

The safer management of controlled drugs

Annual report 2013

August 2014

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.

We also have a statutory duty to oversee the safe management arrangements for controlled drugs in England

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Foreword

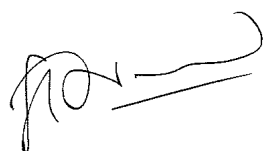
The whole country was shocked at the outcome of the Shipman Inquiry and the reports from its chair, Dame Janet Smith. The inquiry commenced after Harold Shipman's trial in 2000 and the question everybody asked was: how was Harold Shipman able to kill so many patients over so many years using the controlled drug diamorphine without any scrutiny?

In response, the Government agreed a new legislative structure to control diamorphine and other controlled drugs that have the potential to be misused. The regulations required healthcare organisations to appoint a controlled drugs accountable officer to take responsibility for the safe management of controlled drugs within their organisation. The regulations also required networks to be set up to share information about the use of controlled drugs and about individuals who give cause for concern.

The role of the Care Quality Commission (CQC) is to oversee these arrangements, ensuring that the regulations are implemented, the appropriate regulators and agencies work together, and that the networks set up for sharing concerns about controlled drugs are working effectively.

CQC's dedicated team of pharmacy and controlled drugs experts within the Primary Medical Services Directorate are led by Sarah Dennison and supported by Robert Allan. As well as coordinating CQC's national responsibilities for controlled drugs, the team also supports CQC's inspection work across health and social care.

CQC will continue to ensure there are appropriate and robust systems in place to protect patients and the public.



Professor Steve Field CBE FRCP FFPHM FRCGP
Chief Inspector of Primary Medical Services and Integrated Care

Summary

As well as regulating health and care services under the Health and Social Care Act 2008, the Care Quality Commission (CQC) is responsible for making sure that health and social care providers, and other regulators, maintain a safe environment for the management of controlled drugs in England. This arose from the findings of the [Fourth report of the Shipman Inquiry](#) and the [Government's response to the inquiry's recommendations](#).

New regulations governing the management and use of controlled drugs came into force in April 2013. The new regulations carried forward the main provisions of the 2006 regulations and introduced new provisions to ensure consistency with the new structure of the NHS. NHS England developed a single operating framework that introduced standardised procedures and documentation to support its area teams with their responsibilities for establishing and managing arrangements for controlled drugs.

NHS England controlled drugs accountable officers (NHS England CDAOs) now play a critical role in the management and safe use of controlled drugs, although at present, many are under-resourced. We have made a series of recommendations to support and strengthen their roles.

As a result of the implementation of the new regulations, all controlled drug local intelligence networks (CD LINs) have undergone changes to their core membership, procedures and reporting arrangements. One important outcome of the changes is that it will now be possible to collate occurrence reports at national level. In time, this will provide a clear picture of activity and concerns across all area teams, valuable insight into the national picture and enable emerging trends or issues of concern to be identified early.

The Care Quality Commission (CQC) continues to maintain a register of all controlled drugs accountable officers (CDAOs) on its website. Under the new regulations a number of small organisations and those with low controlled drug use are exempt from the requirement to appoint a CDAO. This does not relax the requirements for safe management of controlled drugs but does reduce unnecessary paperwork for all parties. CQC will be authorising the exemptions and monitoring the impact of this change. However, so far, there has been very little take-up of the exemption facility provided for in the revised regulations.

National groups

NHS England and UK Antidoping joined the National Group on Controlled Drugs in 2013. We have highlighted a number of initiatives to show the broad range of activities that member organisations do to improve the safer management of controlled drugs. We have also recommended that CQC should summarise the key messages from the Controlled Drugs National Group meetings and circulate them to NHS England CDAOs to pass on to their CD LIN members. This should enable CDAOs and controlled drug leads to keep up to date with key developments, policy and guidance.

The clinical subgroup of the national group produced three newsletters covering the safe management and use of fentanyl and buprenorphine transdermal patches, oral oxycodone products and MS syringe drivers. These measures build on the work of the National Reporting and Learning System (NRLS) and provide a valuable resource, especially for preventing accidental harm to patients.

During the year, the Cross-Border Group welcomed Jersey, Guernsey and the Isle of Man as members. We have highlighted some of the good practice initiatives taking place in Scotland, Wales, Northern Ireland and Ireland.

Prescribing trends

Prescribing analyses show that the number of controlled drugs dispensed in primary care was similar to the number in 2012 but the costs increased by 10%. Temazepam use continued to fall and it is likely that the non-benzodiazepine hypnotics are now being prescribed instead. Prescribing of controlled drugs by nurses and pharmacists continued to increase, although it still represents only a small proportion of the total. Private prescribing of controlled drugs represents less than 0.1% of overall prescribing and it fell further during 2013.

We conclude that the implementation of the new controlled drug regulations has made it possible to consolidate and build on the good practice developed over the past six years.

This has resulted in a more robust system in which the work of all the stakeholders is better integrated than in the past. We believe that this represents a major step forward in fulfilling the vision of safe management and use of controlled drugs as articulated in the Shipman Inquiry reports. However, we are still only nine months into the new regulations and much work remains to be done.

Recommendations

Based on activity during the past year, we make the following recommendations to support the work of NHS England controlled drug accountable officers (NHS England CDAOs).

Recommendation 1

NHS England controlled drug accountable officers must be adequately resourced to carry out their roles and responsibilities with regard to controlled drugs.

Recommendation 2

NHS England controlled drug accountable officers must be clear about their responsibilities for controlled drug governance arrangements and strengthen their relationships with clinical commissioning groups (CCGs) and commissioning support units (CSUs) so that these organisations are clear as to how they can support them.

Recommendation 3

NHS England controlled drug accountable officers should consider organising learning events for controlled drug accountable officer colleagues and controlled drug leads, to enable them to share learning and best practice.

Recommendation 4

NHS England controlled drug accountable officers should consider extending membership of the controlled drug local intelligence network to other relevant local organisations (such as social enterprise organisations or community interest companies) either on a permanent or 'as required' basis.

Recommendation 5

A formal process should be put in place by NHS England controlled drug accountable officers to ensure controlled drug concerns and good practice are shared nationally where appropriate.

Recommendation 6

Healthcare providers must determine whether they are required to appoint a controlled drug accountable officer or whether they meet the criteria for an exemption.

Recommendation 7

The Care Quality Commission should summarise the key messages from the Controlled Drugs National Group meetings and circulate them to NHS England controlled drug accountable officers to pass on to members of their controlled drug local intelligence networks.

Progress on recommendations made in the 2012 report

In the 2012 report, CQC made five recommendations.

Recommendation 1

“Health and social care professionals must ensure that they know how to contact the lead controlled drugs accountable officer in the new area teams of the NHS Commissioning Board (known as NHS England) and the mechanism for reporting controlled drug concerns (the controlled drugs accountable officer register is on CQC’s website).”

Progress

Since the re-structure of the NHS and the change in regulations on 1 April 2013, progress on this recommendation has been variable across England as NHS England CDAOs are not always aware of all the organisations in their geographical area. We are continuing to remind organisations that are not yet engaged in the wider sharing of controlled drug concerns to be proactive in making contact with their NHS England area team controlled drugs accountable officer.

Recommendation 2

“Because of the changes, controlled drugs accountable officers (CDAOs) should follow the guidance on CQC’s website to update contact details promptly to ensure that the Controlled Drugs Accountable Officer Register is accurate.”

Progress

Although many organisations do notify us of their CDAO in a timely way, some are still not aware of the requirement to appoint a CDAO, whether they need to appoint one, or the process for doing so. This has become more complex with the changes to the NHS structure and the growing number of non-NHS organisations delivering primary care.

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.”

Progress

A framework for NHS England CDAOs has been provided as part of the [Single Operating Model \(SOM\)](#). This stipulates that, as a minimum, area team CDAOs must ascertain what information is available, where it is held, what needs to be transferred, what should be archived and how the transfer should take place.

Recommendation 4

“CDAOs, clinical commissioning groups (CCGs) 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.”

Progress

There has been good progress with controlled drug governance arrangements during 2013 despite changes to both the NHS and the regulations. All area teams notified CQC of their CDAO after April 2013 and controlled drug local intelligence network (CD LIN) meetings are taking place across England. However, we are aware that the CD LINs are at different stages of maturity and some have made more progress than others. Some area teams also need to do work to strengthen the relationship between area team CDAOs and CCGs.

Recommendation 5

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

Progress

From 1 April 2013, primary medical services were 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. The inspection methodology during 2013 included trigger questions to ensure governance arrangements for controlled drugs were included in CQC’s inspection processes for primary medical services.

Background

This is the seventh annual report from the Care Quality Commission (CQC) on the regulation of controlled drugs in England and relates to the year ended 31 December 2013. We describe developments in managing the risks associated with handling and using controlled drugs and look at the prescribing patterns for controlled drugs over the past year. Previous reports are available on our [website](#).

Amended regulations for the supervision of management and control of controlled drugs came into force in England on 1 April 2013 ([the Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#)). These revised and updated the previous (2006) regulations and aligned them with the new structure of the NHS in England. The Ministry of Defence has now also been brought into the scope of the amended regulations. This is the first report under the amended regulations.

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. The elements of this oversight role are set out in the 2013 regulations. CQC took over the responsibilities originally assigned to the Healthcare Commission on 1 April 2009. These 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) and ensuring that local governance arrangements and provisions for incident panels are satisfactory.**

Transition to the 2013 regulations

The new amended regulations carry forward a number of measures in the 2006 regulations that underpin the arrangements to ensure the safe management and use of controlled drugs in England and Scotland. Wales and Northern Ireland have their own equivalent but separate regulations, which continue unaffected by these changes.

The 2013 regulations continue to designate a number of healthcare providers that are required to appoint CDAOs, and set out who may be appointed, under what circumstances they should be removed from this role, and the registration requirements for all CDAOs. The 2013 regulations also continue to set out the core duties and functions of CDAOs that must be established and reviewed to secure the systems for safe management and use of controlled drugs within their own organisation or at those with whom they hold contracts.

To support the changes made in legislation and continue to promote good governance for the safe management and use of controlled drugs across England and Scotland, the Department of Health has published [Information about the Regulations](#).

NHS England and the Single Operating Model (SOM)

NHS England undertook a risk assessment of its responsibilities in relation to controlled drugs from 1 April 2013, and formed a short life working group comprising representatives from NHS England, lead CDAOs, the Department of Health, the Care Quality Commission (CQC) and NHS Business Services Authority, to address the issues identified.

This culminated in the publication of a [Single Operating Model \(SOM\)](#) in November 2013, to support NHS England's area teams with their responsibilities for establishing and managing arrangements for controlled drugs. The SOM is designed to be used in conjunction with the Controlled Drugs (Supervision of Management and Use) Regulations 2013 and the information about the regulations produced by the Department of Health. The SOM provides guidance and templates for lead CDAOs.

Figure 1 on the next page shows the geographical areas served by the 27 area teams of NHS England and Table 1 lists their names.

Figure 1: Areas of NHS England

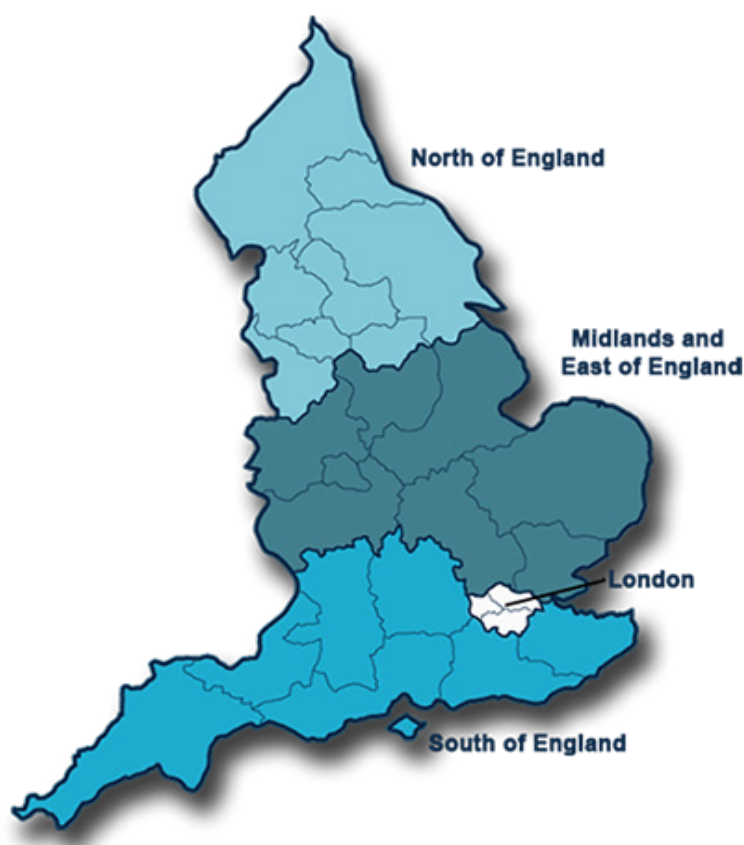


Table 1: NHS England area teams

Arden, Herefordshire and Worcestershire	Kent and Medway
Bath, Gloucestershire, Swindon and Wiltshire	Lancashire
Birmingham and The Black Country	Leicestershire and Lincolnshire
Bristol, North Somerset, Somerset and South Gloucestershire	London (three area teams)
Cheshire, Warrington and Wirral	Merseyside
Cumbria, Northumberland, Tyne and Wear	North Yorkshire and Humber
Derbyshire and Nottinghamshire	Shropshire and Staffordshire
Devon, Cornwall and Isles Of Scilly	South Yorkshire and Bassetlaw
Durham, Darlington and Tees	Surrey and Sussex
East Anglia	Thames Valley
Essex	Wessex
Greater Manchester	West Yorkshire
Hertfordshire and The South Midlands	

Progress to date with the new arrangements

All NHS England CDAOs are carrying out their role but often with limited resources, as the lead CDAO role is bolted on to existing job descriptions. While this was also the case under the previous 2006 regulations, there was often additional resource in the form of a dedicated team member providing support. Under the new arrangements, there is limited or no funding for such an additional resource and this is inevitably placing a greater burden on the lead CDAO. NHS England needs to be mindful of this, and that the 2013 regulations state that CDAOs must be adequately resourced to enable them to carry out their roles and responsibilities.

Most NHS England CDAOs are using their limited resources to commission or purchase services such as professional pharmaceutical advice or rely on goodwill from organisations such as the clinical commissioning groups (CCGs) or commissioning support units (CSUs) to carry out controlled drug-related duties on their behalf. However, the ways in which these limited resources are used varies and some CD LNs are operating more effectively than others with similar resources. NHS England plans to hold two learning events a year for their area team lead CDAOs. These events will provide a forum for sharing good practice and opportunities to discuss how best to use those limited resources more effectively.

To cascade good practice and pertinent controlled drug-related issues further, some NHS England CDAOs are circulating regular newsletters and holding formal learning events for their CD LIN members. These events not only help promote the safe use of controlled drugs but also provide an opportunity for networking. This is particularly valuable now that the National Institute for Health and Care Excellence (NICE) is no longer providing best practice events.

Good practice example 1

Devon, Cornwall and Isles of Scilly Area Team local newsletter

The NHS England Area Team for Devon, Cornwall and Isles of Scilly publishes a local newsletter around three times a year, usually after holding CD LIN meetings. The newsletter is circulated to each CD LIN member and associated bodies such as local professional committees, GP practices and anyone who requests a copy. The newsletter is also distributed to other area teams in the south of England, both for information and to use or adapt if they wish. A copy of the Devon, Cornwall and Isles of Scilly's newsletter (Issue 6) is attached for information (please click 'file attachments' in the menu on the left of this document).

NHS England CDAOs now play a critical role in the management and safe use of controlled drugs. However, as many are currently under-resourced, we have made a series of recommendations to support and strengthen their roles.

Recommendation 1

NHS England controlled drug accountable officers must be adequately resourced to carry out their roles and responsibilities with regard to controlled drugs.

Recommendation 2

NHS England controlled drug accountable officers must be clear about their responsibilities for controlled drug governance arrangements and strengthen their relationships with clinical commissioning groups (CCGs) and commissioning support units (CSUs) so that these organisations are clear as to how they can support them.

Recommendation 3

NHS England controlled drug accountable officers should consider organising learning events for controlled drug accountable officer colleagues and controlled drug leads to enable them to share learning and best practice.

Controlled drug local intelligence networks (CD LINs)

From 1 April 2013, NHS England became responsible for determining the local intelligence networks across England. To ensure all parts of the area team geography is covered by a CD LIN, area teams have found it necessary to operate up to three separate LIN areas in order to adequately cover their geographical area. The expectation, by NHS England, is that the CD LINs will meet at least twice per year with meetings not more than six months apart. However, the majority of the CD LINs are holding meetings more frequently, with at least three to four CD LIN meetings per year. Since 1 April 2013 many CD LINs have already held three meetings.

Core membership of the CD LIN is set out in the 2013 Regulations. As a consequence of the changes made in the 2013 Regulations, all CD LINs have undergone changes to their core membership, and experienced procedural and reporting changes. Some CD LINs have been affected by the changes more than others. Those in which there has been some continuity of personnel have progressed further than those where the NHS England CDAO is starting out afresh and without previous experience or support.

Recommendation 4

NHS England controlled drug accountable officers should consider extending membership of the controlled drug local intelligence network to other relevant local organisations (such as social enterprise organisations or community interest companies) either on a permanent or 'as required' basis.

Sharing and storing of information is integral to an effectively functioning CD LIN. While information sharing is continuing under the new arrangements either through the use of previously established mechanisms or through new mechanisms, the information is often only being shared locally and with neighbouring CD LINs but not nationally when it is appropriate to do so. The changes made in the 2013 Regulations provide an opportunity for developing mechanisms for the wider sharing of both information and good practice. NHS England and its lead CDAOs may wish to consider developing a system in which appropriate information and good practice can be shared nationally.

Recommendation 5

A formal process should be put in place by NHS England controlled drug accountable officers to ensure controlled drug concerns and good practice are shared nationally where appropriate.

Occurrence reporting

Controlled drug designated bodies (organisations required to have a controlled drugs accountable officer) are required to submit a quarterly occurrence report to the NHS England CDAO at area team level. However, to date there has been no mechanism for gathering the data to review trends – either regionally or nationally. As a result of the implementation of the new Regulations, all CD LINs have undergone changes to their core membership, procedures and reporting arrangements. One important outcome of the changes is that it will now be possible to collate occurrence reports centrally. National data collection is required to provide a clear picture of concerns across all area teams. Moreover, from 2014, each controlled drug designated body (CDDDB) will be required to provide a breakdown of the total number of occurrences within their organisation, by category, to their NHS England Area Team CDAO. For this reason an occurrence report template has been provided in the SOM (at Annex 5). The NHS England CDAO will collate the data for all CDDDBs in their area and submit to CQC through a new dedicated mailbox: CDOccurrenceData@cqc.org.uk.

In time, the central collation of occurrence reports will provide a clear picture of activity and concerns across all area teams. This will provide valuable insights into the national picture and enable emerging trends or issues of concern to be identified early.

Good practice example 2

Greater Manchester online incident reporting tool

The Greater Manchester Area Team's (GMAT) Medical Directorate has designed a web-based solution for reporting concerns and incidents to ensure a standardised approach in reporting across the area. The new service went live across the area in August 2013.

This initiative minimises risks associated with registering incidents and provides opportunities to share statistics and identify common trends across the area. The online reporting tool is available on the GMAT website at [Controlled Drugs Reporting](#).

Register of controlled drug accountable officers (CDAOs)

Under the 2013 Regulations, CQC continues to compile, maintain and publish a list of registered CDAOs across England on our website. For the first time, the 2013 regulations make provision for exemptions to the requirement to appoint a CDAO for micro businesses or start-up businesses with fewer than 10 staff, and for businesses with more than 10 staff, but which do not have a high degree of controlled drug activity or usage. These businesses can decide whether to appoint a controlled drugs lead if they choose to, but this is not a regulatory requirement. Where those businesses provide services to the NHS, it is expected that their commissioners will require them to demonstrate adequate arrangements for ensuring the safe management and use of controlled drugs.

The Department of Health has asked CQC to monitor and report the effect of this exemption on the adequate supervision of the management and use of controlled drugs in England.

It must be noted that the controlled drug designated body is still responsible for informing CQC of the appointment of, and changes to its CDAO, and we continue to update the register regularly to reflect these changes. Notifications can only be made using the controlled drugs accountable officer notification webform, although changes of contact details can be emailed. CDDBs are also responsible for checking that their entry in the register is up to date and accurate.

This is the first year in which organisations have been able to notify CQC of an exemption from the need to appoint a CDAO and the number of exemption requests received so far has been very small. Going forward, organisations must review and determine whether they need to appoint a CDAO and notify CQC accordingly.

Recommendation 6

Healthcare providers must determine whether they are required to appoint a controlled drug accountable officer or whether they meet the criteria for an exemption.

Being exempt from the requirement to appoint a CDAO does not relax the requirements for safe management of controlled drugs, but does reduce unnecessary paperwork for all parties. CQC will be authorising and monitoring the impact of this change.

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. NHS England and UK Antidoping joined the group in 2013.

The group meets four times a year (March, June, September and December), to enable sharing and discussion of emerging issues from each different area represented, and to identify ways of working together to reach solutions.

Membership of the Group in 2013 included:

- Association of Chief Police Officers
- Care Quality Commission
- Department of Health
- General Pharmaceutical Council (GPhC)
- 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
- NHS England
- NHS England Patient Safety Team
- NHS Protect
- Ofsted
- Public Health England
- UK Anti-doping
- Veterinary Medicines Directorate.

Reports of activity from the group's main partners show the many ways in which these agencies contribute to the overall safer management of controlled drugs and we have highlighted some of their activities below. To see the full reports of their activities, please follow the link to the stakeholder report on CQC's [website](#).

Stakeholder initiatives

1. GPhC: Learning through bulletins

Throughout the year the General Pharmaceutical Council (GPhC) provided advice about controlled drugs through its bulletin, *Regulate*. A regular feature, *Fitness to Practise – learning*, describes fitness to practise cases that the GPhC has dealt with, and identifies learning points. Three cases were selected in 2013 that illustrated learning points related to controlled drugs:

- Issue 9 (February 2013): a case involving the supply of a different amount of methadone from that requested on the instalment prescription.
- Issue 10 (May 2013): a case of methadone prescriptions not marked or endorsed at the time of supply.
- Issue 11 (July 2013): a case of the theft of morphine sulphate tablets, codeine and dihydrocodeine.

2. NHS Protect: Controlled drug theft reporting initiative

NHS Protect is developing its Security Incident Reporting System (SIRS) to improve the reporting of controlled drug losses. The system is designed to gather information either from local risk management systems or via an online form.

NHS Protect worked with CQC and NHS England to develop a proposed framework for collecting occurrence data reported to the 27 area team lead controlled drug accountable officers to gain a clearer national picture of safer management arrangements for controlled drugs in England. In particular, it aims to monitor the extent of controlled drug prescribing and administration errors, controlled drug losses and governance-related issues. The proposal was accepted by NHS England and incorporated into the NHS England document *The Controlled Drugs (Supervision of Management and Use) Regulations 2013 NHS England Single Operating Model*.

3. Home Office: Updated guidance on General Security and Security of Controlled Substances in Transit

These two guidance documents for existing and prospective licensees have been given a substantive re-vamp to ensure clarity and consistency but there are no changes to the underlying legislation (Misuse of Drugs (Safe Custody) 1973 Regulations).

The security guidance is designed to support prospective and existing Home Office licensees in determining how their premises and their controlled drug stocks should be secured and stored. The guidance document for the safe custody of controlled drugs in transit provides advice and guidance on security measures for the transportation of controlled drugs either domestically (within the UK) or internationally.

In addition the Home Office has worked closely with the Department of Health, Social Services and Public Safety, Northern Ireland (DHSSPNI) to ensure consistency across the UK in terms of expectations.

Both documents are available on the website [here](#).

4. Public Health England: Prison pain management and optimising opioid substitution

Prison pain management

Public Health England (PHE) has developed a guide that gives an overview of best practice in managing persistent pain and describes how this might be implemented in secure environments, including prisons, police custody and immigration removal centres. It offers advice on confirming a diagnosis of persistent pain in a secure setting. The guide, [Managing Persistent Pain in Secure Settings](#), was written in association with the Faculty of Pain Medicine of the Royal College of Anaesthetists, the Royal College of General Practitioners and the British Pain Society, and is supported by the Department of Health.

Optimising opioid substitution treatment

PHE has also developed a good practice guide, [Optimising Opioid Substitution Treatment](#), which focuses on elements of opioid substitution treatment (OST) that can be optimised to improve recovery outcomes: a comprehensive recovery framework; adequate opioid levels; a range of medications; supervised consumption; biological testing; and contingency management.

To keep CDAOs informed of emerging issues and activity discussed at the meetings, CQC will summarise the key points from the meetings and circulate these to NHS England CDAOs to cascade to their CD LIN members. This should enable CDAOs and CD leads to keep up to date with key developments, policy and guidance.

Recommendation 7

The Care Quality Commission should summarise the key messages from the Controlled Drugs National Group meetings and circulate them to NHS England controlled drug accountable officers to pass on to members of their controlled drug local intelligence networks.

Clinical subgroup

The 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 harms. The group met three times in 2013. It is co-chaired by CQC and the Patient Safety Team at NHS England and is made up of medical and pharmacy specialists, CDAOs and regulatory bodies.

The key output from the group in 2013 was the production and circulation of the first three newsletters and supporting information covering fentanyl and buprenorphine transdermal patches, oral oxycodone medicines and MS syringe drivers. These are available on CQC's website via the link [NHS England's Patient Safety Team Newsletters](#). The newsletters build on the work of the National Reporting and Learning System (NRLS) and provide a valuable resource, especially for preventing accidental harm to patients.

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations meets twice a year (March and September). It provides a forum to discuss matters of mutual interest at a strategic level, including:

- Sharing intelligence of general concerns across national borders among those charged with management, monitoring or inspection of the governance arrangements for controlled drugs.
- Sharing intelligence about emerging specific concerns that could impact on neighbouring nations.
- 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.

Jersey, Guernsey and the Isle of Man joined the group in 2013.

We have summarised some of the activity and good practice initiatives being undertaken by our cross border colleagues below.

Scotland

NHS Scotland has published a *Review of Controlled Drug Prescribing in Primary Care in NHS Scotland*, which is based on CQC's annual report on controlled drugs. The report shows that the 'top 10' controlled drugs are broadly similar, except that buprenorphine and fentanyl are in the top 10 for England and not in Scotland, and oxycodone and nitrazepam are in the top 10 for Scotland but not England. The report also shows the very low level of private prescribing in Scotland compared with England.

The report and a number of additional pieces of guidance are listed on the [AO Network website](#).

Wales

There is a specific focus on the prescribing of tramadol and morphine within NHS Wales under the auspices of the All Wales Medicines Strategy Group. In April 2013 a report was published comparing tramadol prescribing in primary care in Wales with that in the north east of England, which has similar regional demographics. The All Wales Therapeutics and Toxicology Centre has produced a resource pack with further prescribing analyses and educational support materials to encourage the review and promotion of appropriate prescribing of tramadol across primary and secondary care. The *Tramadol Educational Resource Materials* is available on the All Wales Medicines Strategy Group [website](#).

The Healthcare Inspectorate Wales maintains a register of CDAOs, which is available on its [website](#).

Northern Ireland

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1 October 2009. These Regulations set out the responsibilities for accountable officers, designated bodies and responsible bodies. A single local intelligence network has been established in Northern Ireland, which meets quarterly and is currently chaired by the Department of Health, Social Services and Public Safety (DHSSPSNI). Contact details, guidance documents and information relating to the local intelligence network are available on the [website](#).

The DHSSPSNI is currently undertaking a review of the above legislation following amendments made to the equivalent English and Scottish Regulations in 2013. DHSSPSNI anticipates that the proposed amendments will come into operation mid-2015.

The Northern Ireland Accountable Officers' [fourth annual report](#) was published in June 2014. This provides information on the activities of the local intelligence network and includes updates from responsible bodies.

Current project: Controlled drug record card

The Health and Social Care Board commenced a regional project in 2013 to develop a controlled drug record card (CDRC) with supporting guidance and patient information. The CDRC is intended to be used by nursing staff from all organisations to record stock of non-oral Schedule 2 controlled drugs and midazolam received by, and administered to, patients in the community. Work is still in progress but we anticipate that the CDRC will become operational towards the end of 2014.

Ireland

The Pharmaceutical Society of Ireland (PSI) regulates and provides legislative and practice guidance regarding the management of controlled drugs within pharmacy services in Ireland (website: [The Pharmaceutical Society of Ireland](#)).

Annual reports (and other publications) are available on the [website](#), as well as a list of [Authorised Officers](#) and guidance in relation to [controlled drugs in nursing homes](#), and other [guidance documents](#) from PSI.

National trends in the use and management of controlled drugs

During 2013, CQC continued to monitor the overall use and management of controlled drugs in England by analysing national prescribing and requisition data, feedback on routine monitoring activity in controlled drugs, and reports from members of the Controlled Drugs 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 Business Services Authority. NHS Prescription Services also analyses private prescriptions for Schedule 2 and 3 controlled drugs that are dispensed in community pharmacies.

By analysing ePACT 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. 2013 was the seventh 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.

Prescribing of controlled drugs in primary care

In 2013, the total number of controlled drugs items prescribed in NHS primary care was 47,044,814, which is a decrease of 1% compared with 2012. The cost of this was £498,942,743 representing an increase of 10% compared with £452,761,855 in 2012. More details can be found in [The Prescriptions Dispensed in the Community 2003-2013 report](#), published by the Health and Social Care Information Centre.

Schedule 1 controlled drugs

In April 2013, Sativex (a cannabinoid oromucosal mouth spray) was reclassified from Schedule 1 to Schedule 4 (part 1).

Schedule 2 and 3 controlled drugs

Prescribing of Schedule 2 and 3 controlled drugs in 2013 stayed broadly similar to that in 2012 (Table 2 and Figure 2). The prescribing of temazepam continued to decrease and numbers of items of methadone and diamorphine also decreased. Prescribing of oxycodone and midazolam increased by 8% and 9.4% respectively.

Morphine, oxycodone and fentanyl are used in the management of severe pain. In primary care, fentanyl is prescribed in the form of transdermal patches that deliver the medicine through the skin over a period of several days. This is useful in long-term, stable pain for example, in cancer treatment. Oxycodone is more potent than morphine and is also used in the management of severe pain. It is taken as an oral liquid, immediate-release capsules and prolonged-release tablets. 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. Low-dose buprenorphine transdermal patches are used for the treatment of severe, non-cancer pain.

Prescribing of temazepam has been declining since 2007. The total number of items of temazepam prescribed in 2013 was 15% lower than in 2012. It is likely that the non-benzodiazepine hypnotics, zolpidem, zopiclone and zaleplon, are now being prescribed instead. Zolpidem prescribing is shown in Schedule 4 (see below); zopiclone and zaleplon are prescription-only medicines (POMs) but are not currently classed as controlled drugs and are therefore not covered in this year's report.

Methylphenidate prescribing continued to increase steadily during 2013, as in previous years. This is likely to be attributable to continuing increases in the diagnosis of, and prescribing for the treatment of attention deficit hyperactivity disorder (ADHD).

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.

Table 2: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care in 2012 and 2013 (by number of items)

Top 10 schedule 2 and 3 controlled drugs	2012	2013
Temazepam	2,349,284	1,993,927
Methadone	2,300,097	2,101,454
Buprenorphine*	2,246,423	2,428,389
Morphine Sulphate	1,964,746	2,188,584
Oxycodone**	1,153,337	1,246,400
Fentanyl†	1,115,923	1,158,078
Methylphenidate	657,358	725,816
Phenobarbital	256,602	246,280
Midazolam [?]	175,742	192,175
Diamorphine	122,706	118,645
All other schedule 2 & 3 CDs	157,853	168,906
Total	12,500,071	12,568,654

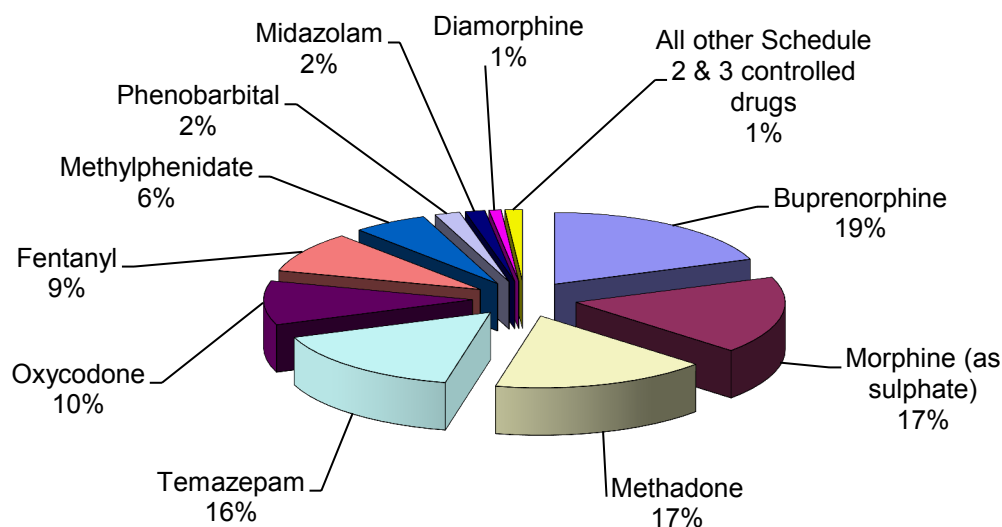
*Buprenorphine figures include the combination product Suboxone (buprenorphine + naloxone)

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

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

[?]Midazolam figures include oral and injectable midazolam

Figure 2: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care in 2013 (by number of items)

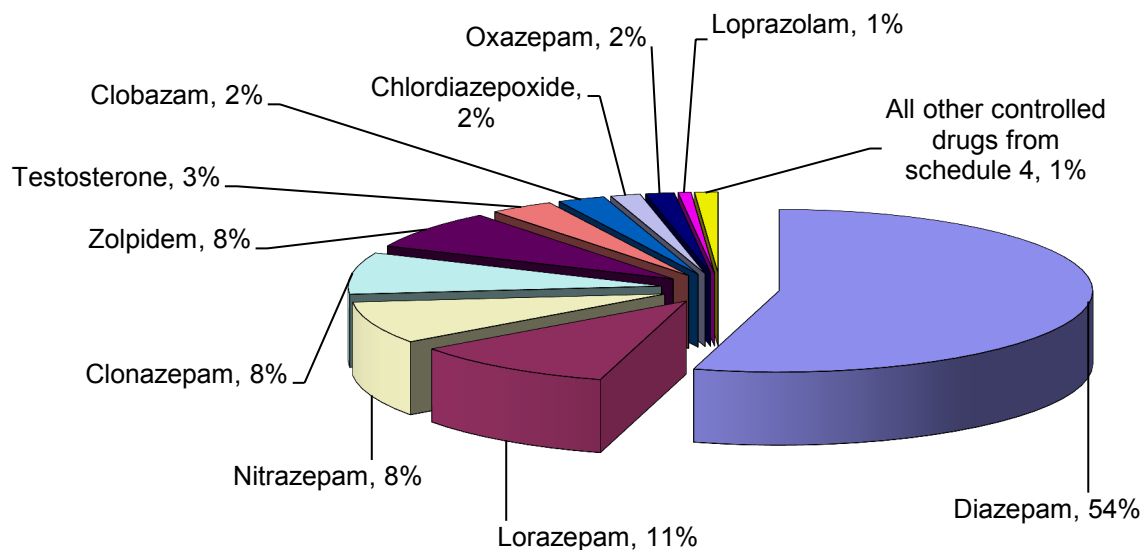


Schedule 4 controlled drugs

The pattern of prescribing for Schedule 4 controlled drugs during 2013 remains broadly similar to that seen in 2012.

Figure 3 shows the profile of prescribing for Schedule 4 controlled drugs during 2013. 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 3: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2013 (by number of items)



Anabolic steroids

Although anabolic steroid prescribing forms only a very small percentage of the overall prescribing of Schedule 4 controlled drugs, there are concerns regarding their illicit use and UK Anti-Doping (UKAD) is undertaking work to monitor this.

Good practice example 3

UK Anti-Doping Report Doping in Sport line

UKAD receives information on people, substances and activities which may relate to doping, through its dedicated Report Doping in Sport line, powered through Crimestoppers. This information may also be reported to police forces and UKAD through the main Crimestoppers number, for example, where controlled drugs, such as anabolic steroids, are being distributed in a gym.

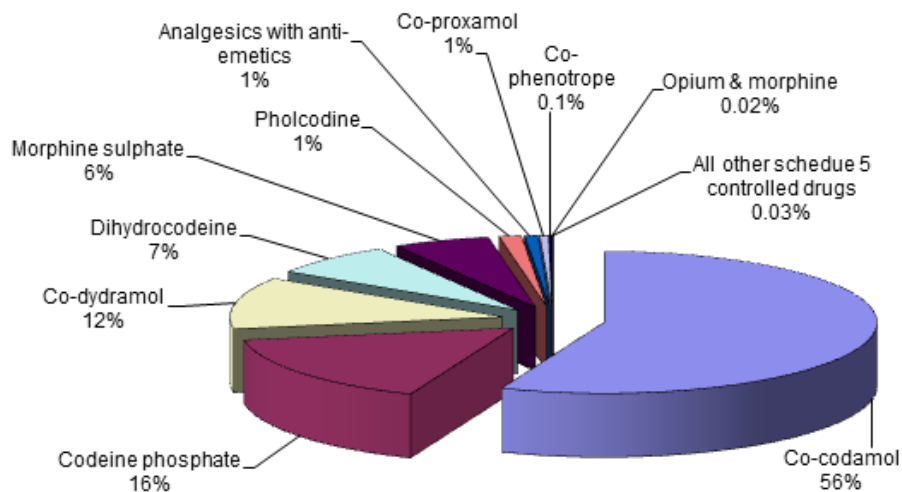
This year, UKAD has contributed to an East Midlands police force drugs profile, to assist in building a bigger picture around drugs and links to gyms, for example.

Schedule 5 controlled drugs

The pattern of prescribing for Schedule 5 controlled drugs during 2013 remains broadly similar to that seen in 2012.

Figure 4 shows the profile of prescribing for Schedule 5 controlled drugs during 2013. Although many of the drug substances are the same as those 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 continues to be co-codamol (a combination of paracetamol and a low dose of the weak opioid, codeine), which, as in 2012, accounts for 56% of prescribing in this group.

Figure 4: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2013 (by number of items)



Nurse and pharmacist prescribing

There was an 11% increase in controlled drug prescribing by nurses in 2013 compared to 2012 and a 16% increase in pharmacist prescribing of controlled drugs in 2013 compared to 2012 in all schedules (see Table 3). However, this still represents only a small proportion of total controlled drug prescribing. Nurses and pharmacists are involved in prescribing methadone and buprenorphine for the treatment of addiction, which accounts for the majority of prescriptions for controlled drugs from these two groups.

Table 3: Nurse and pharmacist prescribing of controlled drugs in NHS primary care (by numbers of items), in 2012 and 2013

	2012	2013
Nurse prescribing	593,649	661,544
Pharmacist prescribing	25,325	29,502

Private prescribing of controlled drugs

The total number of Schedule 2 and 3 controlled drug items prescribed privately in 2013 was 36,935 which is a decrease of about 6% compared with 2012 (Table 4 and Figure 5). Private prescribing accounts for about 0.1% of overall controlled drug prescribing.

The overall pattern of private prescribing was similar to that reported in 2012. The main points are:

- Diamorphine replaced pethidine as the 10th most commonly privately-prescribed Schedule 2 and 3 controlled drug in 2013.
- Methadone continues to be the most common controlled drug prescribed privately, but its use has decreased markedly over the past six years (figure 6).
- Both methylphenidate and dexamphetamine are used in the management of childhood and adult ADHD. Private prescribing of methylphenidate during 2013 increased by 7% when compared against the previous year. Since 2007, private prescribing of methylphenidate has progressively increased year-on-year, but the increase in 2013 was noticeably lower. Dexamphetamine continues to be the second most common controlled drug prescribed privately, although prescribing continued to decrease, with a 17% fall in the number of prescriptions compared with 2012.
- Temazepam prescribing has fallen by about 40% over the past four years and continued to decrease in 2013.

Table 4: Top 10 privately prescribed Schedule 2 and 3 controlled drugs (by number of items) in 2012 and 2013

BNF chemical substance	2012	2013
Methadone	14,953	13,698
Dexamfetamine	6,254	5,191
Methylphenidate	4,835	5,151
Morphine (as sulphate)	4,044	4,145
Temazepam	3,051	2,497
Buprenorphine*	2,616	2,429
Oxycodone**	1,411	1,619
Fentanyl†	614	674
Midazolam‡	427	501
Diamorphine	245	269
All other Schedule 2 & 3 controlled drugs	753	761
Total	39,203[§]	36,935

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

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

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

‡Midazolam figures include oral and injectable midazolam

§The total figure for 2012 has been adjusted down to remove lisdexamfetamine dimesylate. This was included as a Schedule 2 item until June 2013 after which it was no longer classified as a controlled drug.

Figure 5: Top 10 privately prescribed Schedule 2 and 3 controlled drugs (by number of items) in 2013

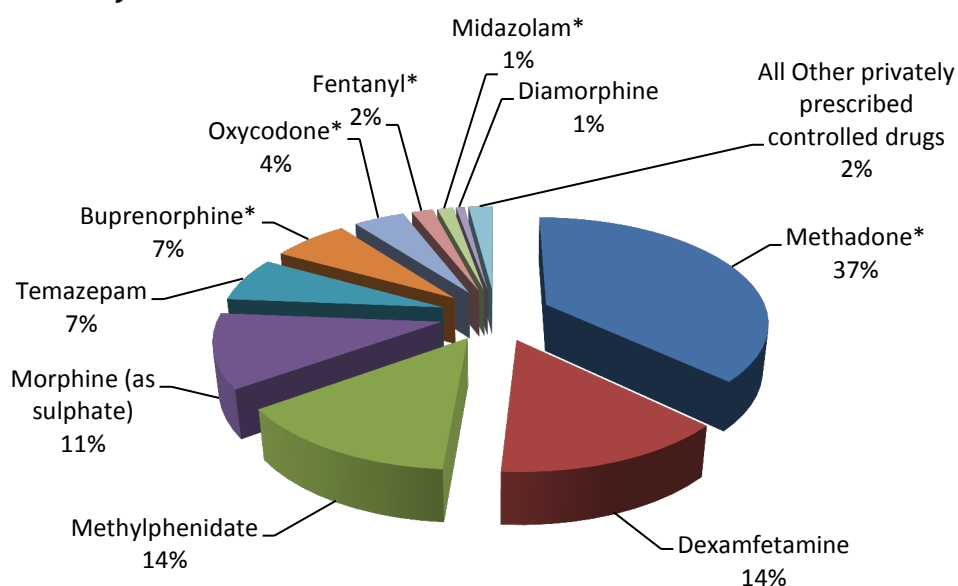
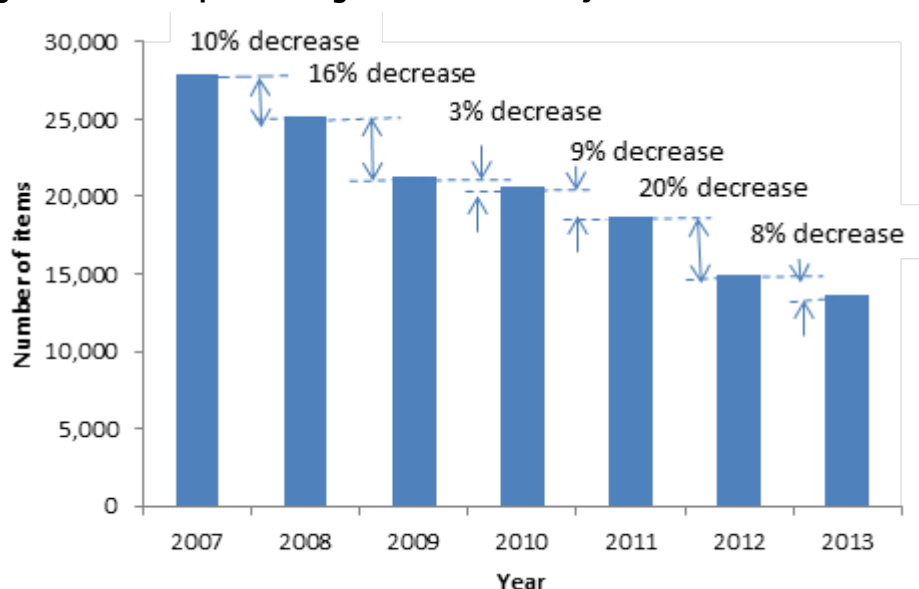


Figure 6. Private prescribing of methadone (by number of items) 2007-2013



Controlled drugs requisitions

Practitioners who wish to obtain a stock of a Schedule 2 or 3 controlled drug from a community pharmacy should use a standard Controlled Drug Requisition Form (FP10 CDF). However, the use of the forms is not mandatory and pharmacies are permitted to supply controlled drugs requisitioned on non-standard forms. In the past we have reported that up to 50% of the forms submitted for analysis were non-standard forms with incorrect prescriber codes and it has therefore not been possible to extract any meaningful data. The Home Office is currently working to amend the legislation to require standard requisition forms to become mandatory, which will allow more meaningful data to be gathered in future.

Analysis of the requisition data shows that 19,120 controlled drug items were requisitioned in 2013. This is a 2% increase when compared with 2012, where 18,784 controlled drug items were requisitioned. The four most-commonly requisitioned controlled drugs were oxycodone, morphine sulphate, fentanyl and diamorphine – this has been the case since 2008.

However, we are unable to draw any further conclusions as the picture is confused by the changes in NHS structure in April 2013. At the beginning of 2013, primary care trusts (PCTs) were responsible for issuing FP10 CDF forms, but in April 2013 this responsibility passed to NHS England area teams.

Overall conclusion

The implementation of the new regulations has made it possible to consolidate and build on the good practices developed over the past six years. This has resulted in the development of a more robust system in which the work of all the stakeholders is better integrated than in the past. We believe that this represents a major step forward in fulfilling the vision of safe management and use of controlled drugs as articulated in the Shipman Inquiry reports. However, we are still only nine months into the new regulations and there is still much work to be done.

Next steps

During 2013, we focused on the change in regulation and on putting the systems in place to ensure that the arrangements for the safe management of controlled drugs were maintained.

Going forward into 2014, we must ensure that good practice initiatives are developed and embedded so that the systems put in place in 2013 are as effective as possible. Two such examples of the systems that are now in place are the collection of national occurrence data and access to centrally produced prescribing reports; these give us the opportunity for better national oversight of the safer management arrangements.

Appendix A: Home Office controlled drugs legislation: The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

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.

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

The legitimate, clinical use of controlled drugs is governed by [The Misuse of Drugs Regulations 2001](#). These divide controlled drugs into five therapeutic 'schedules' according to the level of control they need. Further information on the classification and scheduling of controlled drugs can be found [here](#).

Appendix B: Safer management of controlled drugs

Measures to strengthen governance arrangements for controlled drugs were introduced as a result of recommendations made by the Shipman Inquiry in 2001. The Shipman Inquiry was an independent public inquiry set up to examine the issues arising from the case of Harold Shipman. The reports are now held in the National Archives and can be accessed at [The Shipman Inquiry Reports](#).

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced following The Shipman Inquiry and came into force in England on 1 January 2007. They 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 Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#).

There is also [Information about the 2013 Regulations](#) available from the Department of Health.

The regulations require that large healthcare organisations (such as NHS trusts and independent hospitals) appoint a controlled drug accountable officer (CDAO) who has responsibility for all aspects of controlled drugs management within their organisation. Smaller organisations are not required to appoint a CDAO. However, they must still comply with the Misuse of Drugs Regulations and must have arrangements in place to ensure the safe and secure management of controlled drugs and the reporting of controlled drug concerns.

Under the new regulations, each area team of NHS England is also required to appoint a CDAO and they are required to designate the controlled drugs local intelligence networks (CD LINs) for their area for the purpose of sharing controlled drug concerns. They determine the membership of their CD LIN and the frequency of meetings.

Details of all the CDAOs within England are held in the Controlled Drugs Accountable Officer Register, which is published on the [CQC website](#).

Appendix C: Signposting - links to further information

Links to relevant controlled drugs legislation and guidance

1. [The Health and Social Care Act 2012](#)
2. [The Controlled Drugs \(Supervision of Management and Use Regulations 2013](#)
3. [The Controlled Drugs \(Supervision of Management and Use\) Regulations 2013 - Information about the regulations](#)
4. [The Shipman Inquiry Reports](#)
5. [The Human Medicines Regulations 2012](#)
6. [The Misuse of Drugs Act 1971](#)
7. [The Misuse of Drugs Regulations 2001](#)
8. [NHS England's Controlled Drugs Accountable Officers' Single Operating Model](#)

Care Quality Commission and NHS England Patient Safety Team's newsletters

1. [Safe Use of Fentanyl & Buprenorphine Transdermal Patches](#)
2. [Supporting information](#)
3. [Preventing Harm from Oxycodone Medicines](#)
4. [Supporting Information](#)
5. [Preventing Harm Still Occurring with CDs Administered via MS Syringe Drivers](#)
6. [Supporting Information](#)

The links below provide information about the Care Quality Commission. There are also links to appropriate areas of our website in relation to CDAO notifications and CDAO Register.

[CQC's role and remit for Controlled drugs](#)

[Controlled Drugs Accountable Officers](#)

Controlled drugs accountable officer notifications

Please note that the [Controlled drugs accountable officer notifications](#) forms are password-protected. Please email us at enquiries@cqc.org.uk, quoting your name, role and organisation, and we will email the password to you.

Changes to your controlled drugs accountable officer's contact details

Please ensure you inform us of changes to the contact details (phone number or email address) of your CDAO as soon as possible by emailing us at CDAOregisterdata@CQC.org.uk.

Exceptions to the requirement to appoint an accountable officer

Controlled drugs designated bodies (CDDBs) that fulfil the exemption criteria, as set out in the 2013 Regulation under Regulations 3 and 4, must notify CQC of their exemption using the exemption notification webform. Exemption requests, if approved, are valid for one calendar year (January to December). A new CDAO exemption form must then be submitted within one month of its expiry in order to renew the exemption.

Register of accountable officers in England

We record the details of healthcare organisations' accountable officers in an online accountable officer register, which we update monthly.

Information for service providers

Whether you are the owner of a new organisation and need to register with us, or you work for an existing registered provider, you can find everything you need on our [Information for Service Providers](#) web page.

Registering for the first time

Find out about how to apply to register as a new provider or registered manager of a health or social care service by following our quick step-by-step guides.

[Step-by-step guide to applying as a new provider.](#)

[Step-by-step guide to applying as a new registered manager.](#)

Already registered?

If you have already registered with us as a provider or manager and want guidance on our standards, we have produced [Guidance on meeting standards](#).

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.
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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