

Community Pharmacy

Controlled Drugs Audit

AUDIT REPORT

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1. INTRODUCTION

- 1.1 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 Inquiry and are particularly relevant to community pharmacy
- 1.2 In light of these changes and increased risks associated with this group of drugs it was decided that the PCT led multidisciplinary audit would explore how pharmacists have adapted their practice in relation to all aspects surrounding controlled drugs.

2. AIMS AND OBJECTIVES

- 2.1 To seek reassurance that pharmacy contractors have adapted their practice in the handling of controlled drugs in response to the changes made by the RPSGB and the NPSA alert.
- 2.2 The data collection exercise aims to establish if prescriptions written for controlled drugs fulfil all legal requirements.
- 2.3 An action plan will be developed in line with recommendations in this report.

3. CRITERIA AND STANDARDS

Criteria	Standard
1. A SOP is in place to cover the receipt of controlled drugs	100%
2. A SOP is in place to cover the safe custody of controlled drugs	100%
3. A SOP is in place to cover the supply / dispensing of controlled drugs	100%
4. A SOP is in place to cover the handing out / delivery of controlled drugs	100%
5. A SOP is in place to cover the destruction of controlled drugs	100%
6. A SOP is in place to alert the accountable officer when complications arise	100%
7. All SOPs relating to controlled drugs are up to date and signed by relevant staff	100%
8. All prescriptions for controlled drugs are dispensed in line with the NPSA Rapid Response Alert	100%

4. METHODOLOGY

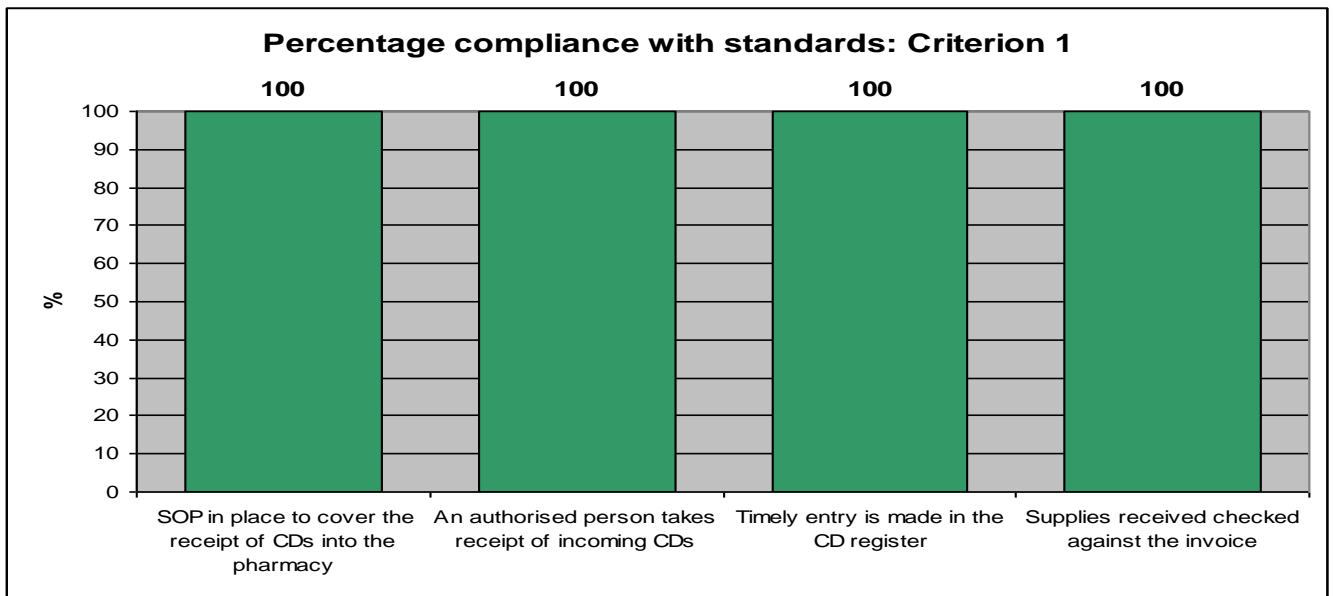
- 4.1 All 118 Pharmacies were required to complete a questionnaire on their procedures surrounding the handling of controlled drugs
- 4.2 All Pharmacies had to review prescriptions for a two week period, count the number of controlled drug prescriptions processed and make a record of the reason if the prescription did not fulfil all legal requirements.

5. RESULTS

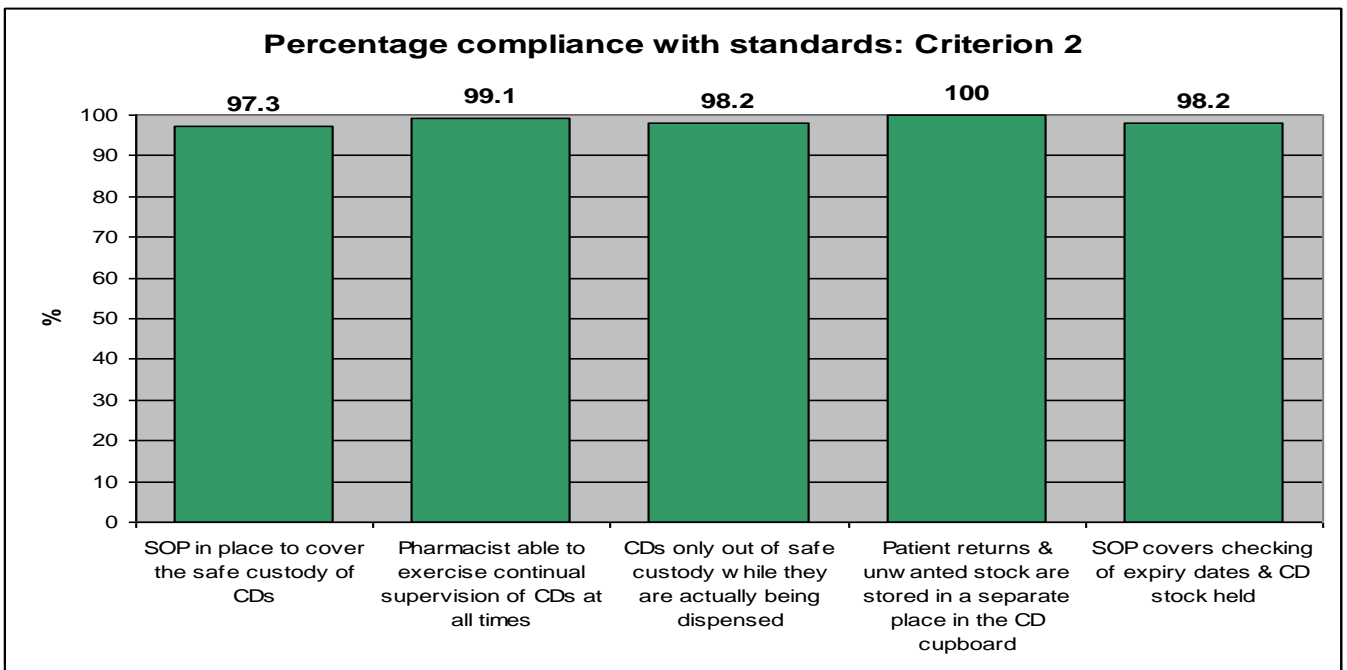
5.1 A total of 112 community pharmacies and one dispensing practice participated in this audit, giving a participation rate of 95% (113/119). The audit consisted of three sections and the response rates were as follows: Appendix A: 111 completed questionnaires returned; Appendix B: 110 completed prescription data collection sheets returned; and Appendix C: 87 completed reflective action plans. All data received was included in the analysis below.

5.2 The charts below illustrate the percentage compliance with eight criteria relating to controlled drugs, which are detailed below. This data was compiled using the information obtained from the 111 Pharmacy completed questionnaires returned (Appendix A in the Audit pack distributed to community pharmacies). N = 111 (unless stated otherwise)

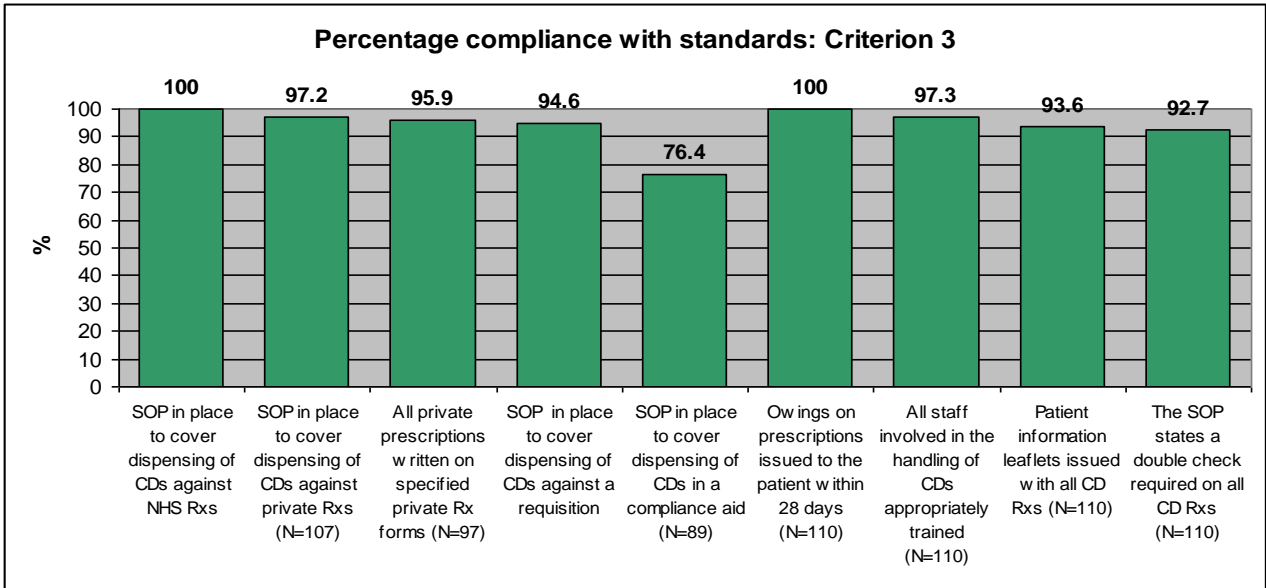
5.3 Criterion 1: A SOP is in place to cover the receipt of controlled drugs.



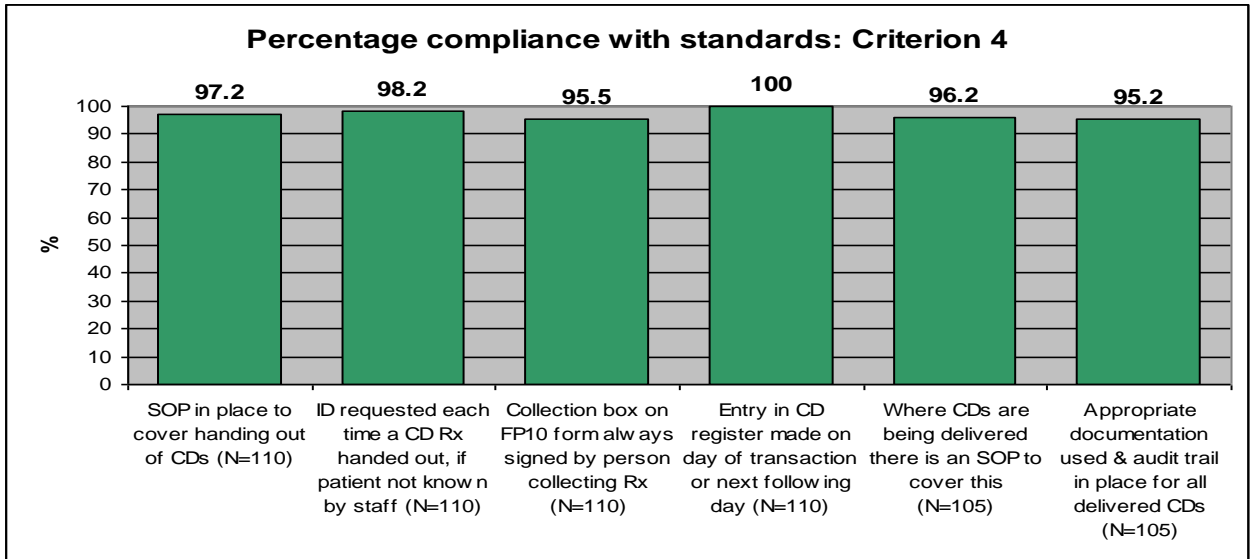
5.4 Criterion 2: A SOP is in place to cover the safe custody of controlled drugs.



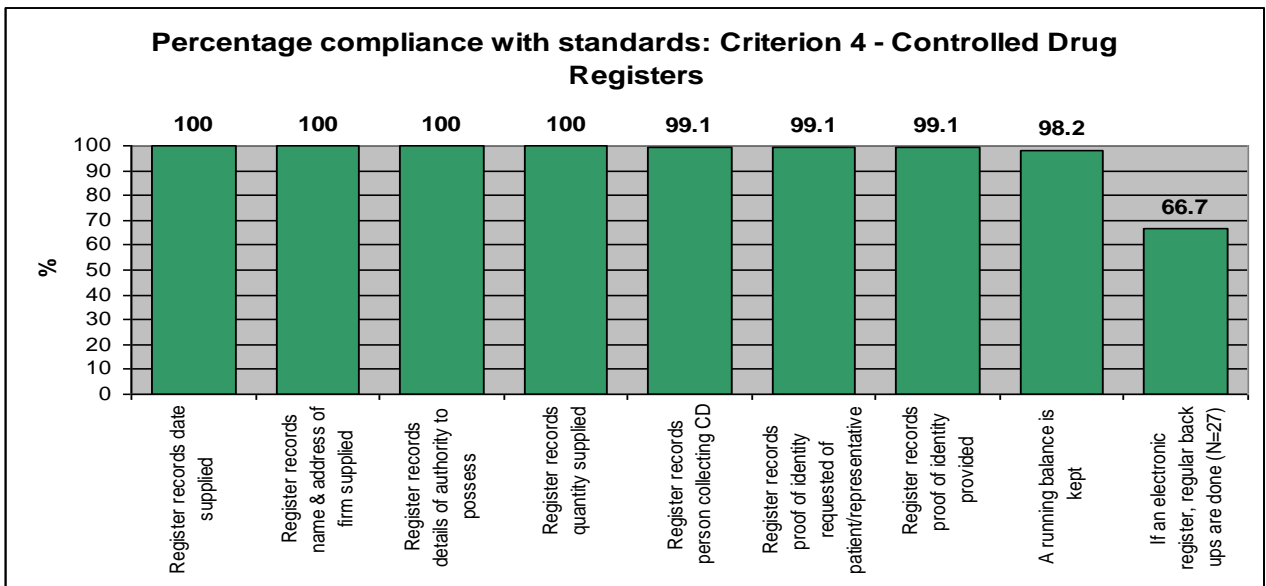
5.5 Criterion 3: A SOP is in place to cover the supply/dispensing of controlled drugs.



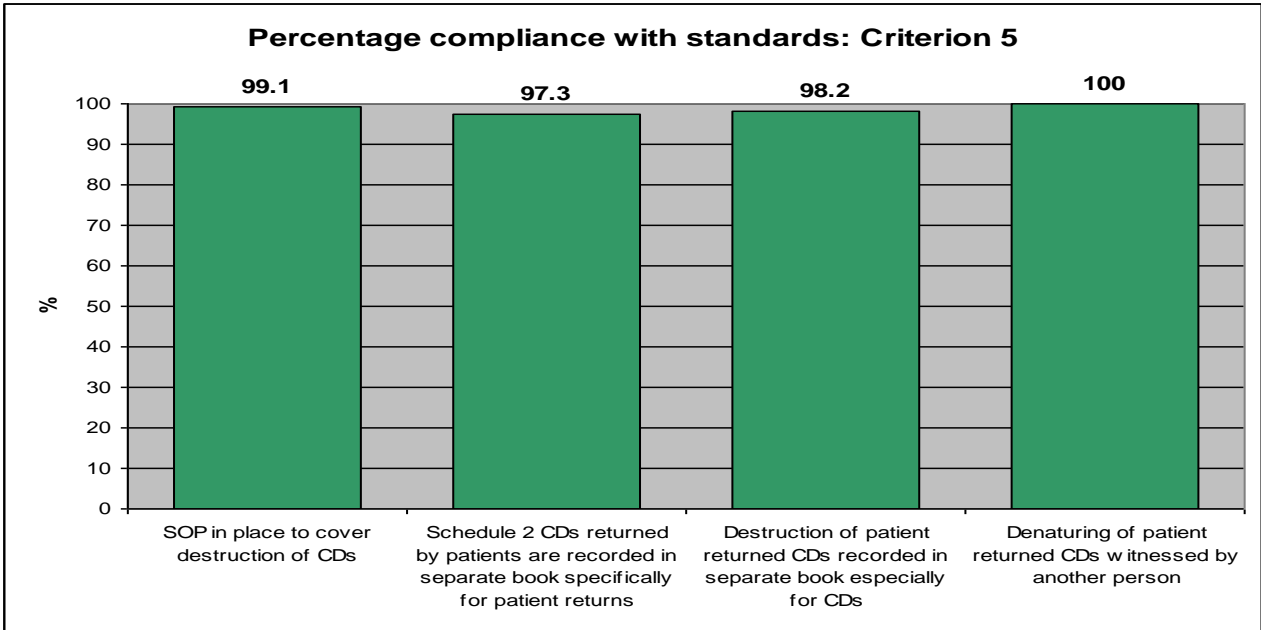
5.6 Criterion 4: A SOP is in place to cover the handing out of controlled drugs.



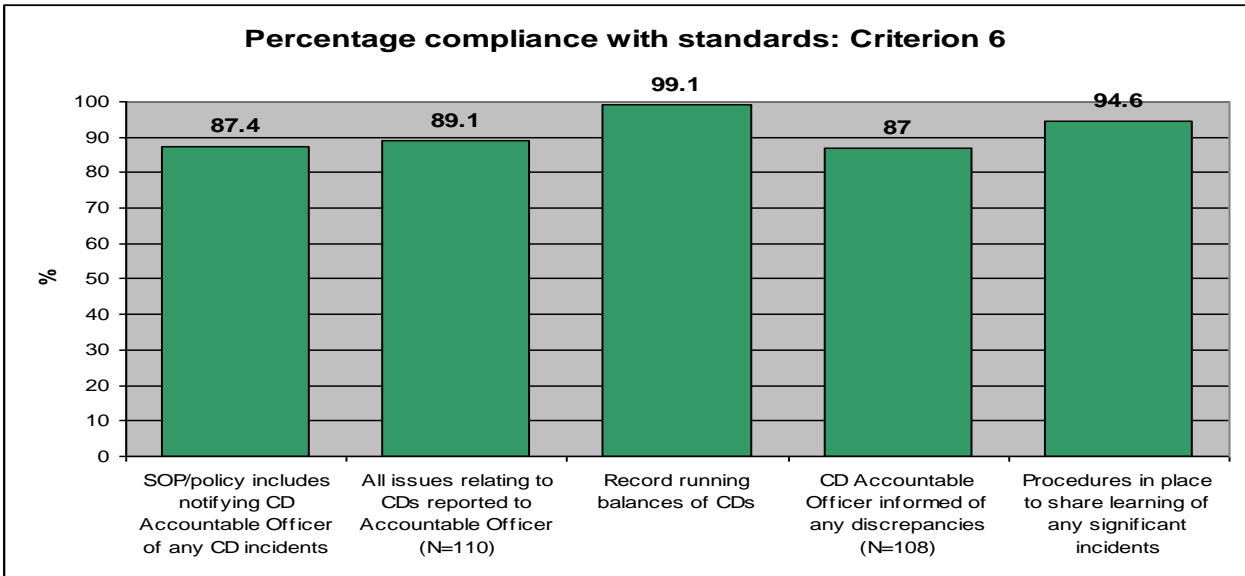
5.7 Criterion 4a: Controlled Drugs Register should record the following items (see chart).



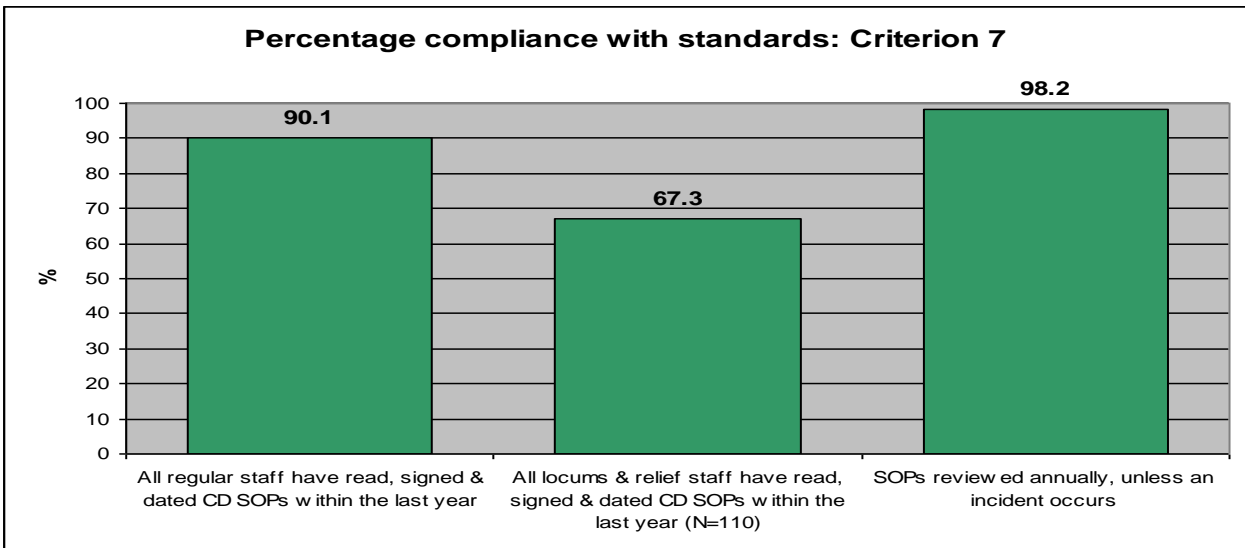
5.8 Criterion 5: A SOP is in place for the destruction of controlled drugs.



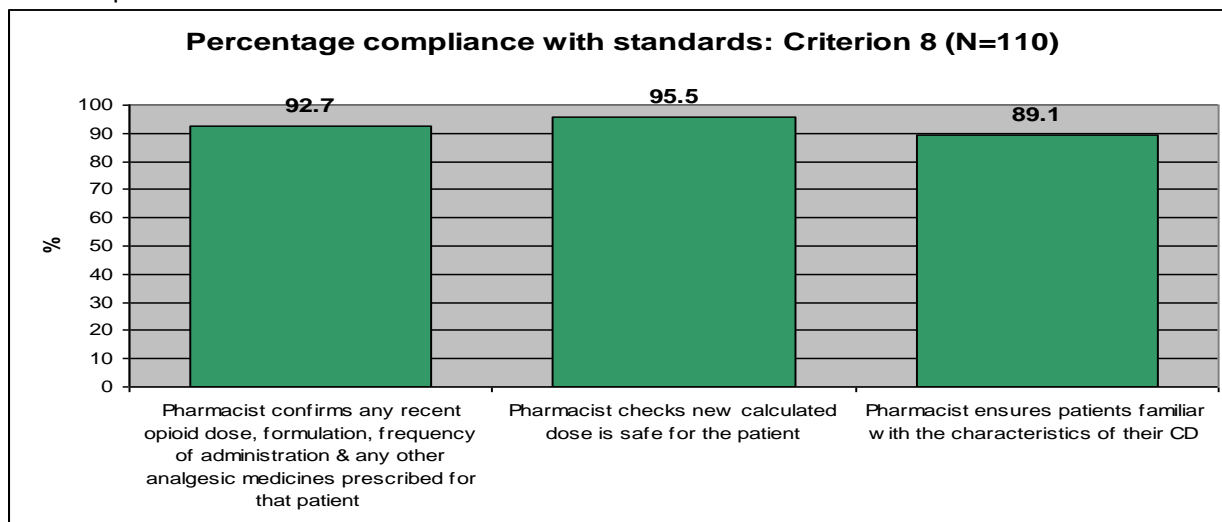
5.9 Criterion 6: There is a SOP for notifying the CD Accountable Officer of an CD incidents.



5.10 Criterion 7: SOPs and records relating to them are up to date and read by all staff.






5.11 Criterion 8: All prescriptions for controlled drugs are dispensed in line with the NPSA Rapid Response Report.



5.12 The table below summarises the results obtained from the prescription data collection sheets, of which 110 were completed (Appendix B in the Audit Pack distributed to community pharmacies). This part of the audit focused on controlled drugs prescription errors.

	Number	Percentage
Total No. prescriptions received for controlled drugs during audit period	3973	
Total No. prescription errors reported	208	5.2
Total No. prescriptions with errors	205	5.2
No. not signed	18	8.7
No. not dated	15	7.2
No. not got address of GP	4	1.9
No. dose missing or incomplete	96	46.2
No. form missing	5	2.4
No. strength missing	4	1.9
No. total quantity in words and figures incorrect	30	14.4
No. spelling mistake	0	0
No. private script not on FP10PCD	1	0.5
No. private script is missing (Prescribers ID No.)	0	0
No. dental script is missing	0	0
No. 'other' errors reported	35	16.8

Compliance to Standards	Standard Achieved
1. A SOP is in place to cover the receipt of controlled drugs	100%
2. A SOP is in place to cover the safe custody of controlled drugs	98.5%
3. A SOP is in place to cover the supply / dispensing of controlled drugs	94.1%
4. A SOP is in place to cover the handing out / delivery of controlled drugs	97.1%
5. A SOP is in place to cover the destruction of controlled drugs	98.6%
6. A SOP is in place to alert the accountable officer when complications arise	91.4%
7. All SOPs relating to controlled drugs are up to date and signed by relevant staff	85.5%
8. All prescriptions for controlled drugs are dispensed in line with the NPSA Rapid Response Alert	92.4%

	Compliant
	Partly Compliant
	Not Compliant

6. DISCUSSION

6.1 The results from the audit show that the majority of pharmacies have SOPs in place for the receipt, safe custody, supply, handing out / delivery and destruction of controlled drugs. This is a positive outcome of the audit. The responsible pharmacists must ensure that procedures are current and are being operated, if there is a need to temporarily amend a SOP (e.g. due to sickness) then an audit trail should be in place stating when, how and why the SOP changed and when the change reverted back.

6.2 **Receipt of Controlled drugs.** Pharmacies achieved 100% compliance to this standard. All pharmacies had SOPs in place to cover the receipt of controlled drugs into the pharmacy.

6.3 **Safe Custody.** Controlled drugs must be under the direct personal supervision of the pharmacist at all times,¹ they should only be out of the CD cupboard whilst actually being dispensed. The majority of pharmacies were working in line with these guidelines (99.1% and 98.2% respectively). Procedures for date checking of medication held in the pharmacy should be robust and ensure that they clearly cover stock not stored on the 'normal' dispensing shelves, e.g. CD cupboard, fridge. 98.2% had SOPs in place to reflect this.

6.4 **Supply / dispensing of controlled drugs.** Private prescriptions and requisitions for controlled drugs occur infrequently and as a result the need for an SOP may be deemed unnecessary. (97.2% and 75.6% of pharmacies did not have either a SOP for CD supplies on private prescriptions or requisitions, respectively). If presented with a private prescription or requisition for a CD then expertise in how to process it is likely to be low, simply due to the unfamiliarity of it. Having an SOP to support the process would be a useful tool to support the pharmacy team in dispensing against such requests, as well as fulfilling best practice requirements.

6.5 24.4% of the 90 pharmacies who dispense controlled drugs into compliance aids for patients do not have SOPs to cover this. The dispensing of controlled drugs into compliance aids is accompanied

with increased risk. Compliance aids are not child resistant and the storage requirements need to be borne in mind, both in the pharmacy and in the patients care setting. Consideration of the risks and benefits involved in supplying CD's in a compliance aid need to be considered, discussed with the prescriber and patient and the outcome documented. If the benefits outweigh the risks of supplying in a compliance aid then robust procedures should be in place to ensure risks are managed appropriately.

6.6 Prescriptions for controlled drugs are only valid for 28 days from the date of issue, this includes any overages that may be on the prescription¹, and 1.8% of pharmacies do not ensure this occurs. Supplies over the 28 days are not legal. Patient information leaflets (PILs) should be supplied with all medication.¹ Sometimes pharmacists have to dispense smaller quantities from larger packs that do not supply multiple PILs, this can pose problems but pharmacists should ensure patients have written information on their medicines.

6.7 From January 2005, pharmacies have had a professional obligation to ensure that all staff involved in the dispensing process are competent in the areas in which they are working to a minimum standard equivalent to NVQ level 2, or working towards this. Dispensing / pharmacy assistants should be enrolled on a training programme within three months of commencing their role (or as soon as practical within local training arrangements). 3.6% of pharmacies use untrained staff in the handling of CD's.

6.8 Handing out of Controlled drugs. The majority of pharmacies (96.4%) have a SOP in place to cover the handing out of controlled drug prescriptions. There have been a number of changes around this process as a result of recommendations from The Shipman Inquiry.² Pharmacists / pharmacy staff should request to see identification of the person collecting the prescription if they are not known to staff (97.3% compliant), get the person collecting the CD prescription to sign the box on the back of the FP10 form (94.6% compliant) and an entry should be made in the CD register on the day of the transaction or the next following day (99.1%). If prescriptions are to be delivered an audit trail should be in place which includes the receiver of the controlled drug being subject to the same checks as the patient that picks it up from the pharmacy. A signature either on a delivery sheet or prescription should be obtained and ID confirmed (if not known by staff). 95.2% of pharmacies have an audit trail in place.

6.9 **Controlled Drug register.** In 2008 some of the requirements that need to be recorded in the CD register changed and the following are all the current legal requirements; Date of transaction (100%), name and address of supplier / recipient (100%), Person who has authority to possess, (100%), quantity (100%), name of person collecting (99.1%), record if proof of ID was requested (99.1%), record if proof of ID was supplied (99.1%). It is a recommendation that running balances are kept, all except two pharmacies do this. Since 2005 CD registers can be stored electronically, 29 of pharmacies have opted to record in this way. Adequate backups must be made of computerised records. 62.1% of the 29 pharmacies carry out regular back ups.

6.10 **Destruction of controlled drugs.** Pharmacies should have a SOP to cover the destruction of controlled drugs. 99.1% of pharmacies have procedures in place. The Home Office advice that

schedule 2, 3 and 4 part 1 controlled drugs must be denatured before placing in waste containers. Furthermore all drugs in schedule 1 and 2 that are subject to record keeping requirements need to be witnessed by an authorised witness. This occurs in all pharmacies. Recording of patient returned CD's is not currently a legal requirement under the misuse of drugs regulations, however the controlled drugs regulations require standard operating procedures to be in place for maintaining a record of CDs in schedule 2 that have been returned by patients.¹ The records should be made in a separate register which covers the acceptance and destruction of the CD. 98.2% of pharmacies kept a record of such destructions.

6.11 **Accountable officer.** Pharmacies must have a SOP in place to cover who is to be alerted if complications arise.¹ It is recommended that the primary care organisations Accountable Officer are informed.³ 87.4% of pharmacies reported that their SOP states that the Accountable Officer should be informed if incidents occur. The results however showed that more (89.1%) pharmacies inform the AO even though it is not stated in their SOP. It is good practice to keep running balances in the CD register 99.1% stated this is done. Stock checks should be carried out at least weekly and any unresolved discrepancies reported. 87% of pharmacies reported discrepancies to the Accountable Officer (currently Peter Magirr in Sheffield). Carrying out regular stock checks makes the reason for any discrepancies easier to trace.

6.12 **Standard operating procedures.** The need to have in place and operate Standard Operating Procedures was introduced in 2005. The aim of SOPs is to help to minimise risks associated with the dispensing process, by all staff following the same procedures. Up until the introduction of the responsible pharmacist (October 2009) SOPs had to be reviewed annually, it is now recommended that they are reviewed at least every two years unless a significant event occurs that renders a need to do it sooner. All staff that carry out work that is covered by an SOP should have read, understood signed and dated the SOP and operate within it. 90.1% of pharmacies complied with this.

6.13 The results showed that 67.3% of locum / relief staff have read and signed the SOPs that relate to controlled drugs. It is the responsibility of the pharmacy contractor / superintendent to make SOPs available to relief staff, this may be, for example, in a locum file or accessible on line. The locum should ensure they read and sign them and work within the SOPs. In some cases Locums may wish to develop their own SOPs covering the pharmacies in which they work. These should fall within the parameters of the SOP prepared by the pharmacy and may form part of the locum's agreement to work.⁴

6.14 **NPSA Rapid Response Report.** This was sent to pharmacies in July 2008 with a deadline to complete by 30 January 2009.⁵ The three main actions for community pharmacists were;

- Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed. 92.7% of pharmacies were compliant with this action.
- Ensure dose increases are intended and safe for the patient. 95.5% compliant
- Ensure patients are familiar with the characteristics of their medicine. 89.1% compliant

Ensuring these checks are made reduces associated risks surrounding opioid medication.

- 6.15 **Multidisciplinary aspect of the audit.** Over a two week period pharmacies across Sheffield processed 3973 prescriptions for controlled drugs in schedule 2 and 3 (excluding temazepam). The prescribing of controlled drugs in schedule 2 and 3 (except temazepam) is subject to a number of requirements. Failure to comply with these requirements or to dispense a prescription which doesn't meet all the requirements is an offence. Of the 3973 prescriptions presented to community pharmacy 5.2% (208) did not fulfil all legal requirements. The most common error was the incomplete instructions for the dose. (46.2% of all errors recorded - 96 prescriptions). 'Other errors' accounted for 16.8% of errors, the types of errors reported were; faxed prescriptions, out of date prescriptions, instalment quantity not matching the total quantity to be dispensed, incorrect form requested, specific dosage instructions and dates to be dispensed on instalment prescriptions absent / not clear. The table in 5.12 lists the distribution of other errors.
- 6.16 When faced with an incomplete prescription pharmacist have to exercise their professional judgement and consider the needs of the patient before making a decision on whether or not to dispense such prescriptions. The intentions of the prescriber should be clear and all actions taken should be in the patients' best interest and documented so an audit trail is in place and a record of who is accountable.
- 6.17 Overall the majority of pharmacies are complying with standards and recommendations around the handling of controlled drugs. There are some gaps that the audit highlighted and the recommendations made below will help to bridge these gaps.

7. RECOMMENDATIONS

- 7.1 The following recommendations are made as a result of the audit:

Pharmacists

- 7.2 All SOPs written should be read, signed and dated by all staff involved in the handling of controlled drugs, and they should operate within them.
- 7.3 Locum pharmacists and relief staff should have access to standard operating procedures and having read them, should sign and date to confirm this. These could be made available in a locum pack or on the internet / via e-mail.
- 7.4 If controlled drugs are dispensed into compliance aids then robust Standard operating procedures should be in place. Furthermore, a risk - benefit analysis should be carried out and documented for each patient.
- 7.5 Prescriptions for controlled drugs should undergo a check by a different person than the one who dispensed it; this should be stated in the SOP.
- 7.6 Patient information leaflets should be given with all medicines dispensed.
- 7.7 Ensure an audit trail is in place for the delivery of controlled drugs.
- 7.8 If controlled drug registers are kept electronically then regular backs should be carried out.
- 7.9 All incidents, including discrepancies, involving controlled drugs should be reported to the Accountable Officer, this should be stated in the SOP.

- 7.10 If an incident, or discrepancy occurs, a root cause analysis should be carried out and learning shared with all relevant staff.
- 7.11 All controlled drug prescriptions should undergo a clinical check that clarifies the strength, dose, frequency and form is intended and correct for that patient. New doses should be checked and calculated to ensure it is suitable (e.g. for oral morphine or oxycodone in adult patients, not normally more than 50% higher than the previous dose) – see NPSA Rapid Response Report “Reducing Dosing Errors with Opioid Medicines”
- 7.12 Pharmacists should ensure patients are familiar with the characteristics of their medicine; form, usual starting dose, frequency of administration, standard dosage increments, symptoms of overdose and common side effects.
- 7.13 Carry out a legal and clinical check of all controlled drug prescriptions as soon as they are received in the pharmacy. If any discrepancies are apparent these should be discussed with the patient and resolved with the prescriber, documenting any significant actions taken.

Prescribers

- 7.14 Ensure when prescribing controlled drugs that a dose is clearly stated for each controlled drug prescribed. The instruction ‘take one as directed’ or ‘apply one as directed’ constitute a dose whereas the instruction ‘as directed’ does not.
- 7.15 Ensure the total quantity of controlled drug to be supplied on the prescription is written in both words and figures.
- 7.16 Prescriptions should be double checked to ensure they are signed and dated before issuing to the patient or placed in the prescription collection box. N.B. Controlled drug prescriptions are only valid for 28 days.
- 7.17 If a prescription is to be used for instalment prescribing it must be on a FP10 (MDA) form. The prescription must contain a direction specifying the **amount** of the instalment to be supplied and the **intervals** to be observed when supplying.

8. REFERENCES

¹ Medicines Ethics and Practice, July 2009. RPSGB.

² <http://www.rpsgb.org.uk/pdfs/shipmaninqrep4resp.pdf>

³ Legal and Ethical Advisory Service. Fact Sheet One. Controlled Drugs and Community Pharmacy.

⁴ Legal and Ethical Advisory Service. Fact Sheet Ten. Employing a locum / working as a locum

⁵ Rapid Response Report. Reducing dosing errors with opioid medicines

Part A:

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.	

ACTION PLAN

Recommendation (List from Audit Report)	Action to be Taken (Steps Needed to Make Changes)	Lead (Who Will Do It?)	Deadline (When Will It Be Done?)
Ensure the recommendations made in the NPSA’s Rapid Response Report on opioids are being followed each time a prescription for opioids is dispensed. (7.11 and 7.12)	Send NPSA poster to all community pharmacies to raise the profile of the alert	Heidi Taylor	February 2010
Ensure all prescriptions issued fulfil all handwriting requirements. (7.14-7.17)	Distribute audit results and recommendations to prescribers so that learning can be shared.	Susan Rutherford	March 2010