Care Quality Commission

The safer management of controlled drugs

Annual report 2010

August 2011

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act. Whether services are provided by the NHS, local authorities or by private or voluntary organisations, we focus on:

- Identifying risks to the quality and safety of people's care.
- Acting swiftly to help eliminate poor-quality care.
- Making sure care is centred on people's needs and protects their rights.

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Summary

The Care Quality Commission is responsible for making sure that providers of health and social care and other regulators create a safe environment for the management of controlled drugs.

This is the fourth annual report on the regulation of controlled drugs, covering the year ended 31 December 2010. We report how CQC and our partners have continued working to improve the safer management of controlled drugs and we look at how changes in healthcare legislation are affecting the arrangements for safer management of controlled drugs. We also report on the progress that has been made with the recommendations set out in the 2009 report. As safe handling of controlled drugs remains an essential part of good quality care, we have made further recommendations to assure the safety of people who use health and social care services.

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 and accompanying guidance from the Department of Health set out the responsibilities post Shipman for the Care Quality Commission in relation to controlled drugs and external scrutiny of the arrangements.

Safe management of controlled drugs in health and social care organisations

The regulations require:

- The appointment of a controlled drugs 'accountable officer', who has specified responsibilities, in controlled drug designated bodies (primary care trusts, other NHS trusts including foundation trusts, and private hospitals).
- Organisations, regulators and agencies involved in handling controlled drugs to share information through the PCT-led controlled drug local intelligence network (CD LIN).

We continued to maintain the register of accountable officers on our website throughout 2010. However, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009 that came into force for the registration of independent healthcare providers created an additional workload in managing the register in the last quarter of the year, due to the individual assessments now required for new registrations.

Information sharing between organisations is continuing to improve and we describe a number of examples of good practice. We have also recommended that non-designated bodies should also participate more in the information-sharing process to ensure that intelligence-gathering is thorough and complete, capturing information from all sources for example, community pharmacists, the Ministry of Defence, care homes, substance misuse services, and new provider services.

CD LIN working arrangements need to be robust and firmly embedded so that they can be passed on to the appropriate bodies in the new NHS structures. The Regulations (SI 3148) will continue to apply as the NHS is reorganised.

Partner organisations

The National Group on Controlled Drugs is a strategic group of regulators and key agencies that have areas of responsibility for controlled drugs within their remit.

During 2010, the National Group met to share findings and discuss concerns. There were a number of key initiatives from partners to refine management systems and support frontline workers.

National trends in the use of controlled drugs

During 2010, we continued to monitor the overall use and management of controlled drugs by analysing national prescribing and requisition data, feedback from monitoring routine activity in controlled drugs, and reports from members of the National Group.

There was little change in the overall volume of NHS (primary care) prescribing of controlled drugs in 2010 (an increase of 3% compared with 2009), but we noted that, although a small proportion of the whole, prescribing of controlled drugs by nurses and pharmacists continued to increase. This is in keeping with policy and the Government's agenda to improve people's access to medicines through the introduction of more non-medical prescribers.

The profile of prescribing in the private sector was markedly different from that of NHS prescribing, with high amounts of methadone and dexamfetamine prescribed privately. There were also increases in the use of methylphenidate and midazolam liquid. The reasons for these differences are not entirely clear at present, and further work is needed to look at this area.

Serial analyses of controlled drug prescribing over the past four years are now enabling us to see longer-term patterns of drug usage. These data sets will enable us to identify trends more accurately and monitor the impact of changes in practice or regulations.

There has also been further discussion during 2010 on how the system for collecting information on controlled drug requisitions can be enhanced.

The Royal College of Physicians, Royal College of General Practitioners and Royal College of Psychiatrists have confirmed that existing published guidance on best practice, *Drug misuse and dependence: UK guidelines on clinical management,* is equally applicable in both NHS and independent healthcare practice.

Overall view of activities in 2010

- Stakeholders, and partner organisations have continued to actively support the safer management and use of controlled drugs with enthusiasm. In several cases, organisations have devised innovative approaches to improve practice. We believe that the many examples of good practice in this report reflect an appropriate level of concern for safe management and use of controlled drugs.

- The planned changes to the NHS, including changes to the structure of PCTs, will affect the appointments of accountable officers and the CD LIN arrangements. It is important that these changes are clearly communicated to all providers in the local community so that information and concerns about controlled drugs can continue to be shared effectively.

- CD LINs need to continue to function effectively through the primary care structure changes and make adequate preparations to ensure that their existing arrangements are sufficiently robust to store intelligence securely. They also need to be sufficiently independent to be transferred to any future host body. The engagement of all health and social care providers, both new and existing, in sharing information and intelligence must not be overlooked.

- The newly-created provider organisations that are not required by the regulations to appoint an accountable officer must still make arrangements to ensure the safe management of controlled drugs within their organisation and report to their commissioning PCT.

- We still wish to emphasise that managing and monitoring the systems for controlled drugs at both national and local levels will require ongoing activity and vigilance to sustain the positive developments that have been achieved in the past four years.

Next steps for primary care

- Ensure that all systems for the safer management of controlled drugs are robust and up-to-date, ready for handover to the new organisations.
- Ensure that the private prescribing of controlled drugs, especially dexamfetamine, methylphenidate and midazolam liquid continues to be closely monitored.

Recommendations

1. **Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda during the reorganisation of the NHS to ensure that the gains in safety made over the past four years are not lost.**

2. **Chief executives and accountable officers should ensure that CD LINs have robust working arrangements and are fit for purpose and adequately prepared for the transition.**

3. **Non-designated bodies should also be encouraged participate more in the information-sharing process to ensure that intelligence-gathering is thorough and complete, capturing information from all sources for example, community pharmacists, the Ministry of Defence, care homes, substance misuse services and new provider services.**

4. **All professionals and providers of care, whether practising in the NHS or independent sector, should take account of best practice guidance that is published by relevant professional bodies and agencies. All sectors should be made aware of the document, *Drug misuse and dependence: UK guidelines on clinical management* and that it applies across all sectors.**

1 Progress on recommendations from the 2009 report

The table below summarises the progress that has been made with the recommendations made in our 2009 annual report.

Table 1: Progress against recommendations in the 2009 report

Recommendation	Progress
1. Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda.	Following our 2009 report, the Chief Pharmacist, Dr Keith Ridge, wrote to all NHS CEOs to remind them of their responsibilities (www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_118486.pdf). In March 2011, a further reminder was issued in the DH bulletin for NHS CEOs 'The Week' (Issue 188; 18-24 March 2011) www.dh.gov.uk/en/Publicationsandstatistics/Bulletins/theweek/DH_125383
2. The royal colleges should develop guidance on appropriate use of opioids and amphetamines for all sectors, to ensure best practice across all areas.	The royal colleges have confirmed that they consider existing published guidance on best practice to be equally applicable in both NHS and independent healthcare practice. The Department of Health's *Drug misuse and dependence: UK guidelines on clinical management* commonly known as the 'clinical guidelines' or the 'orange book' is currently under review and a new edition is anticipated in 2011[1] www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf
3. The Department of Health should revisit the requisition regulations and guidance to ensure that they capture and identify the purchase of controlled drugs by all individual doctors and healthcare professionals, in line with the original policy intent.	Following discussions with partner organisations, the Home Office is now reviewing the regulations with a view to drafting the necessary amendments that, after consultation, can be incorporated into future consolidation changes to the Misuse of Drugs Regulations.

2 Introduction

This is the fourth annual report on the regulation of controlled drugs, covering the year ended 31 December 2010. Previous reports can be found at (www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs/ourrole.cfm).

It covers aspects of good governance in managing the risks associated with the handling and usage of controlled drugs and strategies to identify concerns or problems in the early stages.

The role of the Care Quality Commission

The Care Quality Commission has responsibility for making sure that health and social care providers and regulators maintain a safe environment for the management of controlled drugs. This arose from the findings of the Fourth Report of the Shipman Inquiry[2] and the Government's response to the inquiry's recommendations[3] (see appendix 2 for further information).

The Controlled Drugs (Supervision of Management and Use) Regulations 2006[4] were introduced in 2007, and accompanying guidance from the Department of Health set out the responsibilities of the former Healthcare Commission in relation to controlled drugs and external scrutiny of the new arrangements.[5] The Care Quality Commission took on these responsibilities on 1 April 2009.

We use our regulatory powers to inspect compliance against essential standards of quality and safety and further to investigate services where concerns have been raised or untoward incidents reported.

Changes since 2009 report

On 1 April 2010 the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009 came into force. All NHS trusts (including primary care trusts as providers) were required to register with CQC by 1 April 2010. And from October 2010, all registered adult social care and independent healthcare providers that were previously registered under the Care Standards Act 2000 were required to register under the same legislation.

All providers of regulated activities are required to meet essential standards of quality and safety (as defined in the CQC publication, *Guidance about compliance: Essential standards of quality and safety*[6] (www.cqc.org.uk/standards). This document sets out 'outcomes' that describe quality and safety from the perspective of people who use services and makes clear to providers the outcomes required to comply with the regulations.

Demonstrating safe handling of controlled drugs is included in Outcome 9 ('Management of Medicines') that underpins Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

The designated bodies that are required to appoint an accountable officer are defined in the Controlled Drugs (Supervision of Management and Use) Regulations 2006[4]. These bodies are: primary care trusts (PCTs), NHS trusts, NHS foundation trusts and independent hospitals in England.

Part 1 of the Regulations define an 'English independent hospital', as a hospital in England that is not a health service hospital and is providing certain defined services. This definition was a good fit with the previous registration categories of the Care Standards Act 2000, enabling us to use these registration categories to determine which organisations were designated bodies and therefore required to appoint an accountable officer.

The requirement for registration with CQC under the Health and Social Care Act 2008 depends on the registered, regulated activity undertaken rather than the type of organisation, as under the Care Standards Act. This has had an impact on determining the designated body status, particularly for independent healthcare services new to registration.

- Private hospitals previously registered under the Care Standards Act before 30 September 2010 that were designated bodies requiring an accountable officer still require an accountable officer for that site.

- Each new independent healthcare service coming into registration is now assessed individually on a case-by-case basis as to whether it is a 'Private Hospital Designated Body' as set out in the Part 1 definition of the Regulations, and so needing to be included in the accountable officer register.

Some new service types coming into registration with CQC in 2011/12 are not controlled drug designated bodies. For example, the new community interest companies (CICs) and social enterprise organisations are not included in regulation as designated bodies, and therefore the commissioning PCT still needs to retain responsibility for accountable officer oversight. For these organisations to be included, there will need to be a future change in regulation.

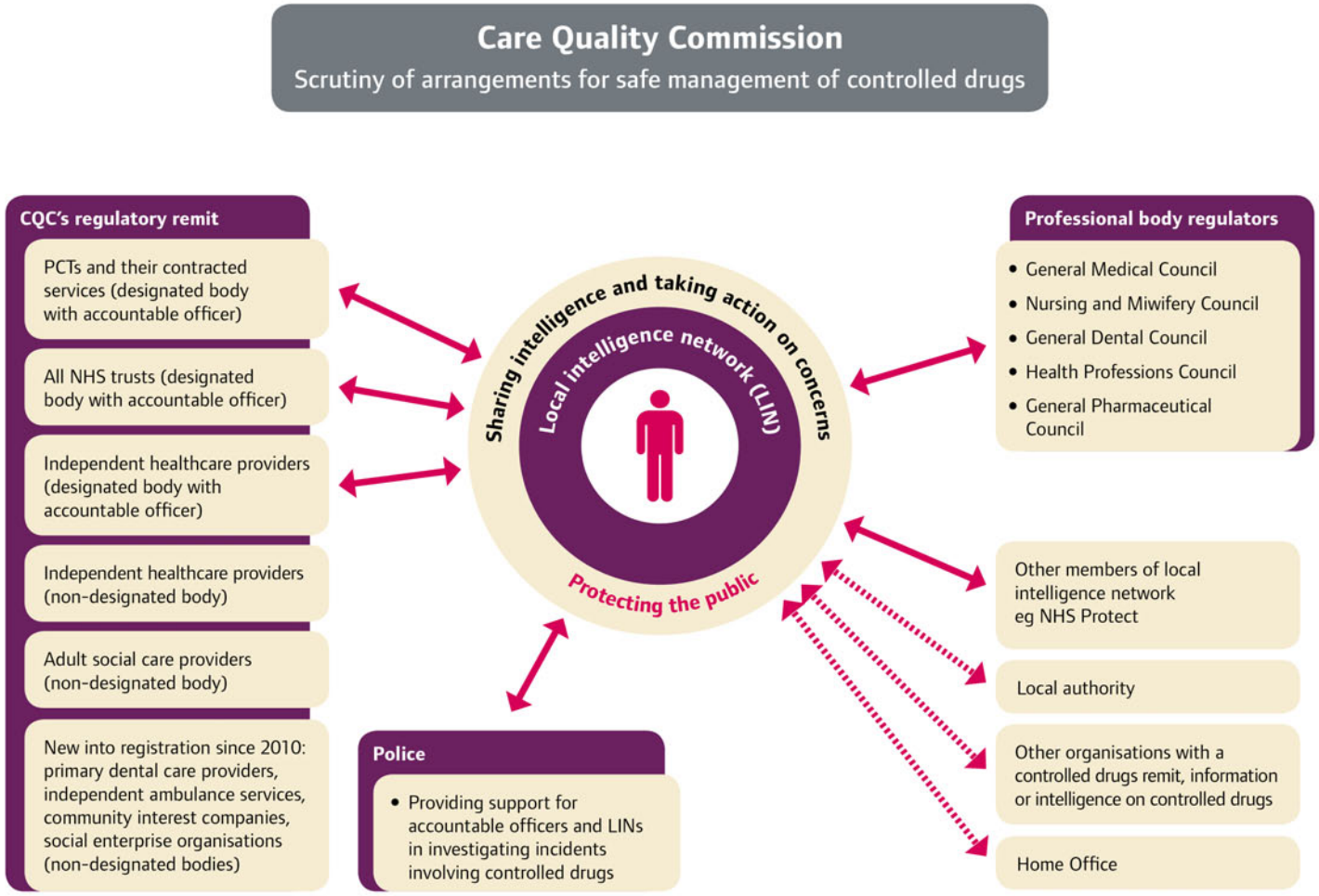
However, after new services become registered with CQC, PCT accountable officers will no longer need to follow up issues concerning controlled drugs when concerns are reported or carry out periodic inspections in these premises themselves, as set out in Regulation 19. Any such concerns should be shared with the relevant regulator.

The role of CQC in relation to external scrutiny

CQC has national oversight of the arrangements for the safer management of controlled drugs. This includes:

- Providing assurance of systems of regulation of controlled drugs.
- Leading a national group of the regulators and agencies involved in different aspects of the management and use of controlled drugs.
- Providing external scrutiny on how other regulators and agencies work together.
- Reporting annually to Government on the safer management of controlled drugs, including findings on the management of controlled drugs and sharing trends both in good practice and in common system errors, to promote improvement.
- Making judgements on how health and social care providers look after controlled drugs safely.
- Maintaining and publishing a register of controlled drug accountable officers.
- Participating in and monitoring the effectiveness of local intelligence networks (LINs) led by primary care trusts, and ensuring that local governance arrangements and provisions for incident panels are satisfactory.

Figure 1: Arrangements in place for the safe management of controlled drugs



3 Safe management of controlled drugs in health and social care organisations

All healthcare professionals have a duty to ensure that controlled drugs in their own practice are managed safely.

In addition, all health and social care organisations are responsible for making sure that they have arrangements in place to assure the safe and effective management of controlled drugs and for making sure that these systems are working effectively.

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 further require:

- The appointment of a controlled drugs accountable officer, with specified responsibilities, in controlled drug designated bodies (primary care trusts, other NHS trusts including foundation trusts, and private hospitals).
- Sharing of information between organisations, regulators and agencies involved in handling controlled drugs through the PCT-led controlled drug local intelligence network (CD LIN).

When assessing how well an organisation is managing its controlled drugs, we consider all of the related legislation and we follow up and investigate when necessary.

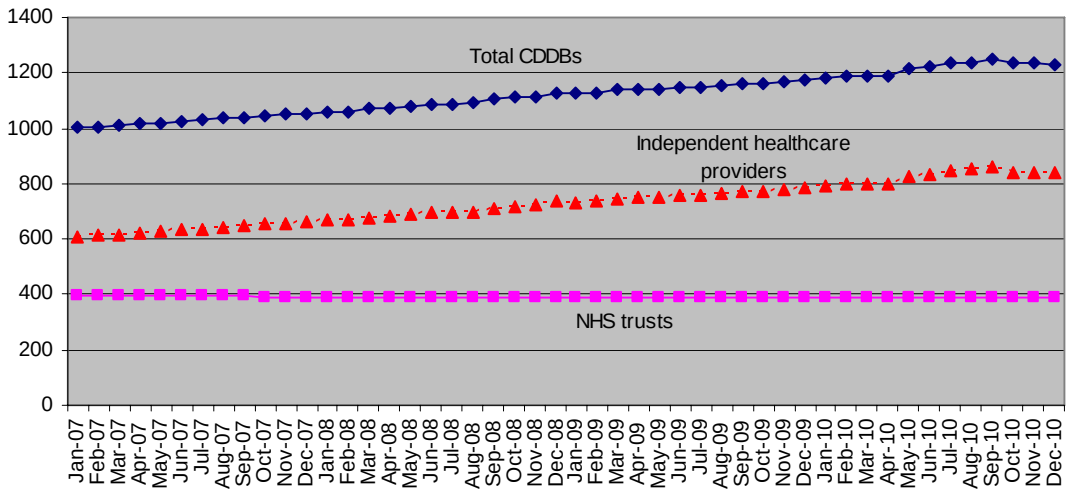
Accountable officers and the AO register

The accountable officer is the person within a 'controlled drug designated body' who has organisational responsibility for controlled drugs. The responsibilities of the accountable officer are set out in detail in the 2006 Regulations.[4]

It is the responsibility of the controlled drug designated body to inform CQC of the appointment of, and changes to, their accountable officer and we regularly update the register to reflect these changes. Notification can only be made using a web-form (www.cqc.org.uk/guidanceforallhealthcarestaff/managingrisk/controlleddrugs/accountableofficers/accountableofficernotificationform.cfm).

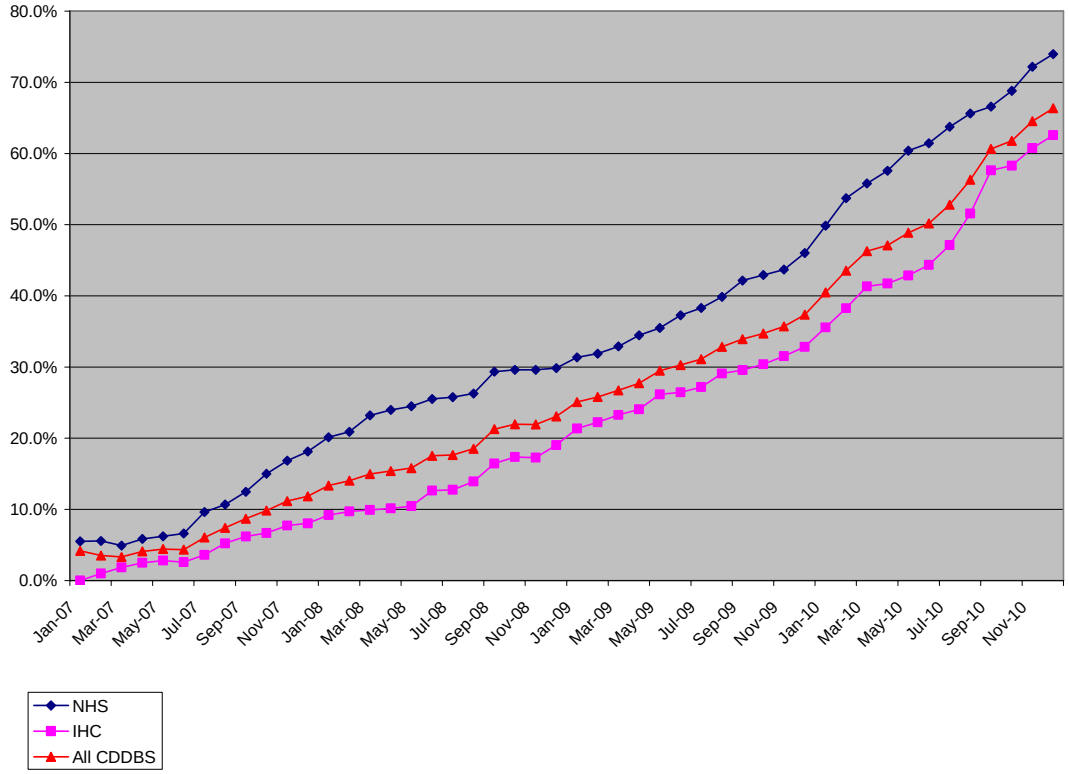
We continued to maintain and publish the register of accountable officers on our website throughout 2010. The changes to independent healthcare registration have caused additional workload in managing the register in the last quarter of the year, due to the individual assessment now required for new registrations.

Figure 2: Number of registered controlled drug designated bodies by month and type of organisation (2007-2010)



As reported in previous years, the number of designated bodies registered with CQC has gradually increased from 2007 to 2010. While the number of NHS trusts has remained constant the number of independent healthcare organisation designated bodies increased by 7% during 2010 (from 785 at December 2009 to 840 at December 2010). The turnover of accountable officers in both sectors also continues to increase, with 74% of NHS and 63% of independent healthcare organisations changing their accountable officer at least once since 2007.

Figure 3: Percentage of controlled drug designated bodies that changed accountable officers at least once (2007-2010)



Smaller organisations and those not named in the regulations as designated bodies are not required to appoint an accountable officer. However, the fact that an organisation does not need to appoint an accountable officer does not alter any of the requirements to comply with the Misuse of Drugs Regulations[7] and to make arrangements for the safe management of controlled drugs.

Larger non-designated bodies may also choose to nominate a suitable individual in their organisation to take a similar role and liaise on behalf of their organisation with the local PCT accountable officer.

Controlled drug local intelligence networks (CD LINs)

Local intelligence networks (CD LINs) enable organisations, regulators and agencies to raise concerns about the activities of any healthcare professional or organisation in relation to their management and use of controlled drugs, and to share these at the earliest stage with other agencies who may also potentially be affected or who may have additional information. Accountable officers in PCTs are responsible for establishing and operating CD LINs.[4]

Organisations should analyse their own local incidents and concerns through a process of root cause analysis. They have a responsibility to report the outcomes to CD LINs in quarterly occurrence reports. Urgent items should be notified to the PCT accountable officer leading the CD LIN immediately, rather than waiting for the next quarterly occurrence report.

If concerns need further external scrutiny, the PCT's accountable officer should take the lead in setting up an incident panel of the relevant agencies or individuals. Each agency is responsible for taking appropriate action within its regulatory remit.

Information sharing by CD LINs

There has been continuing progress in maintaining CD LINs and further improvement in sharing information. However, changes in primary care structures are signalling more amalgamation of CD LINs following moves to PCT 'clustering arrangements'. While such arrangements have to be decided locally, it is important that they are transparent and clearly communicated to all providers within the area so that information on concerns can be shared and sharing can continue. It is important to maintain robust arrangements to store intelligence throughout these changes, so that CD LINs can continue to benefit from using the information. Some areas have developed innovative ways of addressing this.

As well as designated bodies and responsible bodies, other members of the local health and social care networks (for example, community pharmacies, care homes, the Ministry of Defence and substance misuse services) have a unique perspective on controlled drug usage by others, such as prescribers. Although they are not statutory members of CD LINs they could contribute a useful insight and information. It is important to raise awareness of practices that could give rise for concern and encourage all organisations to report them by telling them how to make contact.

1: SCAN – Online collaboration tool in Hampshire

SCAN (South Central Alliance Network) is an online collaboration tool. Its primary objective is to help PCTs to work more collaboratively together using a safe online technology.

SCAN is used by the Southampton, Hampshire, Isle of Wight and Portsmouth (SHIP) Local Intelligence Network for virtual sharing of intelligence and information relating to the management and use of controlled drugs by health staff in the NHS and independent sectors.

The site is secure and available to all members by invitation only. Access is password-protected.

Within the site there are 'project' pages that can be restricted even further. The CD LIN has a secure project section, available only to members of the SHIP LIN, which is then further divided to provide separate areas for commissioners, regulators, NHS providers and independent providers. Only members of the relevant groups can access these sub-areas, permitting free discussions on group-specific topics. All members are able to access information such as the minutes of meetings, up-to-date regulations and acts and 'shared names'. At present, all LIN members have been given read and write access, to permit local updating, primarily for 'shared names'.

Changes to a web page generate an alert, which is sent automatically to those members that have configured their logon to receive them. This 'push' mode, prompts members to read the update without the need to visit the site frequently to check for changes.

Although it is not possible to view 'visit rates' for the CD LIN project pages, statistics for the whole site demonstrate increasing use over the past three years. Feedback at CD LIN meetings supports this trend for the CD LIN pages. Being web-based, the site is accessible worldwide and user statistics show access from across Europe, USA and Brazil. There has even been one login each from Australia and Japan. www.scan-collaborate.nhs.uk/display/PORTAL/Home

2: Tees valley online occurrence reporting system

NHS Tees LIN has been developing an online occurrence reporting tool that allows accountable officers to report any occurrence directly and permits others a 'view only' access. As well as enabling occurrences to be reported in real time, electronic occurrence reporting also helps to gather information both for trend analysis in preparation for CD LIN meetings and for analysing in depth any concerns that are identified.

The accountable officer leading the CD LIN reported that the scheme has continued to work well in 2010.

3: Controlled drug record card in Cornwall

NHS Cornwall & Isles of Scilly piloted the controlled drugs record card (CDRC) as part of a comprehensive controlled drug management scheme. One of the benefits was accurate tracking of surplus controlled drugs at the end of treatment.

Their approach has been to minimise the amount of 'left over' controlled drugs by:

- Encouraging prescribers to reduce prescribed quantities, especially by not prescribing whole boxes while titrating doses.
- Educating patients and carers that good anticipatory prescribing does not mean that every prescription must be dispensed on receipt, but can be held in reserve until needed.
- Promoting good reconciliation of medicines at transfers of care to minimise the risk of loss or diversion of drugs.
- Validating use by requiring service users to return used ampoules to pharmacies; this may not prove that they have used them, but it does establish that they are no longer in the community.
- Promoting good destruction procedures by equipping staff with standard operating procedures and suitable bins, while setting themselves a target of attending to witness destructions of stock within 10 working days.
- Regularly checking standard operating procedures for the destruction of controlled drugs and registers of returned controlled drugs from patients on pharmacy contract visits.

Future changes to the NHS

Currently, the responsibilities of PCTs are set to remain unchanged until 2013. PCTs are expected to continue to discharge their statutory functions, as well as to continue with self-assessments of services they contract.

Although there have been changes to PCT clustering arrangements, each PCT remains the legal entity requiring an accountable officer – the cluster is not in itself a controlled drug designated body.

We do not currently know what the future arrangements will be. However, it is likely they may require a change to existing legislation. It is therefore important to concentrate on ensuring that current arrangements are as robust as possible, to enable a smooth transition when the future arrangements are known.

CD LIN working arrangements need to be robust and firmly embedded so that they can be passed on to the appropriate bodies in the new NHS structures. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 (SI 3148)[4] will continue to apply as the NHS is reorganised.

Conclusions

Changes to the structures of PCTs are affecting the appointment of accountable officers and the CD LIN arrangements. It is important that these changes are clearly communicated to all providers in the local community so that information and concerns about controlled drugs can continue to be shared effectively.

The newly-created provider organisations that are not required by the regulations to appoint an accountable officer must still make arrangements to ensure the safe management of controlled drugs within their organisation and report to their commissioning PCT.

CD LINs need to continue to function effectively through the changes to primary care structure and make adequate preparations to ensure that their existing arrangements are sufficiently robust to store intelligence securely. They also need to be sufficiently independent to be transferred to any future host body. The engagement of all health and social care providers, both new and existing, in sharing information and intelligence must not be overlooked.

It is vital that the gains in safety made over the first four years are not overlooked and lost in reorganisation of NHS architecture.

Recommendation 1

Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda during the reorganisation of the NHS to ensure that the gains in safety made over the past four years are not lost.

Recommendation 2

Chief executives and accountable officers should ensure that CD LINs have robust working arrangements and are fit for purpose and adequately prepared for the transition.

Recommendation 3

Non-designated bodies should also be encouraged to participate more in the information-sharing process to ensure that intelligence-gathering is thorough and complete, capturing information from all source, for example community pharmacists, the Ministry of Defence, care homes, substance misuse services and new provider services.

4 Work with partner organisations

National Group on Controlled Drugs

This is a strategic group of regulators and key agencies that have areas of responsibility for controlled drugs within their remit.

The group continued to meet quarterly during 2010, and reports of activity from the main partners are available on our website. The group continues to be a useful forum to share and discuss emerging issues from the different areas represented and identify ways of working together to reach solutions. Membership of the National Group on Controlled Drugs in 2010 included:

- Association of Chief Police Officers.
- Care Quality Commission.
- Department of Health.
- Health and Social Care Information Centre.
- Home Office.
- Medicines and Healthcare products Regulatory Agency.
- National Clinical Assessment Service.
- National Patient Safety Agency.
- National Treatment Agency.
- NHS Protect.
- Ofsted.
- RPSGB (until September 2010).
- General Pharmaceutical Council (from September 2010).
- Veterinary Medicines Directorate.

We are grateful to these organisations for participating and for their contributions and ongoing commitment to the safer management of controlled drugs agenda.

Cross-border group

There has been progress on setting up a cross-border group for safer management of controlled drugs in the devolved administration (England, Scotland, Wales, Northern Ireland and the Republic of Ireland) to:

- Share intelligence across borders among those charged with management, monitoring or inspection of the governance arrangements for controlled drugs.
- Share learning and best practice methodologies that are supporting the safer management of controlled drugs in each nation.
- Share analysis of trends in the use of and management of controlled drugs.

Initiatives from partner organisations

During 2010, partner organisations continued to refine management systems and support frontline workers with a variety of useful initiatives.

Partner initiative 1: NHS Counter Fraud and Security Management Service

Drug testing kits to combat drug misuse

At a care trust in the south, a local security management system (LSMS) and local counter fraud service (LCFS) working together have obtained funding through their accountable officer to introduce drug testing to combat drug misuse in their area. This has come about as a result of a number of cases in the area, where people have unlawfully obtained controlled drugs by multiple registrations with GPs or by providing false details. The drug testing kits are used to test urine for opiates, benzodiazepines and methadone. With results available immediately, it is proving effective.

It has been used in one case where a person was registered with three GP practices and obtaining prescriptions for benzodiazepines from all three. A test confirmed that the person was not taking the prescribed medicines and she was found to be selling or passing the drugs on. The drug testing kits are supported by all the GPs in the area and the LSMS and LCFS now have close working relationships with all the practices in the area.

Partner initiative 2: National Patient Safety Agency

Tips for safer opioid use

Analysing reports submitted to the NPSA has made it possible to identify aspects of opioid use that can be made safer.

In the supporting documentation to the 2010 Rapid Response Report on 'Preventing fatalities from medication loading doses', 25 patient safety incidents involving loading doses of morphine were cited, including two that resulted in moderate harm. NPSA recommends that organisations should review the use of loading doses of morphine and, if necessary, take steps at local level to minimise patient safety concerns.

The Safer Medication Practice and Medical Devices team has undertaken internal 'mini-scopes' on fentanyl patches and Oramorph. Patient safety incidents and error-prone practices have been clearly described. Organisations need to be aware of the risks associated with these products and take steps at local level to ensure safe practice.

Partner initiative 3: National Prescribing Centre

Further enhancements to the NPC Accountable Officers' Support Programme

The NPC hosts a secure website for accountable officers as part of its support programme. During the year it made further enhancements to the website and discussion forum by adding the following resources:

- A handbook for accountable officers, containing detailed core requirements for their role and any specific activities relevant for each healthcare sector. The handbook also contains a set of aide-memoire checklists to allow the accountable officer to reflect on governance arrangements and where improvements could be made.
- A set of brief '5-minute guides' providing best practice advice for a range of activities required by GPs, community nurses and community pharmacists.
- Presentations with voice-over narrative covering the issues set out in the quick guides, but in considerably more detail.
- A suite of quizzes for the key audiences to test their knowledge and understanding of the areas covered within the guides and presentations.

Resources from other users of the site have also been uploaded to enable useful documents and initiatives to be shared. These include:

- An updated list of accountable officers who have authorised groups of people to witness the destruction of controlled drugs in multiple bodies before onward disposal.
- Local prescribing policies.
- Prescribing standards.
- Standard operating procedures.
- Inspection and monitoring forms.
- Training presentations.
- Terms of reference for CD LINs.
- Template frameworks for accountable officers' board reports.

Partner initiative 4: Department of Health

Controlled drug record cards (CDRCs)

The Department of Health commissioned the National Prescribing Centre (NPC) to lead a working group on the national implementation of a Controlled Drugs Record Card (CDRC) for the tracking and audit of Schedule 2 injectable controlled drugs. The proposal for a CDRC was a recommendation in the fourth report of the Shipman Inquiry. The working group concluded that a national CDRC would be complex to implement and would be unlikely to deliver the expected comprehensive audit trail, as originally envisaged. Since the original proposals, additional governance and monitoring arrangements have been introduced around controlled drugs, including the role of accountable officer. The report made further recommendations about a number of measures that could be taken forward at local level to strengthen audit and tracking of these medicines. These recommendations have been accepted by ministers.

The CDRC review reports are available on the NPC website and the NPC will also report on the progress of the supporting recommendations (www.npc.nhs.uk/controlled_drugs/cdrc.php).

Conclusions

Our partners have continued to commit to sharing their findings at national level. In times of change, it is useful for organisations to continue to meet at this level to monitor usage of controlled drugs and to discuss concerns. Partner organisations have also continued to engage with the ethos of safer management of controlled drugs and have continued to develop and implement schemes to support frontline staff.

Overall, the processes for the safer management of controlled drugs have matured to the point where there is now dialogue at all levels, in line with what was originally envisaged in the fourth Shipman report.

5 National trends in the use and management of controlled drugs

During 2010, the Care Quality Commission continued to monitor the overall use and management of controlled drugs by analysing national prescribing and requisition data, feedback on routine activity in controlled drugs monitoring, and reports from members of the National Group.

All data on prescribing in NHS primary care (including prescribing by GPs and other non-medical primary care prescribers) is collected by NHS Prescription Services. Private prescriptions for Schedule 2 and 3 controlled drugs that are dispensed in community pharmacies are also analysed by NHS Prescription Services. The output from the database is known as ePACT (electronic prescribing analysis and costs).

By analysing the data on prescribing, we are able to examine the national picture and identify areas where the prescribing of controlled drugs deviates from the normal pattern. 2010 was the fourth year of reporting on the analysis of prescribing of controlled drugs and some trends are beginning to emerge. However, the data are somewhat limited and should be interpreted cautiously.

In this report, rather than showing tables of drug usage and expenditure, we have picked out the main features and presented them graphically in order to focus on important changes or to emphasise consistency.

The Misuse of Drugs Act[8] categorises controlled drugs by class (Class A, Class B, etc) corresponding to the level of penalty for illegal possession. The classes of the Misuse of Drugs Act are of no practical importance to practitioners.[9] In the Misuse of Drugs Regulations[7], the drugs are classified into five schedules corresponding to their therapeutic usefulness and misuse potential. The lower the Schedule number, the greater the potential for harm and the greater the degree of control required (see appendix 1).

Key findings

Prescribing of controlled drugs in primary care

In 2010, the total number of controlled drugs items prescribed in NHS primary care was 46,509,136, which is an increase of 3% compared with 2009. The cost of this was £455,013,758, representing an increase of 9%.

While the overall changes were modest, there were some notable changes in usage patterns within certain groups of drugs that deserve mention.

Figure 4: Top 10 prescribed controlled drugs within primary care, 2010

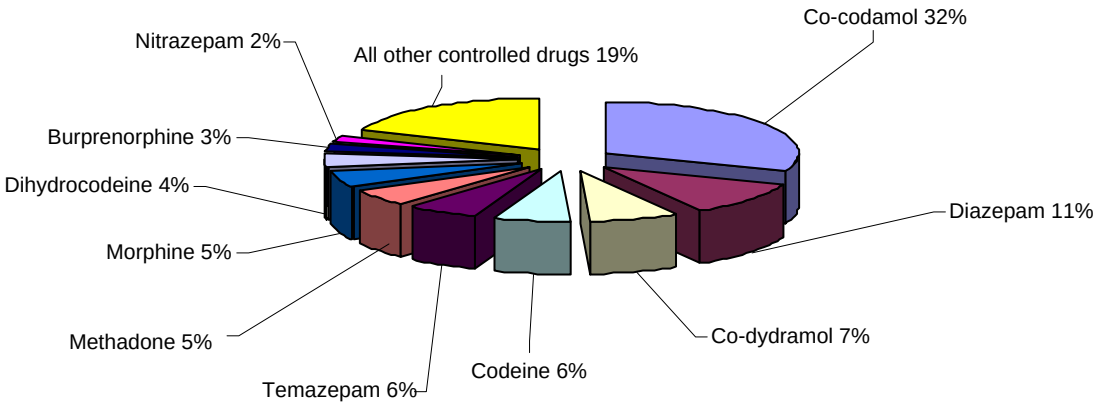
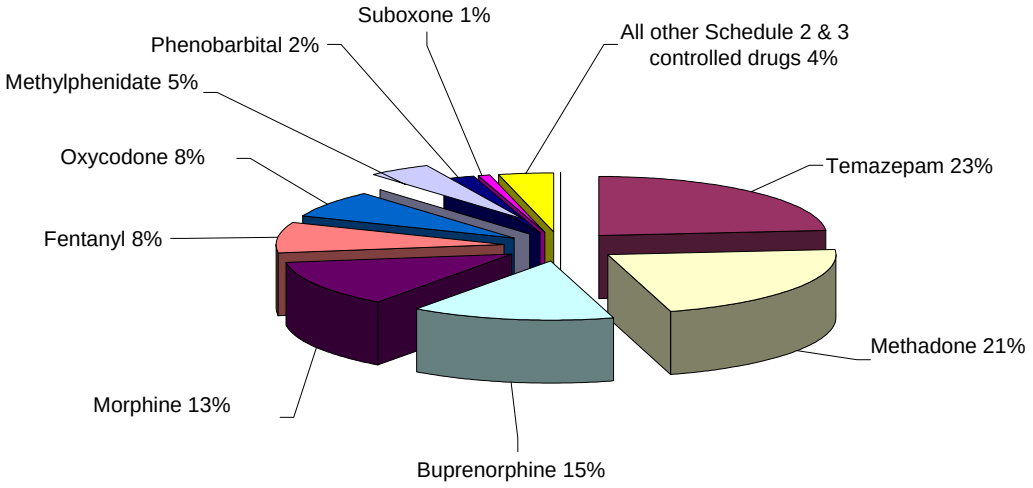


Table 2 Top Schedule 2 & 3 controlled drug prescribed items in primary care

Top Schedule 2 & 3 controlled drugs	2007	2008	2009	2010
Temazepam	3,218,072	3,091,328	2,940,796	2,789,203
Morphine	1,047,991	1,193,622	1,338,062	1,489,334
Methadone	180,2827	2,166,665	2,413,048	2,581,954
Buprenorphine	979,170	1,237,964	1,506,727	1,716,747
Fentanyl	656,802	791,520	898,188	986,157
Oxycodone	497,244	619,078	755,669	887,674
Methylphenidate	420,421	459,600	492,247	541,516
Phenobarbital	282,766	279,500	273,148	268,337
Suboxone	14,757	43,143	71,893	83,893
All other Schedule 2 & 3 controlled drugs	336,037	350,574	401,947	463,838
Total schedule 2 & 3 controlled drugs	**9,256,087**	**10,232,994**	**11,091,725**	**11,808,653**

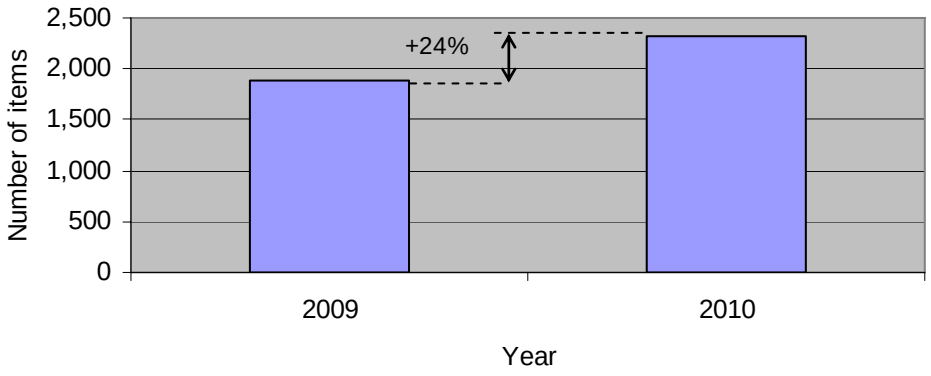
Figure 5: Top prescribed controlled drug items for Schedule 2 & 3 in primary care, 2010



Cannabis-based products

There was a 24% increase in the use of Sativex, the only licensed cannabis oromucosal spray, which is now being used increasingly. In June 2010, this cannabis oromucosal spray received a marketing authorisation in Europe and became available for routine prescribing. The only indication for this product is the relief of symptoms in multiple sclerosis.

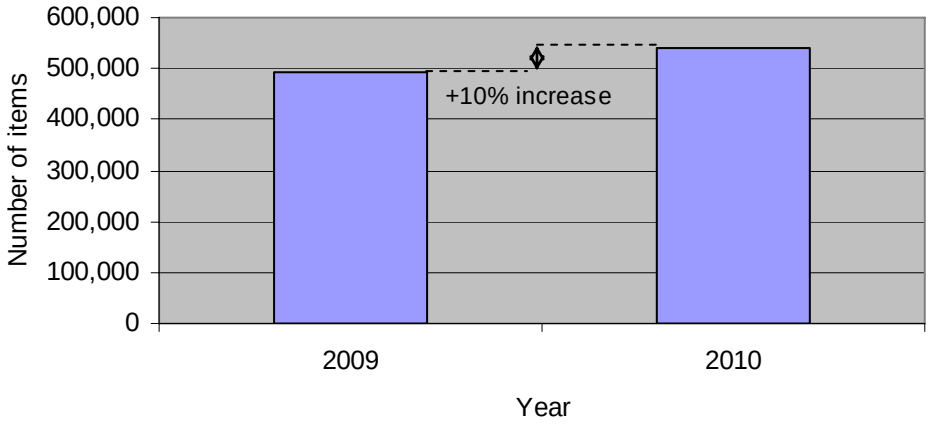
Figure 6: NHS primary care prescribing of Sativex (Schedule 1) in 2009-2010



Methylphenidate

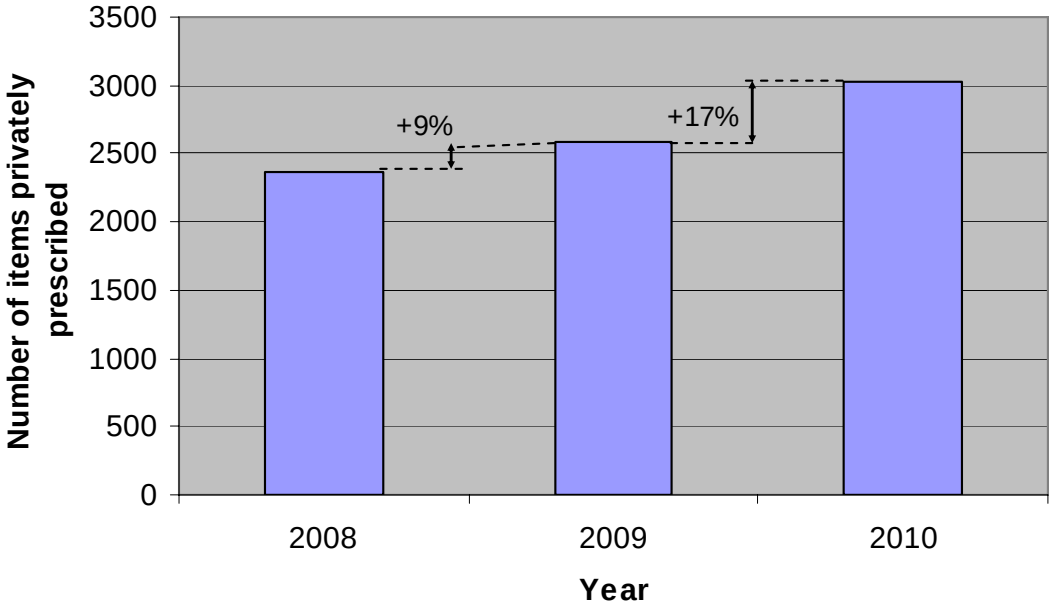
The prescribing of methylphenidate in primary care increased by 10% in 2010 compared to 2009. This is almost certainly attributable to increased diagnosis of, and prescribing for, the treatment of childhood attention deficit hyperactivity disorder (ADHD).

Figure 7: Total number of NHS methylphenidate items prescribed in primary care



It is interesting that private prescribing of methylphenidate has also increased over the past three years (see figure 8). This is likely to be due to an increase in the diagnosis of and prescribing for adult ADHD.

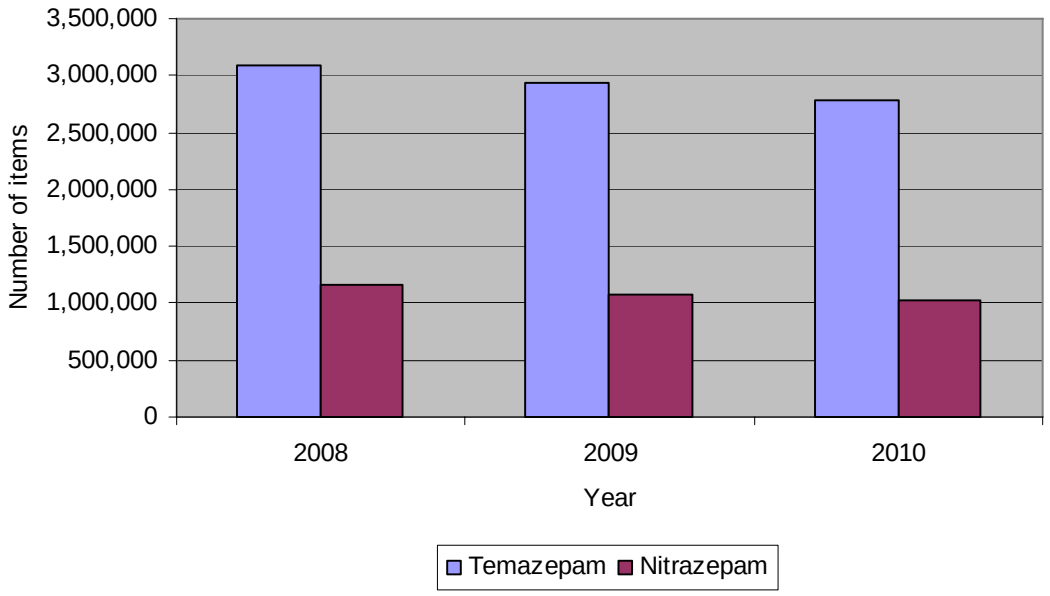
Figure 8: Total number of methylphenidate items prescribed privately, 2008-2010



Temazepam and nitrazepam

The use of the hypnotic (sleeping) agents, temazepam and nitrazepam has continued to fall steadily (see figure 9). This could suggest that prescribers are following recommendations in the British National Formulary (BNF) to limit the use of these products to short periods.

Figure 9: Temazepam and nitrazepam prescribing 2008-2010



Temazepam surveillance pilot

During 2010, we undertook a surveillance exercise to look at temazepam prescribing in six PCTs identified as having the highest prescribing levels. The exercise was run as a pilot scheme and we used both the responses and feedback received from the participating PCTs to evaluate the usefulness of the pilot as well as to help shape the process for future surveillance activity of controlled drugs.

We selected temazepam for the pilot surveillance project as it has specifically been mentioned by the NHS Security Management Service as one of four controlled drugs most commonly sought or obtained on stolen or forged prescriptions. It is important to note that in some of the outlier PCTs identified for high prescribing, temazepam is the hypnotic drug of choice on the basis of its low cost.

For the purpose of the pilot exercise, we identified the six PCTs that had the highest expenditure on temazepam after adjusting for the ASTRO-PU weighting* to take into account age, sex and temporary residents.

* ASTRO-PU weightings were designed to weight individual practice populations for age, sex and temporary residents. They were last revised in July 2009 and are now known as ASTRO(09)-PUs.

We then used the ePACT prescribing database to identify unusual prescribing patterns by individual GPs. We raised questions on these prescribing patterns and asked the PCT controlled drug accountable officers to follow up and report back to us. Our analyses drilled down to the individual prescriber rather than practice level, and we provided some specific questions for the accountable officer to ask. In general, our findings indicated that those patients on high doses or long-term treatment were generally known to the prescribers. The reasons for unusual prescribing patterns included patients being elderly and reluctant to stop treatment, terminal illness, complex psychiatric needs and some joined-up working between drug and alcohol teams. However, we also found that informing the accountable officers of our findings prompted some review and challenging of prescribing, which had some success in both decreasing daily doses and the duration of the prescription.

The accountable officers of these PCTs were very cooperative with our requests and it was extremely encouraging to see how much work was already being undertaken at a local level to review hypnotic prescribing generally. We hope that the project further supported this work and bought into sharper focus some of the high prescribing in their areas, encouraging some of the prescribers to review their practice. We have also taken into account the helpful comments made by the accountable officers and medicines management teams in this pilot to refine our process and methodology for future projects.

This was our first surveillance project and we will be following up with further controlled drug surveillance items during 2011 and beyond, as part of our role in external scrutiny. We also intend to repeat a follow-up on temazepam prescribing in the future to see if the picture has changed.

Nurse and pharmacist prescribing

Although prescribing of controlled drugs by nurses and pharmacists represents a smallish proportion of the whole, there have been considerable increases in prescribing by both groups since 2008. In both cases, this is mainly attributable to nurses and pharmacists being involved in prescribing for the treatment of substance misuse in line with policy to improve access to treatment for patients.

Figure 11: Monthly trend in all nurse prescribing in primary care of Schedule 2 controlled drugs

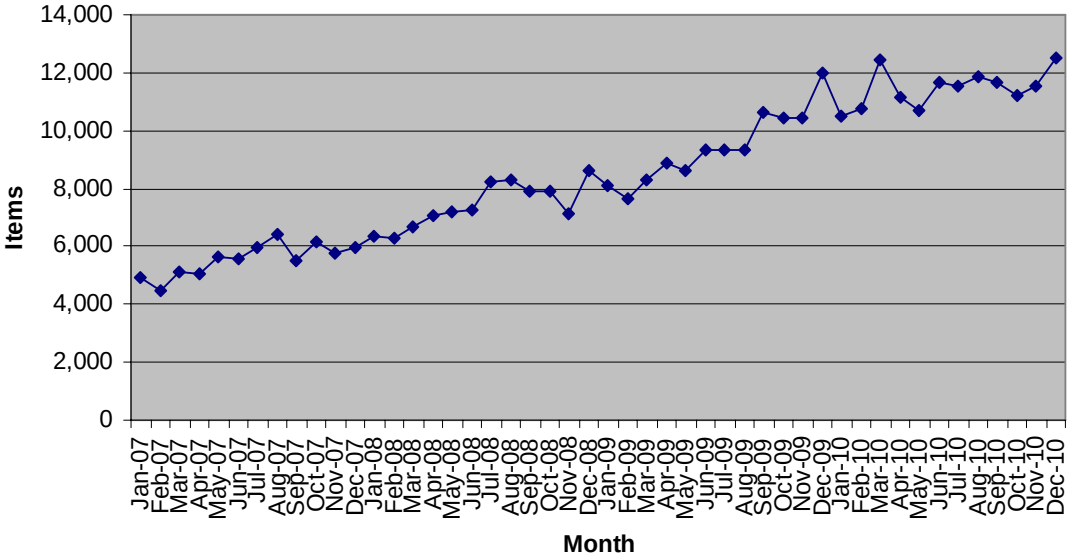


Figure 12: Nurse prescribing of controlled drugs in primary care (Schedule 2 to 5)

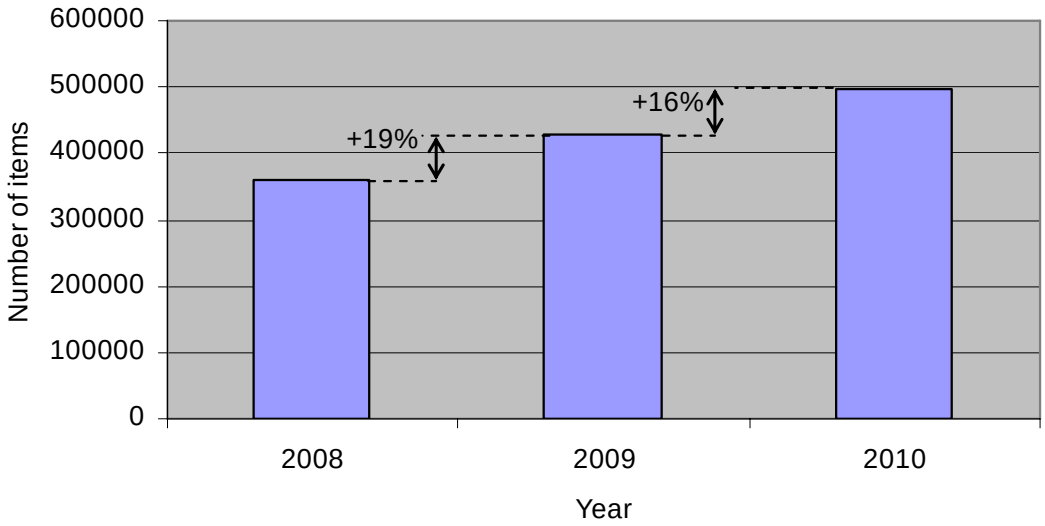
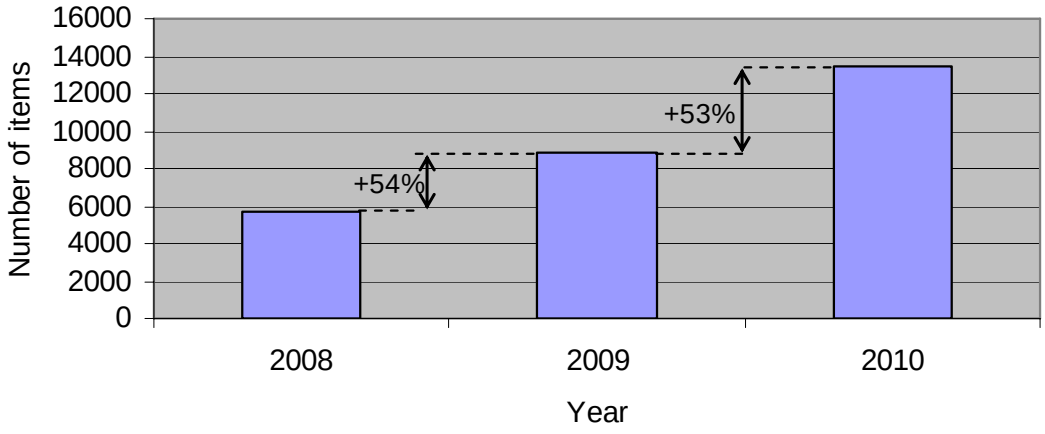


Figure 13: Pharmacist prescribing of controlled drugs in primary care (Schedule 2 to 5)



Private prescribing of controlled drugs

The total number of controlled drug items prescribed privately in 2010 was 46,501, a modest increase of 7% compared with 2009.

Private prescribing accounts for about 0.1% of overall controlled drug prescribing.

Figure 14: Top 10 privately prescribed Schedule 2 & 3 controlled drugs, 2010

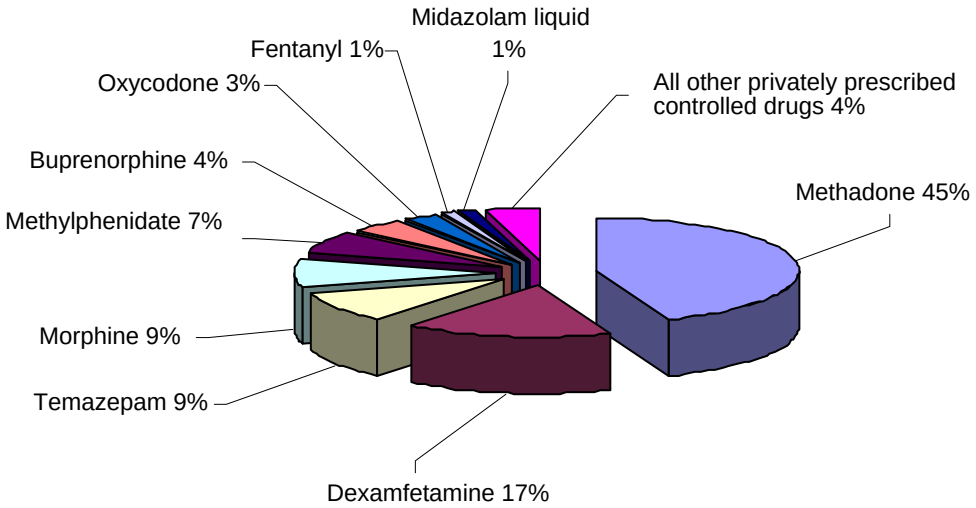


Table 3: Top 10 privately prescribed Schedule 2 & 3 controlled drugs				
Controlled drug	**Count of controlled drug 2007**	**Count of controlled drug 2008**	**Count of controlled drug 2009**	**Count of controlled drug 2010**
Methadone	27,885	25,202	21,291	20,597
Dexamfetamine	9,433	8,034	7,414	7,689
Temazepam	4,934	5,121	4,143	4,381
Morphine	2,901	4,133	3,000	4,322
Methylphenidate	1,910	2,317	2,581	3,031
Buprenorphine	1,865	2,443	1,824	2,502
Oxycodone	1,015	954	1,089	1,239
Fentanyl	457	506	687	607
Midazolam Liquid	39	308	186	570

"Amphetamine prescribing for amphetamine addiction is not supported by the evidence base or best practice guidelines."

Dr Owen Bowden-Jones
Chair, Faculty of Addictions, Royal College of Psychiatrists

The most common controlled drugs prescribed privately in 2010 have largely stayed the same when compared to 2009. The main points are:

- Methadone continues to be the most common controlled drug prescribed privately.
- We remain concerned about the continued high use of dexamfetamine. Although this could, in part, be attributed to prescribing for adult ADHD, there is concern that this might reflect prescribing of dexamfetamine for amphetamine addiction. We have confirmed that the current clinical guidelines[1] (the 'orange book') apply to both private and NHS prescribing and that there is no place for amphetamine prescribing in the treatment of amphetamine addiction.

- We have again seen a year-on-year increase in the volume of methylphenidate prescribed privately (see Figure 8). This may, in part, be attributed to prescribing for adult ADHD.
- There has been a marked increase in the use of midazolam liquid and the reasons for this are not clear.
- Temazepam prescribing has fallen slightly over the past four years.
- Buprenorphine use has continued at a similar level over the past four years.

The geographical distribution of private prescribing remains unaltered from previous years, with the London area accounting for around 85% of the national total.

Recommendation 4

All professionals and providers of care, whether practising in the NHS or independent sector, should take account of best practice guidance that is published by relevant professional bodies and agencies. All sectors should be made aware of the document, *Drug misuse and dependence: UK guidelines on clinical management* and that it applies across all sectors.

Controlled drugs requisitions

To obtain a stock of a Schedule 2 or 3 controlled drug from a community pharmacy, practitioners must use a written requisition form. This is the third year that we have been able to collect this requisition data following the legislation that was put in place following one of the recommendations from the Shipman inquiry. The aim of the policy was to enable PCTs to capture and identify the purchase of controlled drugs by individual doctors.

The data this year has shown a continuing trend from previous years, with the large volume of requisitions generated by some hospices making it difficult to identify the use by individual practitioners.

The six PCTs with the highest number of requisitions all had large numbers of individual hospices requisitioning their controlled drug stock for pain relief in palliative care from community pharmacies.

We recommended last year that the requisition regulations should be reviewed to make them more focused on capturing the data from individual practitioners. The need to amend these regulations has been accepted and will be included in a future regulatory consolidation update.

The monthly figures for submission of controlled drug requisitions continue to be patchy, with many PCTs having months where there appear to be no items requisitioned. In these PCT areas, community pharmacies should be reminded to return requisitions to the NHS Business Services Agency at the beginning of every month as set out in Part XX of the Drug Tariff.

Conclusions

NHS (primary care) prescribing of controlled drugs increased by only 3% compared with 2010. Prescribing by nurses and pharmacists continued to increase in keeping with policy and the Government's agenda to improve people's access to medicines through the introduction of more non-medical prescribers.

The detailed information about private prescriptions once again showed that the profile of private prescribing is markedly different from that of NHS prescribing, with high amounts of methadone and dexamfetamine prescribed privately that is not seen in NHS practice. In addition, there has been a large increase in the use of midazolam liquid. The reasons for these differences are not entirely clear and further work is needed to look at this area.

The benefits of serial analyses of controlled drug prescribing are becoming clear, now that we have data for the past four years. It is possible to see long-term trends in drug usage and this almost certainly gives a more accurate and meaningful picture than short-term changes. This will enable us to identify trends more accurately and monitor the impact of changes in practice or regulations. This development is particularly important in relation to private prescribing, as none of these data were collected before 2007.

In previous years we have recommended that the Royal College of Physicians, Royal College of General Practitioners and Royal College of Psychiatrists (RCP, RCGP and RCPsych) be invited to draft guidance on appropriate use of opioids and amphetamines. They have confirmed that existing published guidance on best practice, *Drug misuse and dependence: UK guidelines on clinical management*[1], is equally applicable in both NHS and independent healthcare practice. This is helpful because it has clarified that no practice setting where controlled drugs are used is outside the scope of the guidance.

Over the past three years, it has become clear that analyses of controlled drug requisitions are not able to identify purchases by individual doctors, as was originally envisaged. During the past year, several agencies have taken this on board and have started work to improve the system so that meaningful data can be obtained.

6 Overall conclusions, next steps and recommendations

Our overall conclusions for 2010 are that:

- Stakeholders and partner organisations have continued to actively support the safer management of controlled drugs with enthusiasm and, in several instances, have devised innovative approaches to improve the safe management and use of controlled drugs in the widest perspective. We believe that the many examples of good practice in this report reflect an appropriate level of concern for safe management and use of controlled drugs.

- The planned NHS changes, including changes to PCT structures, will affect the appointments of accountable officers and the CD LIN arrangements. It is important that these changes are clearly communicated to all providers in the local community so that information and concerns can continue to be shared effectively.

- The newly-created provider organisations that are not required by the regulations to appoint an accountable officer must still make arrangements to ensure the safe management of controlled drugs within their organisation and report to their commissioning PCT.

- CD LINs need to continue to function effectively through the changes to primary care structure and make adequate preparations to ensure that their existing arrangements are sufficiently robust to store intelligence securely. They also need to be sufficiently independent to be transferred to any future host body. The engagement of all health and social care providers, both new and existing, in sharing information and intelligence must not be overlooked.

- National prescribing data allows us to monitor trends and identify changes. This is particularly valuable for private prescribing of controlled drugs, as no such data were collected before 2007. Now that we are in the fourth year of data analysis, we can see some consistent trends emerging, and we have identified some findings that require further explanation.

- We noted that, although a small proportion of the whole, prescribing of controlled drugs by nurses and pharmacists continued to increase in keeping with policy and the Government's agenda to improve people's access to medicines through the introduction of more non-medical prescribers.

- We noted an upward trend in the private prescribing of methylphenidate and midazolam liquid, together with continued prescribing of dexamfetamine. The reasons for the differing profiles for primary and private prescribing of controlled drugs still remain unclear and will be the subject of ongoing investigations during 2011.

- We still wish to emphasise that managing and monitoring the systems for controlled drugs at both national and local levels will require ongoing activity and vigilance to sustain the positive developments that have been achieved in the past four years.

Next steps

The next steps for primary care will be to:

- Ensure that all systems for the safer management of controlled drugs are robust and up-to-date, ready for handover to the new organisations.
- Ensure that the private prescribing of controlled drugs, especially dexamfetamine, methylphenidate and midazolam liquid continues to be closely monitored.

Recommendations

1. **Chief executives and accountable officers should continue to keep the safe management of controlled drugs a high priority on their organisation's agenda during the reorganisation of the NHS to ensure that the gains in safety made over the past four years are not lost.**
2. **Chief executives and accountable officers should ensure that CD LINs have robust working arrangements and are fit for purpose and adequately prepared for the transition.**
3. **Non-designated bodies should also be encouraged to participate more in the information-sharing process to ensure that intelligence-gathering is thorough and complete, capturing information from all sources for example, community pharmacists, the Ministry of Defence, care homes, substance misuse services and new provider services.**
4. **All professionals and providers of care, whether practising in the NHS or independent sector, should take account of best practice guidance that is published by relevant professional bodies and agencies. All sectors should be made aware of the document, *Drug misuse and dependence: UK guidelines on clinical management* and that it applies across all sectors.**

Appendix 1: The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

Controlled drugs legislation

Controlled drugs are a group of medicines that have the potential to be abused. For this reason, they are 'controlled' by The Misuse of Drugs Act 1971[8]. Many controlled drugs are essential to modern clinical care. They include narcotics, such as morphine and diamorphine, which are used in a wide variety of clinical situations such as the relief of severe pain and the treatment of drug dependence. Controlled drugs also include benzodiazepines (tranquillisers and sleeping tablets), anabolic steroids and growth hormones.

The main purpose of the Act is to prevent the misuse of controlled drugs by imposing restrictions on their possession, supply, manufacture, import and export, as detailed in regulation.

The legitimate, clinical use of controlled drugs is governed by the Misuse of Drugs Regulations 2001.[7] These divide controlled drugs into five 'schedules' according to the level of control they need.

The Misuse of Drugs Act 1971 (the Act) and the Misuse of Drugs Regulations 2001 (the Regulations) restrict the possession, supply, administration and disposal of controlled drugs.

The Misuse of Drugs Act 1971

Controlled drugs are categorised into three classes as specified under Schedule 2 of the Act. This classification is designed to enable the control of particular drugs according to their comparative harmfulness, either to individuals or to society at large, when they are misused. The classes determine the level of penalties (fine and/or imprisonment) applicable to offences (as defined in the Act) involving the different drugs in a descending order of severity, from A to C.

Class A (the most harmful)

Includes: Ecstasy, LSD, heroin, cocaine, crack, magic mushrooms (whether prepared or fresh), methylamphetamine (crystal meth), and other amphetamines if prepared for injection.

Penalties for possession: Up to seven years in prison, an unlimited fine or both.

Penalties for dealing: Up to life in prison, an unlimited fine or both.

Class B (an intermediate category)

Includes: Cannabis, amphetamines, methylphenidate (Ritalin), barbiturates, pholcodine.

Penalties for possession: Up to five years in prison, an unlimited fine or both.

Penalties for dealing: Up to 14 years in prison, an unlimited fine or both.

Class C (the least harmful)

Includes: Tranquilisers, some painkillers, GHB (gamma hydroxybutyrate), ketamine, anabolic steroids, benzodiazepines, growth hormones.

Penalties for possession: Up to two years in prison, an unlimited fine or both.

Penalties for dealing: Up to 14 years in prison, an unlimited fine or both.

The Misuse of Drugs Regulations 2001

Controlled drugs are also categorised into five schedules by the Regulations, corresponding to their therapeutic usefulness and misuse potential. The drugs listed in Schedule 1 have limited medicinal use and may only be lawfully possessed under licence from the Home Office.

Schedule 1

Schedule 1 includes cannabis and cannabinoids.

Schedule 2

Schedule 2 controlled drugs include the opiate-based drugs used in acute and palliative care. They are subject to regulations determining their supply and storage.

Supply: Supply is restricted to licensed wholesalers, practitioners, hospitals and registered pharmacies. Wholesalers are permitted to supply only to a person authorised to possess. Practitioners are restricted to supplying their patients. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners. Pharmacies may supply on receipt of a valid prescription or signed order. Additional prescription writing requirements exist.

Record: A record of all Schedule 2 controlled drugs obtained and supplied must be kept in a register, the form of which must comply with the relevant regulations.

Storage: Schedule 2 controlled drugs are subject to safe custody requirements (The Misuse of Drugs (Safe Custody) Regulations 1973, amended 2007). They must be stored in a locked receptacle, usually in an appropriate controlled drug cabinet or approved safe, which can be opened by a person in possession of the controlled drug or a person authorised by that person.

Destruction: The destruction of Schedule 2 controlled drugs must be appropriately authorised and the person witnessing the destruction must be authorised to do so. Schedule 2 controlled drugs must be denatured before being placed into waste containers.

Schedule 3

Schedule 3 contains a number of substances that are perceived as being open to abuse, but less likely to be so than Schedule 2 controlled drugs. It includes a number of synthetic opioids together with other substances.

Supply: The regulations concerning supply (and the additional prescription writing requirements) are similar to Schedule 2 controlled drugs.

Record: There is no statutory requirement to record the supply of Schedule 3 controlled drugs.

Storage: The majority of Schedule 3 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf. Certain Schedule 3 controlled drugs are exceptions to this exemption.

Destruction: The requirements relating to witnessing of destruction do not apply to Schedule 3 controlled drugs (unless the controlled drugs are manufactured by the individual). However, Schedule 3 controlled drugs must be denatured before being placed into waste containers.

Schedule 4

All Schedule 4 controlled drugs are prescription only medicines (POMs) and are divided into two parts. Part 1 contains most benzodiazepines and zolpidem. Part 2 contains most of the anabolic steroids.

Supply: Supply is restricted to supplies against practitioners' prescriptions or in accordance with Patient Group Directions (PGDs) but there are no additional requirements as to the form of prescription other than those that apply to all POMs.

Record: There is no statutory requirement to record the supply of Schedule 4 controlled drugs.

Storage: Schedule 4 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to witnessing of destruction do not apply to Schedule 4 controlled drugs (unless the controlled drugs are manufactured by the individual). However, Schedule 4, part 1 controlled drugs must be denatured before being placed into waste containers.

Schedule 5

Schedule 5 controlled drugs, which include POMs and over-the-counter medicines, contain preparations of certain controlled drugs such as codeine, pholcodine, cocaine and morphine which are exempt from full control when present in medicinal products of low strength. They are excepted from the prohibitions on importation, exportation and possession.

Supply: Some of the controlled drugs in Schedule 5 are available for over-the-counter sale in registered pharmacies. It is for the pharmacist to use their professional judgement to determine the appropriateness of any supply and be alert to potential misuse of products.

The Schedule 5 controlled drugs that are prescription only medicines (including codeine, dextropropoxyphene and dihydrocodeine tablets) can only be supplied in accordance with a valid prescription or Patient Group Direction.

Record: There is no statutory requirement to record the supply of Schedule 5 drugs.

Storage: Schedule 5 controlled drugs are exempt from safe custody requirements and can be stored on the open dispensary shelf.

Destruction: The requirements relating to destruction do not apply to Schedule 5 controlled drugs.

Appendix 2: The Shipman Inquiry

The Shipman Inquiry

The Shipman Inquiry was an independent public inquiry set up in 2001 to examine the issues arising from the case of Harold Shipman.

The inquiry's Fourth Report focused on the methods Shipman used to divert large quantities of controlled drugs for his own purposes, and considered how he was able to do it for so long without detection. It concluded that there were serious shortcomings in the systems for regulating the governance of controlled drugs. In response, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced.[4] They included provision for:

- The appointment of accountable officers in healthcare organisations described as 'controlled drug designated bodies'. The accountable officer is responsible for all aspects of the safe and secure management of controlled drugs in the organisation.
- Formal, on-site inspections of providers of health and social care by various bodies. Figure 1 shows an overview of the arrangements in place in 2010 for the safe management of controlled drugs.
- The sharing of information, including a legal duty of collaboration among all 'responsible bodies', and making accountable officers in primary care trusts responsible for establishing local intelligence networks.

The regulations came into force in England on 1 January 2007. The Government published additional guidance, *Safer management of controlled drugs: (1) guidance on strengthened governance arrangements* in March 2006 and reissued it in January 2007.[5]

The current governance arrangements for controlled drugs and the monitoring and inspection functions are summarised in appendix 3.

The inquiry's Fifth Report, *Safeguarding Patients: Lessons from the Past - Proposals for the Future*[10] recommended better use of routine monitoring data, improved arrangements for making and responding to complaints and concerns and better regulation of doctors including revalidation. A key role in the process of revalidation will be the appointment of a local responsible officer.

Appendix 3: Governance arrangements for controlled drugs in 2010

Table 15: Governance arrangements in 2010 for sites where controlled drugs are routinely used

Controlled drug handling site	Governance arrangements
Primary care trusts.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in standard operating procedures (SOPs). Collected self-assessments from contracted services. Retain accountable officer responsibilities for commissioned provider services that are not defined in legislation as a designated body. Develop and lead the local intelligence network.
NHS hospital trusts and foundation trusts.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in SOPs. Member of the local intelligence network.
Independent hospitals.	Accountable officer with responsibility for all aspects of safe and secure handling of controlled drugs. All controlled drug activity defined in SOPs. Member of the local intelligence network.
Non-statutory prescribing drug services in community and inpatient (including residential) settings.	All controlled drug activity defined in SOPs. Commissioner of service to specify assurance.
Non-controlled drug designated bodies e.g. private clinics, private doctors.	All controlled drug activity defined in SOPs. For those not registered with the Care Quality Commission, the accountable officer of the primary care trust has the right of entry to investigate reported controlled drug concerns.

Controlled drug handling site	Governance arrangements
Social care settings.	Inspection by Care Quality Commission. All controlled drug activity defined in SOPs/policies and procedures. Care Quality Commission member of the local intelligence network. Individual duty to report concerns to the primary care trust's accountable officer/local intelligence network.
GPs	Inspection by primary care trust's accountable officer. All controlled drug activity defined in SOPs. Self-assessment and declaration to the primary care trust. Individual duty to report concerns to the primary care trust's accountable officer/local intelligence network.

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7. Misuse of Drugs Regulations 2001 (SI 3998), www.opsi.gov.uk/si/si2001/20013998.htm

8. Misuse of Drugs Act 1971 (Amendment) Order 2008, UK SI 3031

9. Royal Pharmaceutical Society of Great Britain, *Medicines, Ethics and Practice: A Guide for Pharmacists and Pharmacy Technicians,* 34th revised edition, July 2010

10. The Stationery Office, *Fifth Report of the Shipman Inquiry: Safeguarding Patients: Lessons from the Past - Proposals for the Future*, December 2004 http://www.shipman-inquiry.org.uk/fifthreport.asp

11. The Health Act 2006, www.opsi.gov.uk/acts/acts2006/pdf/ukpga_20060028_en.pdf

Glossary of terms

Term	Definition
Accountable officer (AO)	The person in a healthcare organisation who takes formal responsibility for all controlled drug handling and governance issues in their organisation. This is a requirement under the Health Act 2006.[11] Details of the role are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.[4]
Advisory Council on the Misuse of Drugs (ACMD)	An independent expert body that advises Government on issues related to the misuse of drugs in the UK.
Analgesic	Pain-relieving medicine
Central nervous system stimulants (CNSS)	e.g. dexamfetamine, methylphenidate
Controlled drugs liaison officer (CDLO)	Police officer or police staff with a specific role in relation to controlled drugs intelligence and investigation.
Controlled drug designated body (CDDB)	A healthcare organisation that is required to have an accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006. In England this includes PCTs, NHS trusts (including foundation trusts) and independent hospitals.
Controlled drug requisitions	Standardised documents that are used when healthcare practitioners requisition supplies of controlled drugs from community pharmacies.
electronic Prescribing Analysis and Costs (ePACT)	A computer system that provides an interface to analyse prescribing information held on the NHS Prescription Services' prescription information database.
FP10PCD	Standardised controlled drugs private prescription form.
Healthcare organisation (HCO)	For example, a PCT, NHS trust hospital or independent hospital.

Independent healthcare	Private or voluntary healthcare delivered outside the NHS.
Local intelligence network (LIN)	Defined in legislation as a network to be established by the PCT accountable officer to share information between organisations and agencies regarding the handling and use of controlled drugs.
Medicines and Healthcare products Regulatory Agency (MHRA)	The government agency that is responsible for ensuring that medicines and medical devices work, and are acceptably safe.
Misuse of Drugs Act 1971 (MDA)	Act of Parliament that aims to control the possession and supply of various drugs.
Misuse of drugs legislation	See MDA and MDR.
Misuse of Drugs Regulations 2001 (MDR)	Legislation governing the legitimate, clinical use of controlled drugs.
Opiate	Naturally-occurring narcotic derived from opium, e.g. morphine.
Opioid	A synthetic narcotic that resembles the naturally occurring opiates e.g. fentanyl.
Prescribing Support Unit	Body responsible for analysis of all NHS and private prescriptions for controlled drugs dispensed in community pharmacies.
Primary care trust (PCT)	Body responsible for commissioning and delivering healthcare and health improvement to the people of its local area.
Relevant person	Healthcare professionals and others whose work involves, or may involve, the supply and administration of controlled drugs on behalf of another registered medical practitioner, dentist, pharmacist, private midwife, or registered person, etc (that is, the non-professionals involved with handling controlled drugs) in assisting the healthcare person (Regulation 23).
Responsible body	Body or organisation defined in regulation with a duty to share information on controlled drugs.
Root cause analysis	A systematic approach to get to the true root causes of process problems.

Serious untoward incident (SUI)	An adverse incident that causes serious harm to a user of healthcare services, a member of the public or a member of staff, or that causes a serious breach of the standard or quality of service.
Strategic health authority (SHA)	Bodies that manage the NHS locally. They develop plans for improving health services in their area, make sure local health services are of a high quality and making sure national priorities are integrated into local health service plans.
Transdermal patches	Adhesive patches that contain a drug (eg buprenorphine or fentanyl) and are used to deliver a drug slowly through the skin.

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Care Quality Commission

How to contact us

Phone us on: **03000 616161**

Email us at: **enquiries@cqc.org.uk**

Look at our website: **www.cqc.org.uk**

Write to us at:
Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Please contact us if you would like a summary of this document in another language or format (for example, in large print, in Braille or on audio CD).

Registered Office:

Care Quality Commission
Finsbury Tower
103–105 Bunhill Row
London EC1Y 8TG

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