CD's?	
Is a timely entry made in the CD register? (on the day of transaction or the next following day)	
Are Supplies received checked against the invoice?	

2. A SOP is in place to cover the safe custody of controlled drugs. (Standard 100%)

Question	Y/N
Is there a SOP in place to cover the safe custody of controlled drugs?	
Is the Pharmacist able to exercise continual supervision of controlled drugs at all times?	
Are controlled drugs only out of safe custody while they are actually being dispensed?	
Are patient returns and unwanted stock (eg. out of date stock) stored in a separate place in the CD cupboard?	
Does the SOP cover the checking of expiry dates of controlled drug stock held?	

3. A SOP is in place to cover the supply / dispensing of controlled drugs. (Standard 100%)

Question	Y/N
Is a SOP in place to cover the dispensing of controlled drugs against NHS prescriptions?	
Is a SOP in place to cover the dispensing of controlled drugs against private prescriptions?	
Are all private prescriptions written on specified private prescription forms? (FP10PCD in England)	
Is a SOP in place to cover the dispensing of controlled drugs against a requisition?	
Is there a SOP in place to cover the dispensing of controlled drugs in a compliance aid, if such aids are used for CDs?	

If there is an owing on a prescription is it issued to the patient within 28 days of the date on the prescription?	
Are all staff involved in handling of controlled drugs appropriately trained?	
Are Patient information leaflets issued with all controlled drug prescriptions?	
Does the SOP state a double check is required on all controlled drug prescriptions?	

4. A SOP is in place to cover the handing out controlled drugs. (Standard 100%)

Question	Y/N
Is a SOP in place to cover the handing out of controlled drugs?	
When handing out a controlled drug prescription, is ID requested on each occasion, if patient is not know by staff?	
Is the collection box on the back of the FP10 form always signed by the person collecting the prescription?	
Is an entry made in the Register on the day of transaction or the next following day?	
If controlled drugs are being delivered is a SOP in place to cover this?	
Is appropriate documentation used and an audit trail in place for all delivered controlled drugs?	
Does the register in use capture the following? <ul style="list-style-type: none"> ◆ Date supplied? ◆ Name and address of firm supplied? ◆ Details of authority to possess (prescriber)? ◆ Quantity supplied? ◆ Person collecting controlled drug (if healthcare professional, name and address)? ◆ Was proof of identity requested of patient / representative? ◆ Was proof of identity provided? (in the case of a healthcare professional, proof of identity should be their professional registration number) ◆ Is a running balance kept? (currently good practice) 	
If the controlled drug register is stored electronically, are regular back ups done?	

5. A SOP is in place for the destruction of controlled drugs. (Standard 100%)

Question	Y/N
Is a SOP in place to cover the destruction of controlled drugs?	

Are Schedule 2 Controlled drugs returned by patients recorded in a separate record book specifically for patient returns?	
Is the destruction of patient returned controlled drugs recorded in the separate record book especially for controlled drugs?	
Is the denaturing of patient returned controlled drugs witnessed by another person?	

6. There is a SOP / company policy for notifying the CD Accountable Officer of any CD incidents. (Standard 100%)

Question	Y/N
Does the SOP / company policy include notifying the CD Accountable Officer (Peter Magirr) of any CD incidents?	
Are all issues relating to CD's reported to the Accountable Officer?	
Do you record running balances of CD's?	
If there are any discrepancies is the accountable officer informed?	
Are procedures in place to share learning of significant incidents?	

7. SOP's and records relating to them are up to date and read by all staff. (Standard 100%)

Question	Y/N
Have all regular staff read, signed and dated the SOP's related to controlled drugs within the last year?	
Have all locums and relief staff read, signed and dated the SOP's related to controlled drugs within the last year?	
Are SOP's reviewed annually, (in light of responsible pharmacist now every 2 years) unless an incidence occurs that requires it to be done sooner?	

8. All prescriptions for controlled drugs are dispensed in line of the NPSA Rapid Response Report. (Standard 100%)

Question	Y/N
When an opioid medicine is dispensed does the pharmacist confirm any recent opioid dose, formulation, frequency of administration and any other	

analgesic medicines prescribed for that patient?	
Where a dose increase is intended, does the pharmacist check that the new calculated dose is safe for that patient?	
Does the pharmacist ensure patients are familiar with the following characteristics of their controlled drug: usual starting dose, frequency of administration, standard dosage increments, symptoms of overdose, common side effects.	

REFLECTIVE ACTION PLAN

Identify areas in your practice where you can make changes to help meet the criteria of this audit?

What changes will you make in the future?

- Set practice guidelines
- Outline at least 3 action points to achieve agreed practice standards
- Set a date for a re-audit and compare results to standards

Practice standard	Action points