Care Quality Commission

The safer management of controlled drugs

Annual report 2012

August 2013

The Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England.

Our purpose

We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

Acknowledgement

We would like to thank Professor Roger Knaggs and Dr Owen Bowden-Jones for their help in interpreting the findings regarding prescribing of controlled drugs and Ms Tracey Hogan for providing details of the Bridge Project.

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Summary

This is the sixth annual report from the Care Quality Commission (CQC) on the regulation of controlled drugs in England and relates to the year ended 31 December 2012. It covers all schedules of controlled drugs, including narcotics and amphetamines as well as benzodiazepines and anabolic steroids. It describes the progress made during 2012 and includes examples of good governance in managing the risks associated with the handling and use of controlled drugs. It also shows how prescribing patterns for controlled drugs have changed over the six-year period and offers some explanations for these changes.

In 2013, changes were made to the regulations governing controlled drugs to align them with the new NHS architecture. This is therefore the last report under the 2006 regulations, and we have taken the opportunity to describe briefly how the changes will affect the regulation of controlled drugs.

Over the past six years there has been considerable progress in developing the systems and processes for good governance in relation to controlled drugs. In view of the changes to the NHS in England that are now being implemented, it is particularly important to ensure that these systems remain in place and continue to work effectively so that the gains made in recent years are not lost.

Safe management of controlled drugs in health and social care organisations

The two main provisions for ensuring safe management of controlled drugs are the appointment of controlled drugs accountable officers (CDAOs) and sharing information between organisations, regulators and agencies through local intelligence networks (CD LINs). These are described in detail in the Controlled Drugs (Supervision of Management and Use) Regulations 2006. The new regulations, the Controlled Drugs (Supervision of Management and Use) Regulations 2013, came into force on 1 April 2013.

CQC continued to maintain and publish the register of CDAOs on our website throughout 2012. We also introduced a scheme to allow CDAOs to update their details on the register by emailing CDAOregisterdata@CQC.org.uk.

The role of the CDAO has developed further to embrace not only responsibility for good governance of controlled drugs, but also for the safe and appropriate clinical use of controlled drugs. The National Group on Controlled Drugs formed a clinical sub-group to provide expert clinical advice and support to help CDAOs to take this forward in their own organisations.

Overall, a robust foundation has been put in place for good governance of controlled drugs in the reorganised NHS, from 2013.

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 2012, the Armed Forces and the Medicines and Prescribing Centre joined the National Group.

The Group met four times during 2012 to share findings and discuss concerns. We highlight some examples of initiatives from partners to further improve the proper management and clinical use of controlled drugs.

National trends in the use of controlled drugs

In 2012, the total number of controlled drugs items prescribed in NHS primary care was 47,308,286, which is an increase of 1% compared with 2011. The cost of this was £452,763,739 representing an increase of 2% compared to £443,380,585 in 2011.

Serial analyses of prescribing of controlled drugs in primary care have revealed some clear trends, including a continuous downward trend in the prescribing of temazepam over the six-year period. At the same time there have been increases in prescribing of buprenorphine, morphine sulphate, oxycodone, fentanyl, methylphenidate, midazolam and diamorphine.

Private prescribing of controlled drugs decreased by 10% in 2012 (39,432 items) compared with 2011 (43,640 items).Private prescribing accounts for about 0.1% of overall controlled drug prescribing. Over the six-year period, the volume of private prescribing of controlled drugs has decreased by 24%.

The profile of private prescribing continued to differ from NHS primary care prescribing, with dexamfetamine appearing as the second most commonly prescribed item. Dexamfetamine does not appear at all in the top 10 Schedule 2 controlled drugs prescribed in primary care.

Dexamfetamine is a central nervous stimulant and can be prescribed as a second line treatment for children and adults with Attention Deficit Hyperactivity Disorder (ADHD). However, due to its potential for diversion and misuse, and in view of concerns that this might reflect inappropriate prescribing of dexamfetamine for amphetamine addiction, this calls for continued vigilance as we recommended last year.

The prescribing of methylphenidate has continued to increase in both the NHS and private sectors. This is similarly likely to be attributable to its use in the management of childhood and adult ADHD and again, due to its potential for diversion, and misuse, its use should also be monitored carefully.

Monitoring the use of controlled drug requisition forms has shown that this system is not yet embedded and the problems need to be resolved before we can gather meaningful data from analysis of requisitions. The Home Office consulted on proposals to make specific changes to the Misuse of Drugs Regulations 2001 during 2011, including the introduction of a mandatory requisition form. Following the consultation, the Advisory Council on the Misuse of Drugs (ACMD) recommended that a mandatory standard requisition form should be introduced for Schedules 2 and 3 controlled drugs. When implemented, this will allow more meaningful data on requisitions for these drugs to be gathered in future. This is in line with a recommendation that CQC made in our 2009 report.

Overall, the system for analysing and monitoring controlled drug prescriptions at a national level is working well and provides information that could form the basis for further, detailed analyses.

Overview of key issues in 2012

- 2012 was the last complete year under the first (2006) controlled drug regulations and there was widespread awareness of the impending changes to NHS architecture. As a result, organisations tended to focus more on consolidating existing governance arrangements for controlled drugs rather than on new developments. Going forward, it is important for CDAOs to further develop their roles in relation to managing the risks associated with the therapeutic use of controlled drugs. The recently formed clinical sub-group of the National Group will provide advice and practical support for this work.
- Many CD LINs continued to function effectively in 2012, despite a lack of clarity about future arrangements. Their value and the need for their work to continue was widely acknowledged.

- Partner organisations continued to give active support to the safer management of controlled drugs and to devise innovative approaches to improve the safe management and use of controlled drugs in the widest perspective. Their contributions during 2012 will support the on-going management of controlled drugs going forward into the restructured NHS. The membership of the National Group was reviewed to ensure that it was fit for purpose both during 2012 and for the changes ahead.
- During 2012, there was little overall change in the total number of controlled drug items prescribed, or the costs, compared with 2011. However, there was evidence of on-going changes in the patterns of use.
- Serial analyses of prescribing of controlled drugs over the past six years have revealed some clear trends, including a decrease in prescribing of temazepam. At the same time, prescribing of buprenorphine, morphine sulphate, oxycodone, fentanyl, methylphenidate, midazolam and diamorphine has increased.
- 2012 was the last full year in which PCTs held responsibility for assessing the governance arrangements for controlled drugs within primary medical services. From April 2013, CQC will regulate this sector.
- NHS Prescription Services has monitored information from the controlled drug requisition form, which has shown that this system is not yet embedded and the problems need to be resolved before any meaningful data can be gathered from analysing requisitions. Now that the Home Office is amending the legislation to require mandatory use of a standard requisition form, there is the prospect of gathering more meaningful data in future.
- Overall, there is now a robust basis for the on-going safe management of controlled drugs. In many ways the strengthening of governance arrangements for controlled drugs over the past six years has corrected many of the weaknesses of the previous systems. We are now in a position to move forward and start to build better systems to ensure that controlled drugs are not only managed securely but are also used clinically in the safest and most effective ways.

Recommendations

1. Health and social care professionals must ensure that they know how to contact the CDAO in the new Area Teams of the NHS Commissioning Board (known as NHS England) and the mechanism for reporting controlled drug concerns (the CDAO Register is on CQC's website).
2. Because of the changes, CDAOs should follow the guidance on CQC's website to update contact details promptly to ensure that the CDAO register is accurate.
3. Effective systems developed at the local level for secure gathering, sharing and recording of intelligence relating to concerns about safe management of controlled drugs should be preserved and transferred into the new NHS structure.
4. CDAOs, clinical commissioning groups and controlled drugs leads must be mindful of their continuing responsibilities for good governance and safe use of controlled drugs; this will be critical to ensure on-going progress during the transition period so as not to lose valuable intelligence and to ensure on-going monitoring and vigilance.
5. Looking forward to 2013, CQC must incorporate providers' governance arrangements for controlled drugs into its inspection model for primary medical services.

1. Progress on recommendations made in the 2011 report

In the 2011 report, CQC made seven recommendations. The following describes the progress made so far with recommendations 1, 3, 4, 5 and 7.

Recommendation 1:

"Designated body organisations should notify CQC promptly when the controlled drugs accountable officer (CDAO) for their organisation changes, to ensure that this is not overlooked in a period of change. The newly-appointed CDAO must also make contact with the accountable officer leading the LIN."

Progress: A mechanism has now been established to enable CDAOs to notify CQC about changes to contact details by email. We believe that this has streamlined the process considerably and made it much easier to keep the register up to date.

Recommendation 3:

"CDAOs should ensure that they have systems in place to assure the safe prescribing and administration of controlled drugs in all situations where controlled drugs are used."

Recommendation 4:

"Medicines safety, risk and clinical governance groups must always include the CDAO when incidents involving controlled drugs are reported, so that opportunities for local and national learning are not missed."

Recommendation 5:

"CDAOs should ensure that suitable systems are in place to ensure the safe and effective use of transdermal fentanyl patches. This should include on-going education of all staff involved in prescribing, dispensing, administering and disposing of transdermal fentanyl patches."

Progress: A subgroup of the National Group was formed in the second half of 2012 to advise on the safe and effective prescribing and administration of controlled drugs, with the overall objective of minimising risks and harm arising from the use of these medicines. The Group will develop support information to help CDAOs and practitioners.

Recommendation 7:

"The use of a standard controlled drug requisition form (FP10 CDF) should be encouraged more actively."

Progress: The Home Office has consulted on this and received advice from the Advisory Council on the Misuse of Drugs (ACMD) to support this change. The statutory instrument to implement this change is being drafted.

2. Introduction

This is the sixth annual report from the Care Quality Commission (CQC) on the regulation of controlled drugs in England and relates to the year ended 31 December 2012.We describe developments in managing the risks associated with handling and using controlled drugs and look at the changing prescribing patterns for controlled drugs over the last six years. The report covers all schedules of controlled drugs, including narcotics and amphetamines as well as benzodiazepines and anabolic steroids.

During 2012, the regulations governing controlled drugs were reviewed and new regulations were developed to align them with the new NHS architecture. This is the last report under the 2006 regulations. We therefore take the opportunity to describe briefly how the changes will affect the regulation of controlled drugs.

Over the past six years the systems and processes for good governance in relation to controlled drugs have improved considerably in response to the findings of the Shipman Inquiry. The changes to the NHS in England that are now being implemented mean that it is particularly important to ensure that these systems remain in place and continue to work effectively so that the gains made in recent years are not lost.

Previous reports are available on our website. The 2007 report provides a detailed background to the legislative and regulatory changes that were introduced as a result of the Shipman Inquiry.

CQC's role in overseeing the safer management of controlled drugs

CQC has responsibility for making sure that health and social care providers and other regulators maintain a safe environment for the management of controlled drugs. This arose from the findings of the Fourth Report of the Shipman Inquiry[1] and the Government's response to the inquiry's recommendations[2] (see Appendix B for further information).
The elements of this oversight role are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006[3] that were introduced in 2007. The Care Quality Commission took over the responsibilities originally assigned to the Healthcare Commission when it became established on1 April 2009. They are:

- Providing assurance of safer management arrangements 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 governance arrangements for controlled drugs including sharing concerns and good practice to promote improvement.
- Making judgements on how health and social care providers look after controlled drugs safely.
- Maintaining and publishing a register of controlled drugs accountable officers (CDAOs).
- Participating in and monitoring the effectiveness of controlled drug local intelligence networks (CD LINs) led by primary care trusts, and ensuring that local governance arrangements and provisions for incident panels are satisfactory.

This role carries on after the change to the regulations in April 2013, and the Government has asked CQC to continue to monitor progress on implementing the regulations and the overall compliance with their requirements.

Legislative and regulatory changes since the 2011 report

The Misuse of Drugs Regulations 2001 were amended in 2012 to allow nurse independent prescribers and pharmacist independent prescribers to prescribe any controlled drug listed in schedules 2 to 5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction.[4] The changes came into effect on 23 April 2012.

The amendments include a provision for nurse and pharmacist independent prescribers, as well as supplementary prescribers acting in accordance with the terms of a clinical management plan for an individual patient to be authorised to mix any drugs listed in Schedules 2 to 5 before administration. The aim of the policy is to enable controlled drugs to be 'compounded' (or mixed) before administering them to a patient as opposed to the 'manufacture' of controlled drugs in general.

The amendments also include changes to the authority that nurses and pharmacists possess when acting in accordance with a Patient Group Direction (PGD). A PGD is not a form of prescribing but allowed specified practitioners to supply medicines to specified groups of patients in defined situations for a defined purpose. Nurses and pharmacists working under a PGD are now authorised to supply, or offer to supply, diamorphine and morphine where administering these drugs is needed for the immediate and necessary treatment of sick or injured people (excluding the treatment of addiction). This removes the restriction that meant a nurse could only supply diamorphine under a PGD to treat cardiac pain in patients admitted to a coronary care unit or an accident and emergency department of a hospital.

From 1 April 2013, primary medical services are required to register with CQC, as we now regulate GP practices and other primary medical services in England to check that they are meeting the national standards of quality and safety.

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

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. In addition, all healthcare professionals have a duty to ensure that controlled drugs in their own practice are managed safely.

The two main provisions for ensuring safe management of controlled drugs are the appointment of controlled drugs accountable officers (CDAOs) and sharing information between organisations, regulators and agencies through local controlled drugs intelligence networks (CD LINs). These are described in detail in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.[3]

Large healthcare organisations defined as 'controlled drug designated bodies' are required to appoint CDAOs. The CDAO is the person within a 'controlled drug designated body' who has organisational responsibility for controlled drugs. The responsibilities of the CDAO are set out in detail in the 2006 Regulations.[3]

Smaller organisations and those not named in the regulations as designated bodies are not required to appoint a CDAO. However, this does not alter any of the requirements to comply with the Misuse of Drugs Regulations[5] and to make arrangements for the safe management of controlled drugs.

CD LINs, led by primary care trusts, provide the forum for sharing information between organisations, regulators and agencies involved in handling controlled drugs.

Transition to the 2013 regulations

Before April 2013, the system operated as described above, but after this date, changes are as follows:[6]

- The NHS Commissioning Board, now known as NHS England, will designate the CD LINs covering England and appoint a CDAO for each Network. In practice, it is expected that NHS England will align these networks with their Area Teams.
- The headquarters in England of regular or reserved Armed Forces are designated bodies under the 2013 regulations and will be required to appoint a CDAO.
- Exemptions to the requirement to appoint a CDAO will apply for an English independent hospital where:
  - fewer than 10 individuals work at the hospital, **or**
  - the need to appoint a CDAO would give rise to difficulties disproportionate to the benefits of such an appointment.
- Social enterprise organisations (SEOs) and community interest companies (CICs) will not be required to appoint a CDAO if their activities do not come within the definition of a 'hospital' as defined in Regulation 2 of the 2013 regulations. However, they can consider appointing a lead to ensure that controlled drug governance arrangements are in place within their organisation.[7]

Table 1: Key changes to controlled drugs governance arrangements

Controlled drug governance arrangements up to 31 March 2013	New governance arrangements after 1 April 2013
Primary care trusts CDAOs lead the local intelligence network for the primary care trust (PCT) area – CDDBs and responsible bodies are members of the CD LIN.	**NHS England Area Teams** NHS England CDAOs are the assigned lead CDAOs. They determine the CD LIN areas and membership.
	Clinical commissioning groups and support units Not required to appoint a CDAO but have a duty of cooperation to the lead CDAO in investigating concerns and analysing data.
NHS hospital trusts and foundation trusts Organisation's CDAO has responsibility for all aspects of safe and secure handling of controlled drugs. Provides quarterly occurrence reports to PCT CDAO.	**NHS hospital trusts and foundation trusts** As before, but provides occurrence reports to lead CDAO.
Independent hospitals Organisation's CDAO has responsibility for all aspects of safe and secure handling of controlled drugs. Provides quarterly occurrence reports to PCT CDAO.	**Independent hospitals** As before, except where an exemption applies, for example: • Small hospitals (fewer than 10 staff). • Larger businesses that employ more than 10 staff, but which do not generally have a high degree of controlled drug use. Provide occurrence reports to lead CDAO.
	Armed forces The headquarters of reserved or regular Armed Forces have now been given the status of a 'designated body' so that a CDAO must be appointed. The Armed Forces must determine how they discharge this function. However, lead CDAOs can now invite such personnel to be members of CD LINs.
Social enterprises and community interest companies (SEOs and CICs) Non designated bodies, so not required to appoint a CDAO and not required to be members of CD LINs. However, they should have governance arrangements in place to ensure safe management of controlled drugs and reporting of controlled drug concerns.	**Social enterprises and community interest companies (SEOs and CICs)** Only required to appoint a CDAO if their activities come within the definition of a 'hospital'. However, commissioners will expect adequate CD governance arrangements to be in place and SEOs and CICs can consider appointing a designated senior officer for this purpose.

Private clinics, private doctors Non-designated bodies, so not required to appoint a CDAO and not required to be members of a CD LIN. Should have appropriate arrangements in place for the safe management of controlled drugs. For those not registered with CQC, the PCT CDAO has the right of entry to investigate reported controlled drug concerns.	**Private clinics, private doctors** As before, 'powers of entry and inspection' provisions to secure the safe management and use of controlled drugs on premises registered as providing healthcare services that are not subject to inspections by regulatory bodies. As before, should have appropriate arrangements in place for the safe management of controlled drugs.
Social care settings Non-designated bodies, so not required to appoint a CDAO and not included as members of CD LINs but should have appropriate arrangements in place for the safe management of controlled drugs. Regulated by CQC (a responsible body member of the CD LIN) who should ensure controlled drug concerns are reported to the CD LIN. Also individual duty to report concerns to the PCT CDAO/CD LIN.	**Social care settings** As before but the individual duty to report concerns is to the Area Team lead CDAO.
Primary medical services and primary dental services Inspection by PCT CDAO. Self-assessment and declaration requested by the PCT. Individual duty to report concerns to the PCT CDAO. Should have appropriate arrangements in place for the safe management of controlled drugs.	**Primary medical services and primary dental services** Primary medical services and primary dental services are now registered with CQC. There should be appropriate arrangements in place for the safe management of controlled drugs. Lead CDAOs should request periodic declarations or self-assessments from a range of healthcare providers regarding their management and use of controlled drugs, where they are not required to appoint a CDAO. This includes GPs on a medical performers' list and providers of dental, nursing or midwifery services. Individual duty to report concerns to the lead CDAO.
Community pharmacists Controlled drug concerns reported to PCT CDAO and GPhC.	**Community pharmacists** Controlled drug concerns to be reported to lead CDAO and GPhC.

Recommendation 1

Health and social care professionals must ensure that they know how to contact the CDAO in the new Area Teams of the NHS Commissioning Board (known as NHS England) and the mechanism for reporting controlled drug concerns (the CDAO register is on CQC's website).

Register of controlled drug accountable officers (CDAOs)

CQC continued to publish and maintain the register of CDAOs on our website throughout 2012.

It is the responsibility of the controlled drug designated body (CDDB) to inform CQC of the appointment of, and changes to, its CDAO, and we regularly update the register to reflect these changes. Notifications can only be made using an online webform.

CDDBs are also responsible for checking that their entry in the register is up to date and accurate.

In response to feedback, CQC improved the system and it is now easier for CDAOs to update their contact details (phone number or email address). These can now be emailed to CDAOregisterdata@CQC.org.uk.

Recommendation 2

Because of the changes, CDAOs should follow the guidance on CQC's website to update contact details promptly to ensure the CDAO register is accurate

Updated self-assessment tools

In 2012, we updated the self-assessment tools on our website for governance of controlled drugs.

To reflect the NHS changes, we divided the primary care tool into separate tools for providers and for commissioners. Although the tools are not intended to collect data, they are a resource to help primary care providers and commissioners to measure their performance and identify ways in which they can improve their governance arrangements. They include a series of detailed questions around the safe management of controlled drugs against which providers or commissioners can assess their current practices.

Similarly, the secondary care self-assessment tool is a resource designed to help NHS trusts and acute NHS foundation trusts to assess their performance in controlled drugs governance so they can identify any gaps and drive improvement. Although the tool is aimed primarily at secondary care NHS trusts, it may also be useful for large, acute independent hospitals to evaluate their responsibilities in relation to controlled drugs.

Developing role of CDAOs

Until now, there has been a stronger focus on the CDAO's role in managing the risks associated with security, record-keeping and unauthorised use of controlled drugs. However, it is important that CDAOs also have regard to managing the risks associated with the clinical use of controlled drugs. The CDAO is empowered to direct, and be responsible for directing, services to protect the safety of patients where the use of controlled drugs is deemed unsafe for patients.[3] The NHS England (Safe Medication Practice Team) noted a lack of evidence for CDAO activity in relation to the clinical use of controlled drugs and that this was particularly notable in primary care.[8]

To provide further support for CDAOs and practitioners, a clinical sub-group to the Controlled Drugs National Group was formed in the second half of 2012 to provide expert clinical advice on the safe use of controlled drugs in practice and minimising risks and harm arising from the use of these medicines. The initial focus for advice will be the safe use of transdermal patches and oxycodone preparations.

Controlled drug local intelligence networks (CD LINs)

Local intelligence networks (CD LINs) provide a forum for organisations, regulators and agencies to raise concerns and share intelligence about organisations or individuals in relation to the safe and appropriate management and use of controlled drugs. This means that concerns can be shared at the earliest stage with other agencies who may also potentially be affected or who may have additional information. PCT CDAOs have been responsible for establishing and operating CD LINs.[3] These arrangements remained in place until April 2013, when the new Regulations (The Controlled Drugs (Supervision of Management and Use) Regulations 2013)[9] came into force.

Over the past six years much work has been done to establish effective working arrangements that have carried forward the original policy intent and started to shape the way that controlled drugs are managed in the 21st century. In some cases this has called for major culture changes, but it has been achieved without compromising the appropriate clinical use of controlled drugs, for example, for the relief of pain. These are significant achievements. The overall result is that a solid foundation of structures, systems and practices has been laid. These foundations will be needed to ensure good governance of controlled drugs in the reorganised NHS and it is vital not to lose the gains that have been made during the transition and beyond.

Recommendation 3

Effective systems developed at the local level for secure gathering, sharing and recording of intelligence relating to concerns about safe management of controlled drugs should be preserved and transferred into the new NHS structure.

Recommendation 4

CDAOs, clinical commissioning groups and controlled drugs leads must be mindful of their continuing responsibilities for good governance and safe use of controlled drugs; this will be critical to ensure on-going progress during the transition period so as not to lose valuable intelligence and to ensure on-going monitoring and vigilance.

From 1 April 2013, primary medical services are required to register with CQC, as we now regulate GP practices and other primary medical services in England.

Recommendation 5

Looking forward to 2013, CQC must incorporate providers' governance arrangements for controlled drugs into its inspection model for primary medical services.

Conclusions

Over the past six years, systems for the safe and effective management of controlled drugs in the NHS have progressed.

During this time, the role of the CDAO has developed and it is acknowledged that it embraces not only responsibilities for good governance of controlled drugs, but also for the safe and appropriate clinical use of controlled drugs.

Local intelligence networks have matured and developed effective systems for secure reporting and recording of concerns.

Alongside these developments, CQC has refined and improved its systems for maintaining an up-to-date register of CDAOs.

Overall, these developments mean that a robust foundation has been put in place for good governance of controlled drugs in the reorganised NHS.

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. Membership of the Group in 2012 included:

- Association of Chief Police Officers
- Care Quality Commission
- Department of Health
- General Pharmaceutical Council
- Health and Social Care Information Centre
- Her Majesty's Inspectorate of Prisons
- Home Office
- Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence (NICE)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Ministry of Defence
- National Clinical Assessment Service
- National Patient Safety Agency (now Patient Safety Team of NHS England)
- National Treatment Agency
- NHS Protect
- Ofsted
- Veterinary Medicines Directorate.

CQC is grateful to these organisations for their on-going commitment and contributions to the National Group; many of the organisations will continue, either in current form or as part of new NHS organisational arrangements, and we will continue to engage with them.

The Armed Forces and the Medicines and Prescribing Centre joined the National Group during 2012. The Medicines and Prescribing Centre provides support to CDAOs. The Ministry of Defence has developed similar governance structures for controlled drugs to those set out in the 2006 regulations and is actively involved in CD LINs in some areas of the country. There will be a further review of membership after April 2013 to ensure that the Group continues to reflect key agencies in the reorganised NHS.

A clinical sub-group to the National Group was formed in the second half of 2012 to provide expert clinical advice for CDAOs on the safe use of controlled drugs in practice and minimising their risks and harm.

The group continued to meet quarterly in 2012, to enable sharing and discussion of emerging issues from each different area represented and to identify ways of working together to reach solutions. Reports of activity from the main partners illustrate the many ways in which these agencies contribute to the overall safer management of controlled drugs (see our website www.cqc.org.uk).

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations (England, Scotland, Wales, Northern Ireland and the Republic of Ireland) provides a forum for:

- Sharing intelligence of general concerns across national borders among those charged with management, monitoring or inspection of the governance arrangements for controlled drugs.
- Sharing learning and best practice methodologies that support the safer management of controlled drugs in each nation.
- Sharing analysis of trends and associated risks pertinent to safer management and use of controlled drugs.

The group holds twice-yearly, face-to-face meetings to discuss matters of mutual interest at a strategic level.

During 2012, the working arrangements for the Cross-Border Group were strengthened to ensure that it was fit for purpose to give it more structure to share good practice. This should position it well to go forward into the reorganised NHS.

Initiatives from partner organisations

During 2012, partner organisations of the National Group on Controlled Drugs continued to refine management systems and support frontline workers with a variety of useful initiatives. The following are some examples, and full reports are published separately on CQC's website.

Partner initiative 1
General Pharmaceutical Council: Advice on incidents involving Schedule 2 controlled drugs

Throughout the year the GPhC provided advice in relation to controlled drugs through its publication, *Regulate*. One of the regular features describes 'fitness to practise' cases that the GPhC has dealt with, and identifies learning points that registrants may find useful. This feature is entitled, *Fitness to Practise – learning*. One of these cases, reproduced in issue 5, June 2012, featured advice on supplying Schedule 2 and 3 controlled drugs, and advice on whom to notify in the event of an incident involving a Schedule 2 controlled drug.

Partner initiative 2
NHS Protect: Security of controlled drugs in the ambulance sector

NHS Protect was commissioned by the Ambulance Pharmacist Network to develop minimum security standards for controlled drugs in the ambulance sector. *Security standards for the management and control of controlled drugs in the ambulance sector* was published in June 2012 and is available on the NHS Protect website at www.nhsprotect.nhs.uk. Following this guidance, a list of frequently asked questions (FAQs) and a security audit checklist was published in early 2013 to help ambulance trusts to implement this guidance.

Partner initiative 3
National Treatment Agency

Medications in recovery: Re-orientating drug dependence Treatment is the report of an expert group chaired by Professor John Strang of the National Addiction Centre, which was published in July 2012. The report set out how methadone should be used only as part of an integrated and adaptive treatment programme and that its use should be regularly reviewed to ensure that opportunities to become drug-free were not missed. It also recommended measures to ensure that adequate doses of opioid substitution therapy were used and that supervised consumption was used correctly.

Conclusions

Our partners have continued to develop and implement schemes to support frontline staff and to ensure that patients receive safe and appropriate treatment.

The value of face-to-face meetings of both the National Group and the Cross-Border Group should not be under-estimated. These meetings make it possible to hold strategic discussions about controlled drugs issues.

The addition of the Armed Forces and the Medicines and Prescribing Centre will strengthen the Group and ensure that it is appropriately constituted to deal with the challenges of the reorganised NHS in future. Membership will be further reviewed after April 2013 to ensure that the Group continues to reflect key agencies in the reorganised NHS.

5. National trends in the use and management of controlled drugs

During 2012, CQC continued to monitor the overall use and management of controlled drugs in England 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. NHS Prescription Services also analyse private prescriptions for Schedule 2 and 3 controlled drugs that are dispensed in community pharmacies.

By analysing the data on prescribing, we are able to examine the national picture in England and identify trends in the prescribing of controlled drugs that have changed over time, for example, in response to prescribing policies or the introduction of new medicines. 2012 was the sixth year of reporting on the analysis of prescribing of controlled drugs and we have taken the opportunity to present some summary data that show the patterns of activity and prescribing over the period.

The Misuse of Drugs Act[10] categorises controlled drugs by class (Class A, Class B and Class C) corresponding to the level of penalty for illegal possession. The classes of the Misuse of Drugs Act are of no practical importance to practitioners. In the Misuse of Drugs Regulations[5], the drugs are classified into five 'schedules' that correspond to their potential for misuse. The lower the Schedule number, the greater the potential for harm and the greater the degree of control required (see Appendix 1).

- **Schedule 1** now only includes products that have no medicinal uses (it did include Sativex until April 2013).
- **Schedule 2** includes drugs such as diamorphine, morphine, pethidine, fentanyl and amphetamine.
- **Schedule 3** includes barbiturates, buprenorphine, midazolam and temazepam.
- **Schedule 4** includes, in part 1, Sativex, most benzodiazepines and the hypnotic, zolpidem. Part 2 contains most anabolic steroids.
- **Schedule 5** includes products containing low strengths of codeine and morphine and some over-the-counter, 'pharmacy only' medicines such as co-codamol.

Key findings

Prescribing of controlled drugs in primary care

In 2012, the total number of controlled drugs items prescribed in NHS primary care was 47,308,286, which is an increase of 1% compared with 2011. The cost of this was £452,763,739, representing an increase of 2% compared to £443,380,585 in 2011.

The overall changes from year to year have been modest for most groups of controlled drugs, but the prescribing of Schedule 2 controlled drugs (which includes for example, morphine and methadone) has increased by about 60% over the six-year period. Figure 1 shows the number of Schedule 2 items prescribed each year from 2007 to 2012.

Figure 1: Schedule 2 controlled drugs by number of items prescribed in NHS primary care from 2007 to 2012

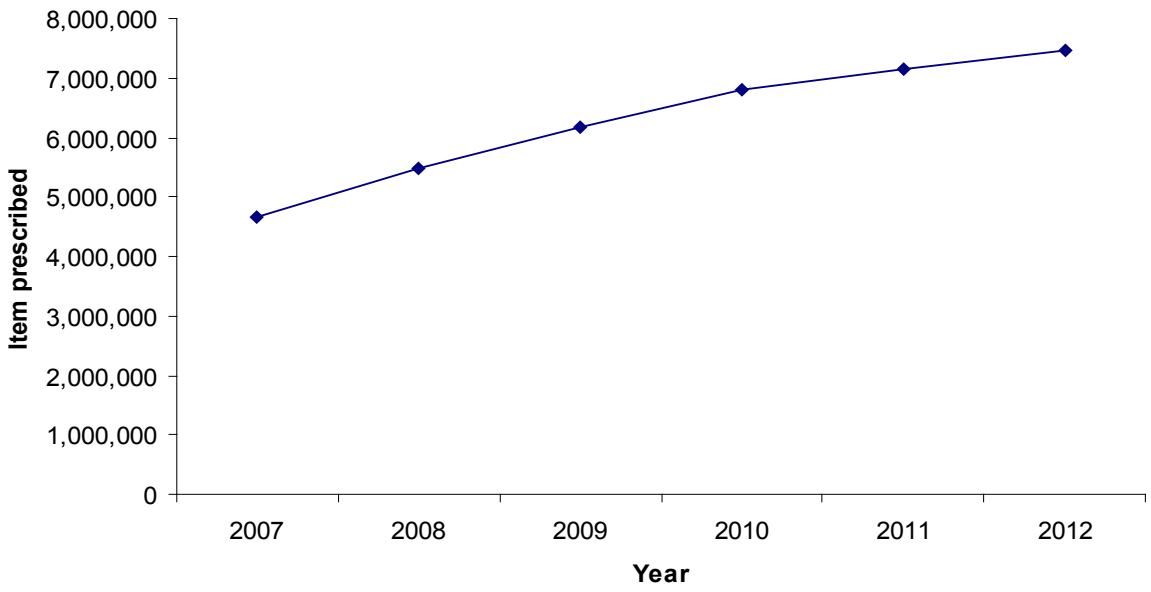


Figure 2 on the next page shows the profile of prescribing for Schedule 2 and 3 controlled drugs in 2012 and Table 2 provides some insight into the changes that have contributed to the large increase in prescribing of schedule 2 controlled drugs.

Figure 2: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care in 2012 (by number of items)

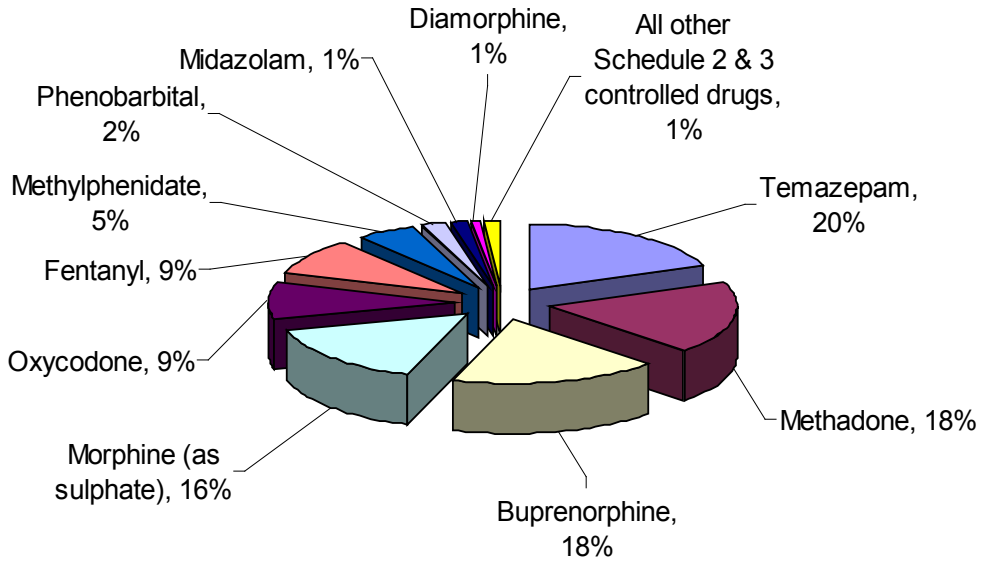


Table 2: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care from 2007 to 2012 (by number of items)

Top 10 schedule 2 & 3 controlled drugs	2007	2008	2009	2010	2011	2012
Temazepam	3,218,072	3,091,328	2,940,796	2,789,203	2,606,758	2,349,284
Methadone	1,802,827	2,166,665	2,413,048	2,581,954	2,477,133	2,300,097
Buprenorphine*	993,927	1,281,107	1,578,620	1,800,640	2,021,261	2,246,423
Morphine Sulphate	1,047,991	1,193,622	1,338,062	1,489,334	1,709,328	1,964,746
Oxycodone**	497,254	619,094	783,584	956,696	1,068,951	1,153,337
Fentanyl†	656,802	791,520	898,188	986,157	1,059,110	1,115,923
Methylphenidate	420,421	459,600	492,247	541,516	593,147	657,358
Phenobarbital	282,766	279,500	273,148	268,337	263,371	256,602
Midazolam◊	54,723	66,039	93,112	120,547	141,101	175,742
Diamorphine	75,896	92,394	104,170	108,862	117,944	122,706
All other schedule 2 & 3 CDs	205,408	192,125	176,750	165,407	155,292	157,858
Total	**9,256,087**	**10,232,994**	**11,091,725**	**11,808,653**	**12,213,396**	**12,500,076**

*Buprenorphine figures include the combination product Suboxone (buprenorphine + naloxone)
**Oxycodone figures include the combination product Targinact (oxycodone and nalaxone)
†Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products
◊Midazolam figures include oral and injectable midazolam

Over the six-year period since 2007, there have been large increases in the prescribing of buprenorphine (126%), morphine sulphate (87%), oxycodone (132%), fentanyl (70%), methylphenidate (56%), midazolam (221%) and diamorphine (62%). During the same period there has been a 27% decrease in the prescribing of temazepam.

Morphine, oxycodone, fentanyl and diamorphine are used in the management of severe pain. In the context of primary care, fentanyl is prescribed in the form of transdermal patches that deliver the medicine through the skin over several days. This is useful in chronic, stable pain for example, in cancer treatment. Oxycodone is taken as an oral liquid, immediate-release capsules and prolonged-release tablets. It is more potent than morphine and is used in the management of severe pain. It is likely that increased use of all these products reflects improved access to treatment for patients.

Buprenorphine is used both for severe pain, as transdermal patches or sublingual tablets, and for the treatment of opioid addiction. It is likely that the increased prescribing of buprenorphine results from both increased use in the management of opioid addiction and vastly increased use in the form of transdermal patches for the treatment of severe, non-cancer pain.

Midazolam prescribing has increased considerably over the past six years and this almost certainly reflects the use of buccal midazolam (in preference to rectal diazepam) in the management of epileptic seizures (buccal administration of a medicine is placing a preparation between the cheek and the teeth or gum). An important factor here has been the introduction of products designed specifically for buccal administration, which previously had to be injected orally (administered into the mouth with a filter straw).

The introduction of the new oral controlled drug, tapentadol, in 2011 may also have begun to have an effect on the overall prescribing of Schedule 2 controlled drugs. However, at this stage it is too early to draw any firm conclusions. Tapentadol (Palexia) is prescribed for treating moderate-severe pain that can only be controlled with opioids.

Methylphenidate

The prescribing of methylphenidate in primary care continued to rise steadily and rose from 593,147 items in 2011 to 657,358 in 2012, an increase of 11% (figure 3). As in previous years, we believe that this reflects increased diagnosis of, and prescribing for, the treatment of attention deficit hyperactivity disorder (ADHD).

Methylphenidate is also commonly prescribed privately. The amount of privately-prescribed methylphenidate increased from 3,899 items in 2011 to 4,835 during 2012 – an increase of 24% (figure 4). We believe that this is probably due to an increase in the diagnosis of, and prescribing for, adult ADHD in line with NICE guidance.

We are also aware of the possibility that methylphenidate could be diverted and abused, and for this reason we recommend that its use should be monitored carefully. We are aware of reports in the media and scientific literature that it is being abused as a 'smart' drug to improve cognitive function; the long-term risks of this practice are not known.[11, 12]

Figure 3: Total number of methylphenidate items prescribed in NHS primary care, 2007-2011

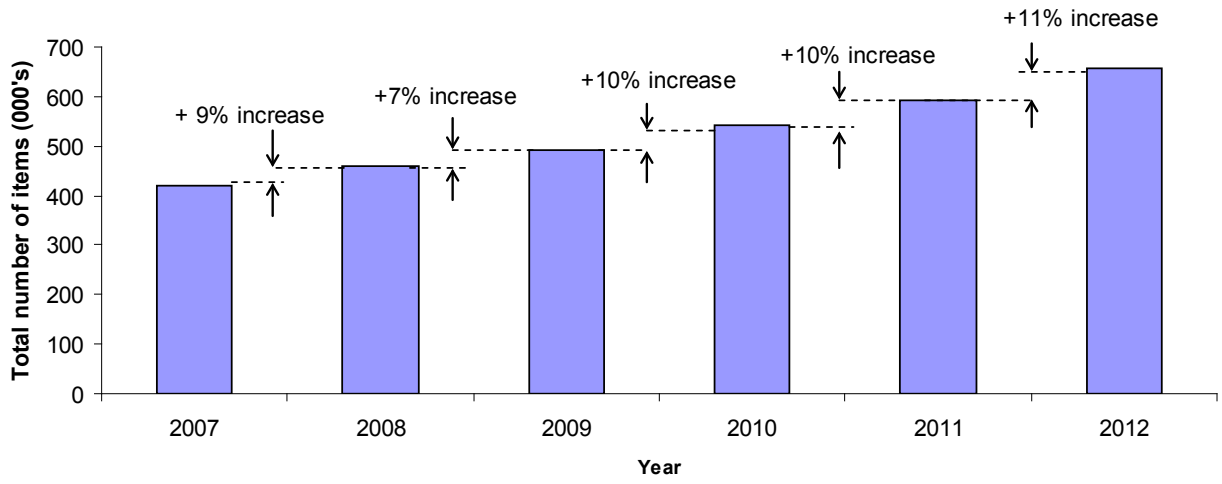
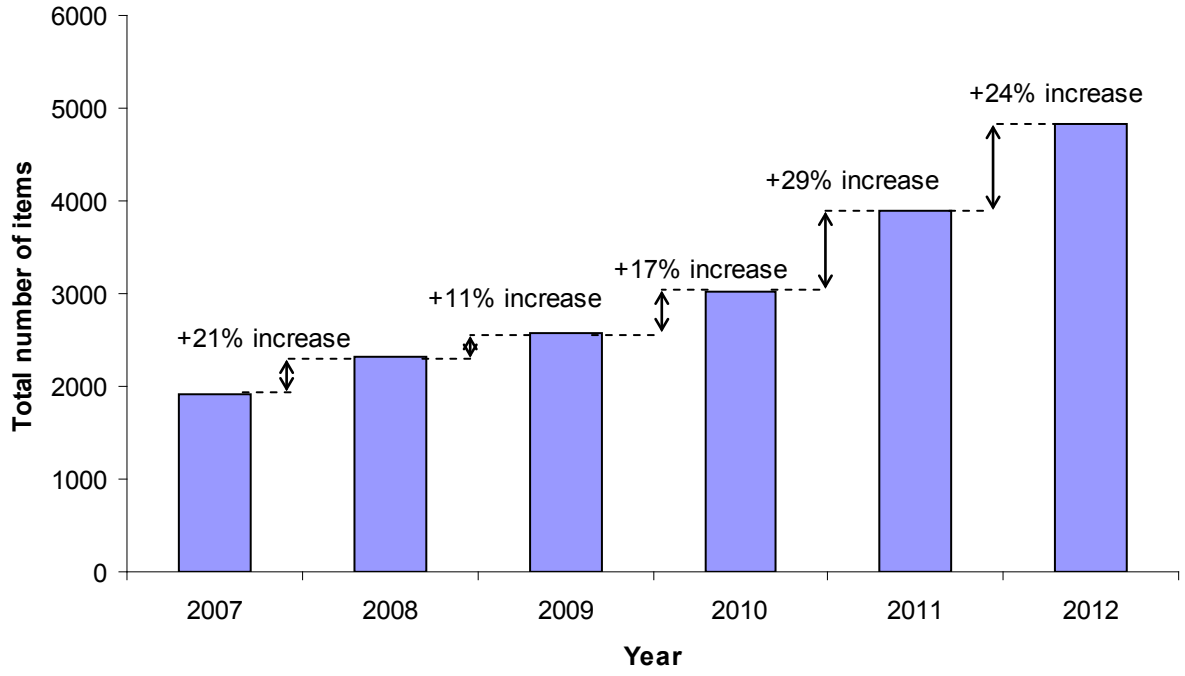


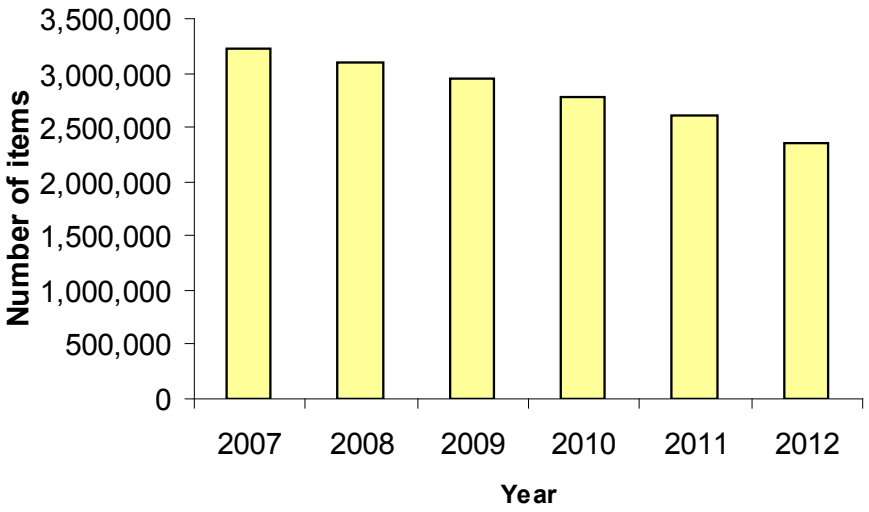
Figure 4: Total number of methylphenidate items privately prescribed, 2007-2011



Temazepam

The use of temazepam – the benzodiazepine hypnotic (sleeping) agent – has continued to fall steadily since 2007 (figure 5). This is an encouraging trend and could be the result of reduced prescribing in line with the recommendations in the British National Formulary (BNF) to limit the use of this product to short periods. It could also reflect some success on the part of charities such as the Bridge Project (in Bradford) that are dedicated to helping people to recover from addictions (see below).

Figure 5: Total number of temazepam items prescribed in NHS primary care from 2007-2012



Good practice example: The Bridge benzodiazepine withdrawal project

The Bridge Benzodiazepine Withdrawal Service is a specialist service designed to help people addicted to prescribed benzodiazepines (including temazepam). The service works with patients and their GPs in primary care settings to enable them to reduce or completely stop their benzodiazepine use and to provide a resource for primary care practitioners to help them change their prescribing practices. The service is provided by a specialist worker with experience in delivering cognitive behavioural therapy and other psychosocial interventions. These therapies are used together with the medication reduction, to give patients the skills and confidence to cope with any rebound withdrawal effects such as disrupted sleep patterns and anxiety caused by reducing and eventually ceasing use of these medications.

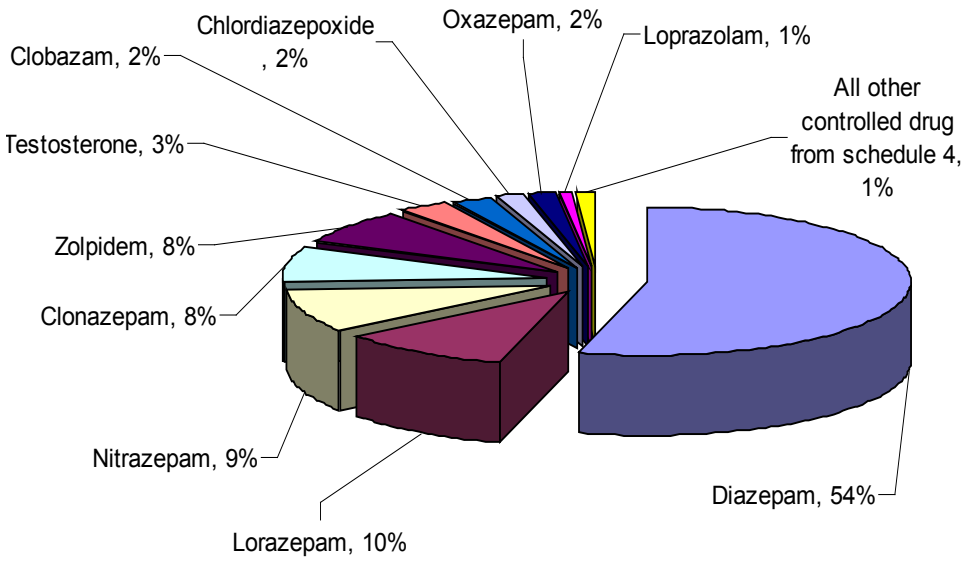
Over the past year, the service has provided nearly 700 sessions and additional booster telephone sessions to over 130 people though 11 practices and has helped 50% of those discharged to become medication free, and a further 45% to reduce their medication use by an average of over 50% from their starting dose. In total, the service has achieved successful outcomes for over 60% of all people accessing support this year. The service continues to develop, looking to expand its remit into other prescribed medications in the near future.

Tracey Hogan, Director of Operations.
www.bridge-bradford.org.uk

Schedule 4 controlled drugs

Figure 6 shows the profile of prescribing for Schedule 4 controlled drugs during 2012. All but 3% of this is accounted for by benzodiazepines. The most commonly prescribed benzodiazepine is diazepam, which accounts for 54% of prescribing in this group.

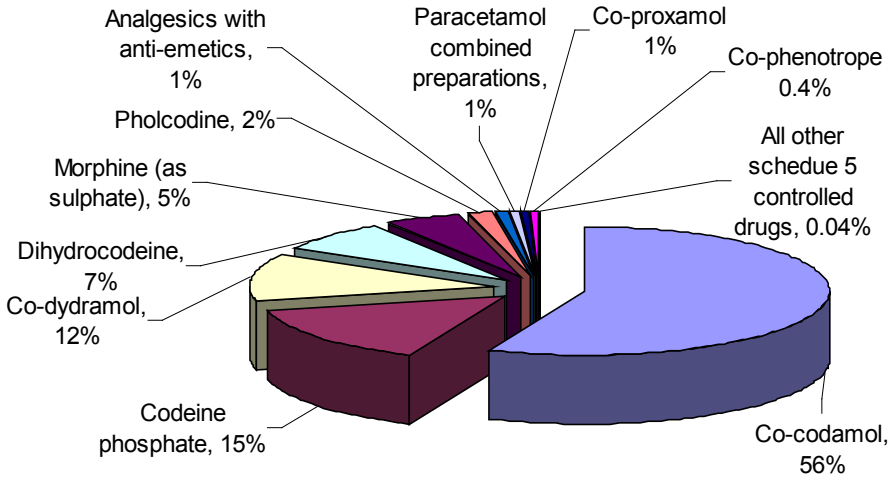
Figure 6: The top 10 Schedule 4 controlled drugs, prescribed in NHS primary care in 2012 (by number of items)



Schedule 5 controlled drugs

Figure 7 shows the profile of prescribing for Schedule 5 controlled drugs during 2012. It should be noted that although many of these are the same substances as in Schedule 2, they are present only in small amounts and therefore are subject to a lower level of control. The most commonly prescribed Schedule 5 item is co-codamol (a combination of paracetamol and the weak opioid, codeine), which accounts for 56% of prescribing in this group.

Figure 7: The top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2012 (by number of items)



Nurse and pharmacist prescribing

Prescribing of controlled drugs by nurses and pharmacists represents a small proportion of the whole but prescribing by nurses has increased steadily and prescribing by pharmacists has increased considerably since 2008 (figures 8 & 9). In both cases, this is mainly attributable to nurses and pharmacists being involved in prescribing methadone and buprenorphine for the treatment of substance misuse, in line with policy to improve access to treatment for patients.

In April 2012, the Misuse of Drugs Regulations 2001 were amended to allow nurse independent prescribers and pharmacist independent prescribers to prescribe any controlled drug listed in Schedules 2 to 5 for any medical condition within their competence, except diamorphine, cocaine and dipipanone for the treatment of addiction. The amendment was made to improve access to effective treatment for a larger number of patients. It is likely that the sharp change in pharmacist-prescribing of controlled drugs is partly a result of this change. Further changes to the prescribing volume can be expected in 2013 as the effects of these legislative changes become embedded.

Figure 8: Nurse prescribing of controlled drugs in NHS primary care, 2007-2012 (Schedules 1 to 5)

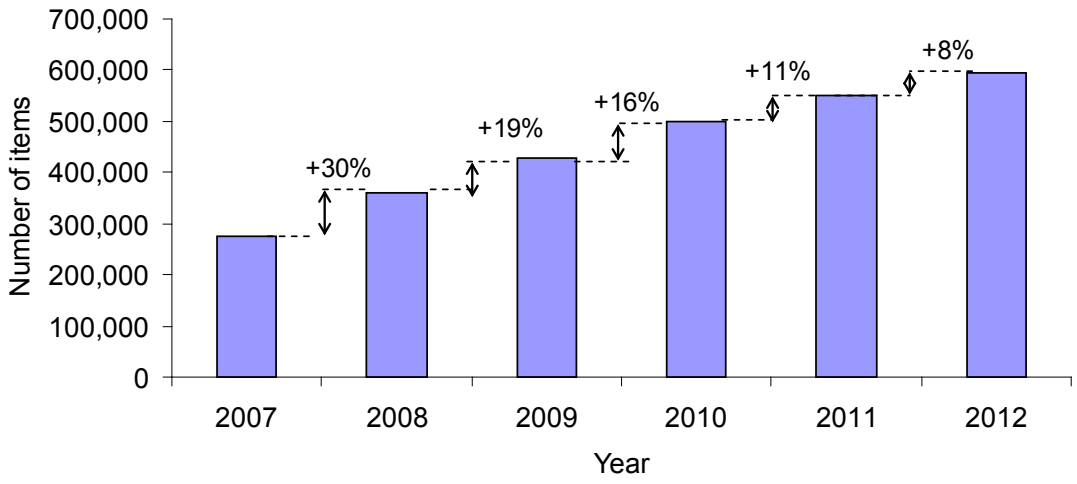
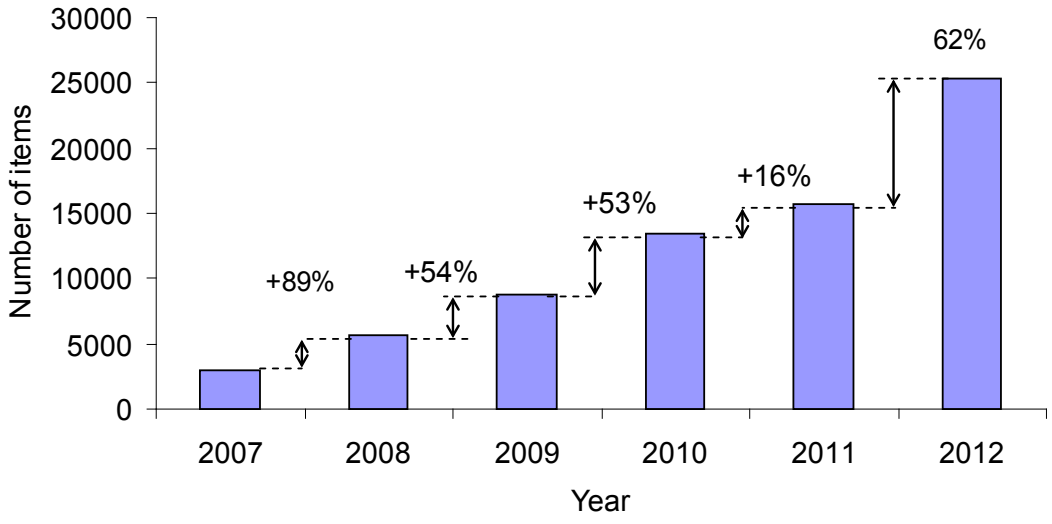


Figure 9: Pharmacist prescribing of controlled drugs in NHS primary care, 2007-2012 (Schedules 1 to 5)



Private prescribing of controlled drugs

The total number of Schedule 2 and 3 controlled drug items prescribed privately in 2012 was 39,332, which is a decrease of 10% compared with 2011 (43,640 items). Private prescribing accounts for about 0.1% of overall controlled drug prescribing. Over the six-year period there has been a steady fall in private prescribing of controlled drugs, and by 2012 there had been a 24% decrease, compared with 2007 (figure 10). There were significant decreases in the amounts of methadone, dexamphetamine and temazepam prescribed (table 3).

Table 3: Top 10 privately prescribed Schedule 2 and 3 controlled drugs from 2007 to 2012 (by number of items)

BNF chemical substance	2007	2008	2009	2010	2011	2012
Methadone	27,885	25,202	21,291	20,597	18,651	14,953
Dexamfetamine	9,433	8,034	7,414	7,689	6,932	6,254
Methylphenidate	1,910	2,317	2,581	3,031	3,899	4,835
Morphine (as sulphate)	2,901	4,133	3,000	4,322	3,964	4,044
Temazepam	4,934	5,121	4,143	4,381	3,644	3,051
Buprenorphine*	1,865	2,454	1,872	2,565	2,728	2,616
Oxycodone**	1,015	954	1,102	1,313	1,405	1,411
Fentanyl†	463	514	688	664	705	614
Midazolam◊	0	383	337	755	572	427
Pethidine	444	473	248	156	341	296
All other Schedule 2 & 3 controlled drugs	751	736	721	994	799	831
Total	51,601	50,321	43,397	46,467	43,640	39,332

*Buprenorphine figures include the combination product Suboxone (buprenorphine + naloxone)

**Oxycodone figures include the combination product Targinact (oxycodone and nalaxone)

†Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products

◊Midazolam figures include oral and injectable midazolam

Figure 10: Number of items of Schedule 2 and 3 controlled drugs privately prescribed, 2007-2012

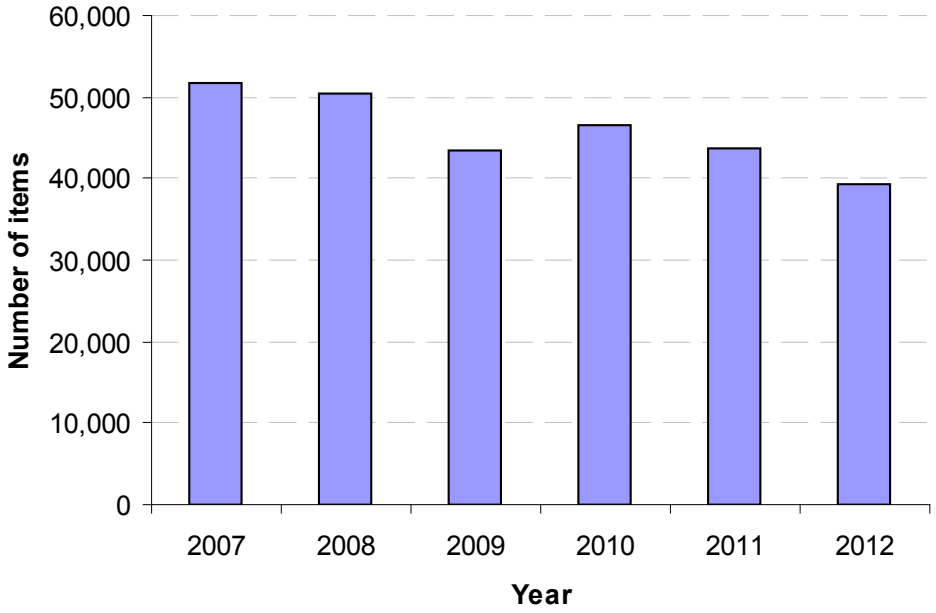
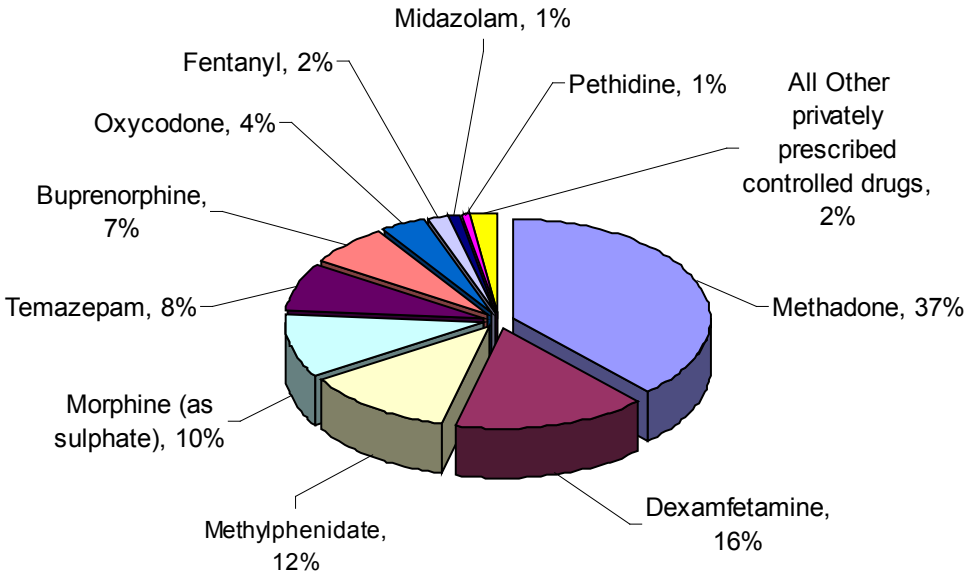


Figure 11: Top 10 Schedule 2 and 3 controlled drugs privately prescribed in 2012 (by number of items)



The overall pattern of private prescribing was similar to that reported in 2011. The main points are:

- Methadone continues to be the most common controlled drug prescribed privately but its use has decreased markedly over the past six years.
- Dexamfetamine continues to be the second most common controlled drug prescribed privately, although the amount prescribed has decreased by 33% over the past six years.

  It is a central nervous stimulant, which can be prescribed as a second line treatment for children and adults with Attention Deficit Hyperactivity Disorder (ADHD). However, due to its potential for diversion and misuse and in view of concerns that this might reflect inappropriate prescribing of dexamfetamine for amphetamine addiction, this calls for continued vigilance as we recommended last year.

- We have, again, seen a year-on-year increase in the volume of methylphenidate prescribed privately. This is likely, in part, to be attributed to prescribing for adult ADHD.
- Temazepam prescribing has fallen by about 40% over the past four years.

Controlled drugs requisitions

To obtain a stock of a Schedule 2 or 3 controlled drug from a community pharmacy, practitioners should use a standard Controlled Drug Requisition Form (FP10 CDF). However, this is not mandatory and pharmacies may supply controlled drugs requisitioned on non-standard forms. Last year we reported that up to 50% of the forms submitted for analysis were non-standard forms with incorrect prescriber codes and it was therefore not possible to extract any meaningful data. Following a consultation on the Misuse of Drugs Regulations 2001, and advice from the Advisory Council on the Misuse of Drugs (ACMD), the Home Office is working to amend the legislation to require standard requisition forms to become mandatory, which will allow more meaningful data to be gathered in future.

Conclusions

During 2012, there was little overall change in the total number of controlled drug items prescribed or the costs, compared with 2011. However, there is evidence of on-going changes in the patterns of use.

Serial analyses of prescribing of controlled drugs in on-going NHS primary care have revealed some clear trends, including a continuous downward trend in the prescribing of temazepam over the six-year period. At the same time there have been increases in prescribing of buprenorphine, morphine sulphate, oxycodone, fentanyl, methylphenidate, midazolam and diamorphine.

The profile of private prescribing continued to differ from NHS primary care prescribing, with dexamfetamine appearing as the second most commonly prescribed item. Dexamfetamine does not appear at all in the top 10 Schedule 2 controlled drugs prescribed in NHS primary care.

Monitoring of the controlled drug requisition form information by NHS Prescription Services has shown that this system is not yet embedded and the problems need to be resolved before meaningful data can be gathered from analysis of requisitions. The Home Office is amending the legislation to require that the use of a standard requisition form becomes mandatory, which will allow more meaningful date to be gathered in future.

Overall, the system for analysing and monitoring controlled drug prescribing at national level is working well and providing information that could form the basis for further, detailed analyses.

Appendix A: 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

The Act now sets out four separate categories: Class A, Class B, Class C and also temporary class drugs. 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.

Use of the temporary control power can be considered if concerns about a drug are such that a faster legislative response is necessary to protect the public.

Class A

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

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

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 potential for misuse. 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: Within the healthcare sector, 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 for the purpose of administration to that individual. Hospitals (in so far as it represents the business of the hospital) may supply patients, wards and practitioners, in limited circumstances and working within that hospital entity. Pharmacies may supply on receipt of a valid prescription or signed order, to individuals who can lawfully possess. There are also additional prescription writing requirements.

Record: A record of all Schedule 2 controlled drugs obtained and supplied must be kept in a register in a form that 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 in the healthcare sector (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.

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, in the healthcare sector, 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.

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.

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

Appendix B: 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 being detected. 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.
- The sharing of information, including a legal duty of collaboration among all 'responsible bodies', and 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.[4] These have now been superseded by the new regulations, the Controlled Drugs (Supervision of Management and Use) Regulations 2013, which came into force on 1 April 2013 to reflect the changes in the NHS.

The inquiry's Fifth Report, *Safeguarding Patients: Lessons from the Past - Proposals for the Future*[7] 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.

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Glossary of terms

Term	Definition
Accountable officer (AO) Controlled drugs accountable officer (CDAO)	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. Details of the role are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.[4]
ADHD	Attention deficit hyperactivity disorder.
Advisory Council on the Misuse of Drugs (ACMD)	An independent expert body that advises the Government on issues related to the misuse of drugs in the UK.
Analgesic	Pain-relieving medicine.
Buccal administration	Administration route where the dose of a medicine (tablet or liquid) is placed between the cheek lining and the teeth (or gums). Absorption of the drug into the bloodstream is more rapid than when the dose is swallowed.
Clinical commissioning group (CCG)	Groups of GP practices responsible for working with other healthcare professionals to commission most health and care services for patients. CCGs replaced PCTs from 1 April 2013.
Commissioning support units (CSUs)	Commissioning support units provide clinical commissioning groups with external support, specialist skills and knowledge to support them in their role as commissioners.
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 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.

Local intelligence network (LIN or CD LIN)	Defined in legislation as a network to share information between organisations and agencies regarding the handling and use of controlled drugs.
Misuse of Drugs Act 1971 (MDA)	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, which sets out four separate categories: Class A, Class B, Class C (and also temporary class drugs) – see Appendix A.
Misuse of Drugs Regulations 2001 (MDR)	The Misuse of Drugs Regulations 2001 divide controlled drugs into five schedules. They detail the restrictions on the manufacture, supply and possession of controlled drugs as well as prescription, record-keeping and destruction requirements - see Appendix A.
NHS England	Before 1 April 2013, and in the Health and Social Care Act 2012 known as the 'NHS Commissioning Board'.
Opiate	Naturally-occurring narcotic derived from opium, e.g. morphine.
Opioid	A synthetic narcotic that resembles the naturally occurring opiates e.g. fentanyl.
Primary care trust (PCT)	Body responsible for commissioning and delivering healthcare and health improvement to the people of its local area. PCTs were replaced by clinical commissioning groups (CCGs) on 1 April 2013.
Responsible body	Body or organisation defined in regulation with a duty to share information on controlled drugs.
Transdermal patches	Adhesive patches that contain a drug (for example, buprenorphine or fentanyl) and are used to deliver a drug slowly through the skin.

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