The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

The Accountable Officers' Report

1January 2013 – 31 March 2014

June 2014

Contents

Introduction

This is the fourth report of the Accountable Officers in Northern Ireland concerning the governance of controlled drugs and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[1] ("the Regulations"). The report is written to record, inform, and provide assurances to patients and the public, Designated and Responsible Bodies, healthcare professionals and other stakeholders of the progress made between 1 January 2013 and 31 March 2014. It highlights some key developments during this period and reflects on prescribing patterns for a range of controlled drugs.

While the report provides an overview of the Northern Ireland situation, it also recognises the position of Accountable Officers and does not detract from their accountability to their own Designated Bodies or indeed the totality of assurances that they would be expected to give over the extent of the legislation. Accountable Officers are answerable to the senior management within their own organisation for implementing the requirements arising out of the Regulations. This report, in conjunction with each organisation's own internal

[1] http://www.legislation.gov.uk/nisr/2009/225/pdfs/nisr_20090225_en.pdf

reporting mechanisms, will support Accountable Officers in providing the necessary assurances to their senior management team or Board. The timeframe for this report has been extended to 31 March 2014 at the request of some Designated Bodies to align with their financial year end reporting period.

Background to the Regulations can be found in Appendix 1.

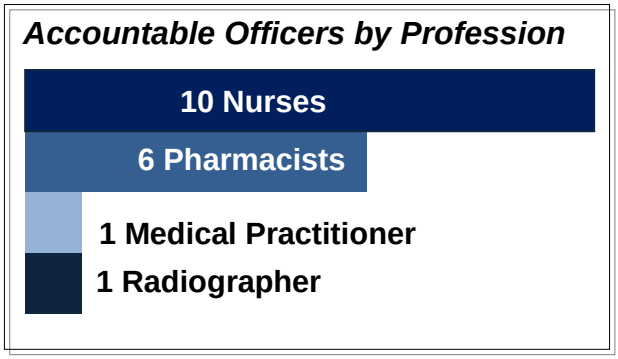
Accountable Officers

Within Northern Ireland there were, during the first quarter of 2014, 19 Designated Bodies with a total of 18 Accountable Officers. The Northern Ireland Children's Hospice has jointly nominated one person to be Accountable Officer for both their hospices (Newtownabbey (Horizon House) and Fermanagh (Horizon West).

The number of Designated Bodies increased from 18 to 19 in the 2nd quarter of 2013 with the registration of the Marie Curie Community Nursing Service[2] as an Independent Hospital by the Regulation and Quality Improvement Authority (RQIA).

[2] Marie Curie Community Nursing Service de-registered with effect from 31 March 2014 due to internal re-structuring within Marie Curie Cancer Care.

Figure 1



The Department of Health, Social Services and Public Safety (the Department) continues to maintain the register of Accountable Officers. An up-to-date contact list can be found on the Accountable Officer section within the Department's website and accessed through the following link: http://www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf.

Accountable Officers are periodically asked to check the accuracy of these details.

Each Designated Body is responsible for informing the Department of the removal and appointment of an Accountable Officer. Between 1 January 2013 – March 2014 a total of 3 Designated Bodies made changes to their nominated Accountable Officers.

A contact list is also held for the representatives of all the Responsible Bodies.

http://www.dhsspsni.gov.uk/responsible-bodies-contact-list.pdf

Presentations

Accountable Officers continue to make presentations to the Local Intelligence Network (LIN) about their organisation where they describe matters such as the types of services provided, the extent to which controlled drugs are used within that organisation and the impact of the Regulations. This continues to promote a better understanding of their individual roles, responsibilities and processes and to further the collaborative work of the LIN.

In June 2013 the Regulation and Quality Improvement Authority (RQIA) made a presentation to the LIN on the findings of their review of the "Management of Controlled Drug Use in Trust Hospitals" which was published on 12 June 2013. The RQIA described the background to the review and the processes used for gathering information from the Trusts. The report can be accessed at: http://www.rqia.org.uk/cms_resources/Management_of_Controlled_Drugs_FinalReport_120613_ISBN.pdf

The Information Commissioner's Office made a presentation in March 2014 on data protection and the responsibilities placed on all organisations to establish robust information security arrangements.

In recognition of the importance of data security the LIN is considering what provision should be made for on-going data protection training.

The Regulators have used the opportunity of presentations to provide guidance on matters such as thresholds for referral, regulatory processes and available sanctions.

Developments

Regional Information Sharing Guidance

The Accountable Officers have sought to develop regional guidance on information sharing to develop, where possible, a consistent process for all Designated Bodies.

Much work has been done with Human Resources colleagues to ensure that the responsibilities of Accountable Officers have been properly understood within their individual organisations. The regional information sharing guidance under development is intended to provide clarity on requirements for the management of any "well-founded" concerns and to ensure that any information shared within the LIN is done in compliance with legal requirements and

best practice. Accountable Officers would like to thank the Departmental Solicitor's Office and the Directorate of Legal Services for their advice and support throughout this work.

Regional Learning

In 2012 the LIN considered how best to manage learning which arose from incidents in relation to controlled drugs and which it agreed had application beyond the LIN. It was considered that the most effective and efficient way to share medicines safety related learning would be through engagement with the multidisciplinary regional forum provided by the Medicines Safety Sub-Group (MSSG).

A sub-group of the LIN established a threshold for submission to MSSG and used this to assess all learning points recorded on Occurrence Reports since October 2009. All those with regional application reaching the threshold were forwarded to MSSG for their consideration and response.

To support the process, a Memorandum of Understanding was developed between the MSSG and the LIN and feedback from MSSG on the progression of the learning is a standing item on the LIN agenda.

Database

Concerns submitted on Occurrence Reports are shared with other LIN members during the quarterly meetings. This potentially limits the timeliness and efficiency of sharing "well-founded" concerns. The LIN is seeking to establish a database to submit Occurrence Reports and to share the details of any "relevant person" about whom there are "well-founded" concerns. This will provide a secure and efficient means for informing all relevant Responsible Bodies of a concern in a timely manner which is independent of the meeting schedule. It is anticipated that the database will also significantly reduce the administrative work associated with chairing the LIN.

To support this development the LIN has worked closely with the Information Commissioner's Office and is grateful for the advice and support provided.

National and Cross Border Meetings

National Group

The National Group is a strategic group of regulators and key agencies that have areas of responsibility for controlled drugs within their remit. The Department has been granted permission to attend the

National Group as an observer and would like to thank the Group for this privilege. Being present as an observer enables Northern Ireland to keep abreast of matters relating to controlled drugs elsewhere.

The Cross-Border Group for safer management of controlled drugs in the devolved administrations

The Chair of the LIN has attended 3 Cross Border Meetings in the current reporting period. The Cross Border Group includes England, Scotland, Wales, Republic of Ireland and Northern Ireland with the Isle of Man, Jersey and Guernsey joining in this reporting period. The Department, RQIA and the Pharmaceutical Society of Northern Ireland are also members of this group. The aims of the Cross Border Group are to:

a) Provide a forum to promote the sharing of general controlled drugs concerns (rather than specific issues or named individuals) across national borders
b) Share learning and best practice methodologies that support the safer management of controlled drugs in each nation
c) Share analysis of trends and associated risks pertinent to safer management and use of controlled drugs.

Review of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

On 1 April 2013, as a consequence of the passing of the Health and Social Care Act 2012, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 (England and Scotland) were revised to reflect the new architecture for the NHS in England. They undertook a fundamental review at this time and, while a number of measures in the 2006 Regulations were carried forward, a range of changes were also introduced.

The LIN has reflected on the changes which have been brought into force in England and Scotland and considered the need for similar changes to the Northern Ireland Regulations. The Department has responsibility for amending this legislation and plans to consult on the proposed changes early in 2015 with the amended Regulations anticipated to come into operation late 2015.

Local Intelligence Network (LIN)

1
Local Intelligence Network

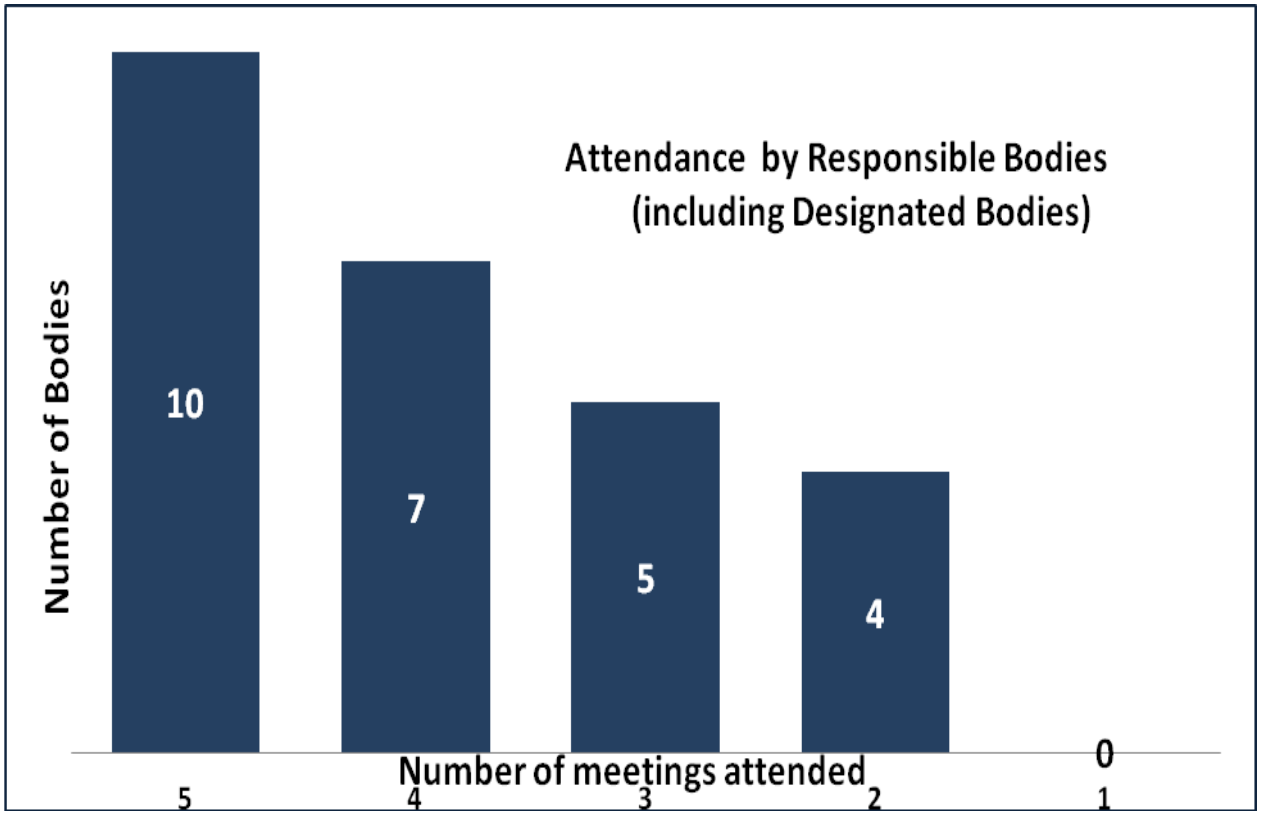
19
Designated Bodies

18
Accountable Officers

1 Jan 2013 - 31 March 2014

Meetings

Figure 2



See Appendix 2 for the attendance record for individual Responsible Bodies

Occurrence Reports

Organisations are required to make and to keep records of controlled drug incidents. The Accountable Officer must then ensure that any such incidents are fully and properly investigated and that those which raise concerns about any relevant person such as a healthcare professional are recorded on an Occurrence Report.

Legislation requires that every Accountable Officer submits a quarterly Occurrence Report to the Chair of the Local Intelligence Network. Submission of Occurrence Reports is aligned to scheduled LIN meetings. During the period 1 Jan 2013 and 31 March 2014 every Accountable Officer submitted an Occurrence Report in each quarter.

An Accountable Officer must submit an Occurrence Report even if there are no concerns to report and the Occurrence Reports are categorised as follows:

1. Nil return: No concerns reported
2. Concerns: The Accountable Officer has reported a concern(s)

The Occurrence Report template also includes sections for the Accountable Officer to record:

- Learning Points arising from an occurrence
- Updates on previous occurrences

Concerns

During 2013 – March 2014, of the 94 Occurrence Reports received 42 had concerns recorded.

It is important to note that not all reported concerns raise issues about relevant person(s). Accountable Officers may report discrepancies or concerns on practice issues, such as inadequate record-keeping for example, as this provides an opportunity to highlight concerns and learning with other organisations and is a forum for discussion. Likewise system breaches, such as a stock discrepancy, might be shared, not because there are concerns about the practice of any individual but because they have led to an improved awareness within an Accountable Officer's organisation which they wish to share with the other Responsible Bodies within the LIN.

Learning Points

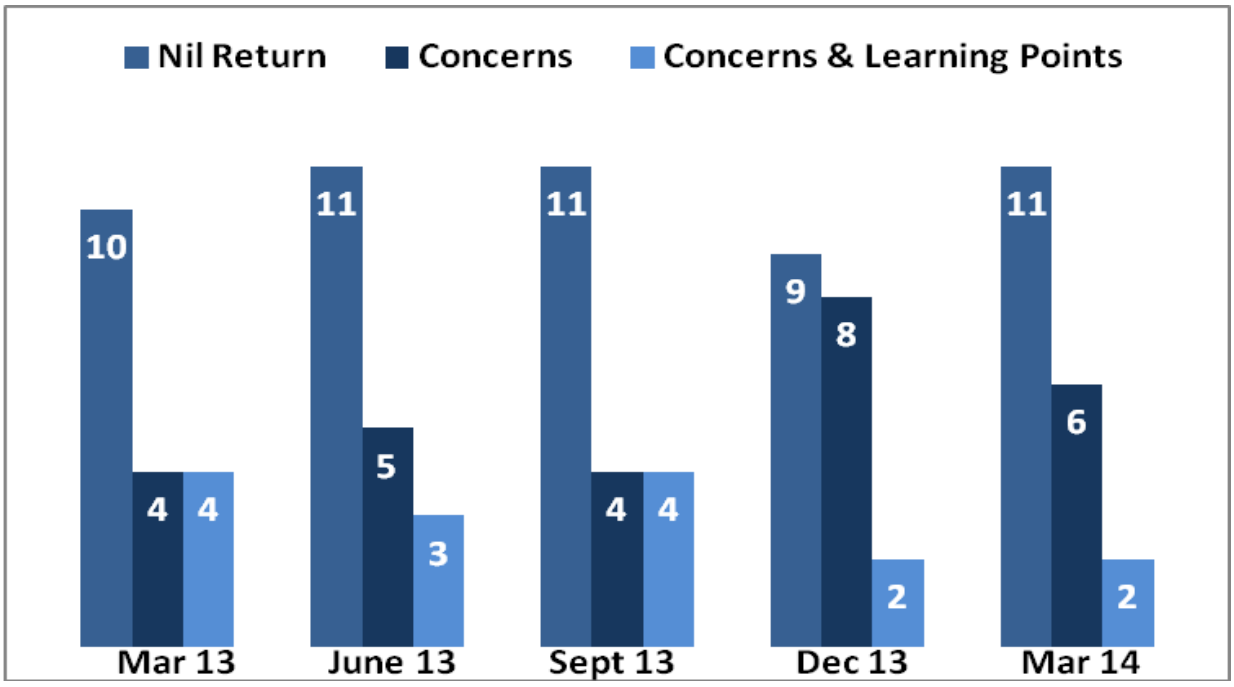
The Occurrence Report includes a section specifically for learning points and Accountable Officers are asked to identify potential learning from their incidents and concerns. This could include, for example, changes to practice or protocols which have been introduced by the reporting organisation to strengthen their arrangements.

Learning points are shared and discussed within the LIN. Organisations can therefore learn both about a concern and, wherever possible, learn from these concerns. This supports Accountable Officers, and indeed other Responsible Bodies, deliver continual improvements in relation to the management and use of controlled drugs.

While the majority of learning points have particular relevance to the originating organisation alone, many have application to other Responsible Bodies within the LIN. In addition there are a small number which the LIN considers should be disseminated more widely. .

Occurrence Reports by Type

Figure 3



N.B. The number of Designated Bodies increased from 18 to 19 in 2nd quarter 2013

Updates provided by Accountable Officers and other Responsible Bodies

1. Health & Social Care Board (HSCB)

SUMMARY OF WORK COMPLETED

a. Secure the safe management and use of controlled drugs (CDs)

Work continues in the HSCB to secure the safe management and use of controlled drugs by doctors, dentists and pharmacists as outlined below.

General Practitioners (GPs)

A business case has been developed to increase capacity in order to put in place an inspection schedule which will result in controlled drug (CD) inspection visits to practices during 2014/15 and witnessed destructions of expired CDs. It is planned that there will be a five year rolling programme of visits to cover all GP practices. This will build on the information gathered during the Declaration and Self-Assessment process, and provide an opportunity to follow-up on any issues identified from that process.

A CD guidance summary document was developed and sent out via The Northern Ireland Medical and Dental Training Agency (NIMDTA) to all locums and sessional GPs. This document was developed to provide an overview for locums and sessional GPs of the key points they need to be aware of with respect to CDs, and is a shortened version of the guidance document sent to GP practices last year.

Community Pharmacists

A declaration and self-assessment form is issued annually by the Department to all community pharmacies and is subject to review by the Medicines Regulatory Group (MRG). MRG also checks that SOPs for the management of controlled drugs are in place. A Memorandum of Understanding has been put in place between the Department and HSCB. This has been operational since April 2011 and has allowed the formal transfer of information between the Department and the HSCB.

Dentists

A controlled drugs declaration and self-assessment questionnaire was sent to all dentists on the Northern Ireland dental list during 2013 to gain an assurance that controlled drugs are being managed

properly by dental practices. The results are in the process of being analysed by the dental advisers prior to review by the Accountable Officer.

The Dental Directorate (HSCB) has also added a declaration and self-assessment to be applied to each dental practice annually as part of the quality assurance return.

Management of CDs in the community

One of the areas of risk in the management of CDs in the community is when they are stored in the patient's home for individual patient use, but are then administered to the patient by nursing staff. A number of incidents have been reported to HSCB and Trusts where CD ampoules or patches appear to have gone missing between nursing shifts, but current recording systems do not lend themselves readily to verification of this data. A regional project commenced during 2013 to develop a Controlled Drug Record Card (CDRC) and 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 and will go some way to providing assurances to nursing staff. Work is still underway with this project and it is anticipated that the final documents will become operational across all relevant nursing staff mid-2014.

b. Adequate destruction and disposal arrangements for CDs

General medical and dental practices are advised to return unwanted and out of date controlled drugs to a community pharmacy for destruction and GPs have been advised to include a section on this in their SOP. As outlined above, a business case has been developed to identify sufficient capacity in order to carry out witnessed destruction.

c. Monitoring and auditing of the management and use of CDs

GPs and Non-Medical Prescribers

HSCB pharmacists continue to undertake quarterly monitoring of all HSC prescriptions for controlled drugs (both patient prescriptions and stock orders) and follow up with prescribers where appropriate. All concerns are recorded on a database and discussion of these is encouraged at local team meetings. The HSCB SOPs governing the monitoring process have recently been merged into one and updated. Monitoring of midazolam prescribing has recently been included in Part 2 of the CD SOP.

Monitoring of privately ordered controlled drugs (on PCD1 prescription forms) is also now undertaken regularly, at least quarterly, with scans of all PCD1 forms sent to relevant HSCB staff (to include Accountable Officer and their deputy the Designated Officer) for review and follow-up as needed. A process has been established for the ordering of PCD1 forms, to ensure that these are only ordered where there is an identified need and when there are no concerns about the prescriber.

Dentists

A monthly review and follow-up of dental CD prescriptions continues to operate in the HSCB, and is directed by an SOP. A line has been included in the Quality Assurance return to allow ready identification of dentists who are providing conscious sedation and this will facilitate development of any further monitoring that is required. A poster presentation of the HSCB Dental CD Monitoring process was delivered at the UK Pharmacy Management Conference in October 2013.

Community Pharmacists

MRG undertakes inspections of community pharmacies monitoring their adherence to legal and professional requirements. A project has been proposed to be taken forward in 2014/15 which will assess whether routine reconciliation of wholesale records against dispensing claims will strengthen the security of the supply chain for Schedules 3, 4 and 5 drugs.

d. Relevant individuals receive appropriate training

A number of learning resources were developed and shared during 2013:

- Training on CD management in Primary Care developed and delivered to GPs in Belfast, South East and Western Local Commissioning Group (LCG) areas. Training is planned to be delivered in Northern and Southern LCG areas in 2014.
- Training delivered through Northern Ireland Sessional Doctors Association (NISDA) and NIMDTA to locums and GP trainees
- CD Frequently Asked Questions bulletin issued to GPs addressing common CD queries and learning from adverse incidents

- Learning from incidents involving CDs included in newsletters to GPs and community pharmacies on an ongoing basis as required
- CD legislation and relevant CD issues highlighted at Clinical Governance training for reception staff
- Guidance on appropriate CD management was provided to new-employee dentists as part of vocational training
- Ongoing training is provided to HSCB pharmacists on CD-related issues as required
- Practice specific training on CD related issues such as SOPs is provided as needed to GPs and their staff.
- A dental prescribing newsletter was published in December 2013 and provided advice about CD prescribing for Health Service and private patients.

e. Maintain a record of concerns regarding relevant individuals

A database continues to be maintained to allow all CD monitoring and auditing by HSCB pharmacists to be recorded. Additionally, the Accountable Officer keeps a database where all controlled drug concerns and their status is recorded. All dispensing errors that relate to CDs are recorded and managed as adverse incidents by the HSCB Medicines Governance Advisers.

f. Assess and investigate concerns

After the Accountable Officer has been advised, concerns are investigated locally in the first instance by the HSCB pharmacist with support from other HSCB staff, such as the Medicines Governance Adviser and Medical Adviser, as required. Some sixty eight concerns were reported in 2013 compared with sixty in 2012. Those that breech the agreed threshold level are reported to the LIN.

Where there are concerns, these are followed up and an action plan is developed. If the concern is not resolved the Accountable Officer will, either solely or in partnership with other agencies, investigate or prepare a file for referral to the appropriate regulatory body.

g. Take appropriate action if there are well-founded concerns

Action has been taken where appropriate with individual practitioners. Any local or regional learning from these has been identified and shared.

h. Establish arrangements for sharing information

Each of the organisations' Accountable Officers, as well as other Responsible Bodies (including regulatory bodies), meets as part of the NI LIN. The group meets quarterly to share information about potential CD concerns and potential or actual systems failures. HSCB can provide extensive monitoring information on the use of controlled drugs in primary care and this information has been shared within the LIN to help inform risk management arrangements.

Northern Ireland Primary Care Controlled Drug Usage Reports 2013

Chart 1

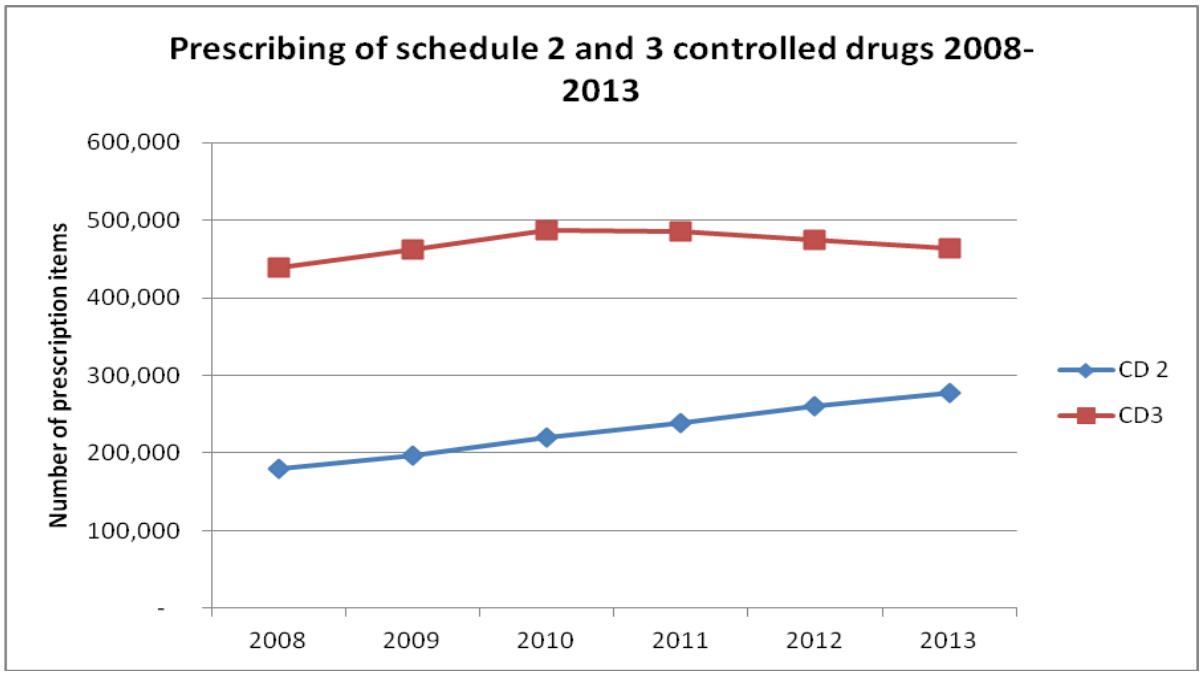


Chart 2

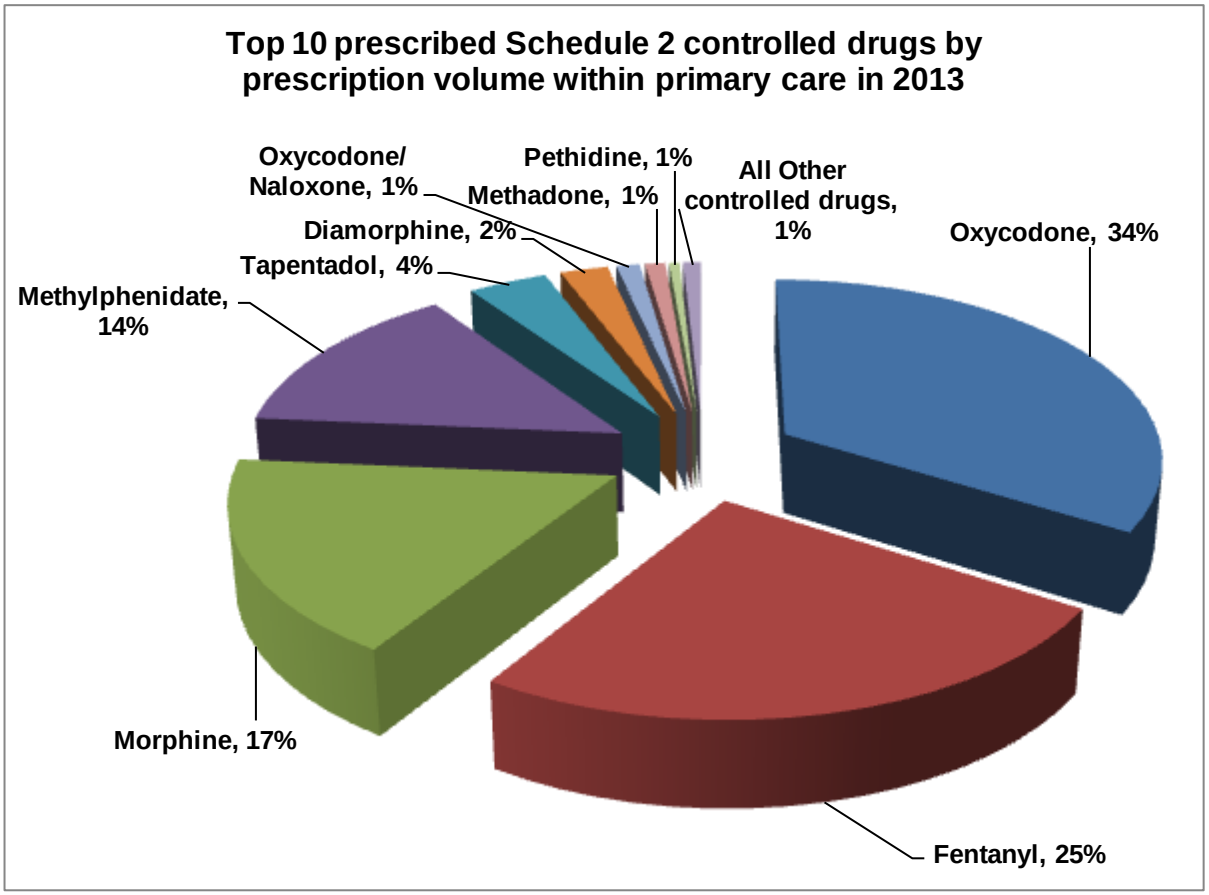
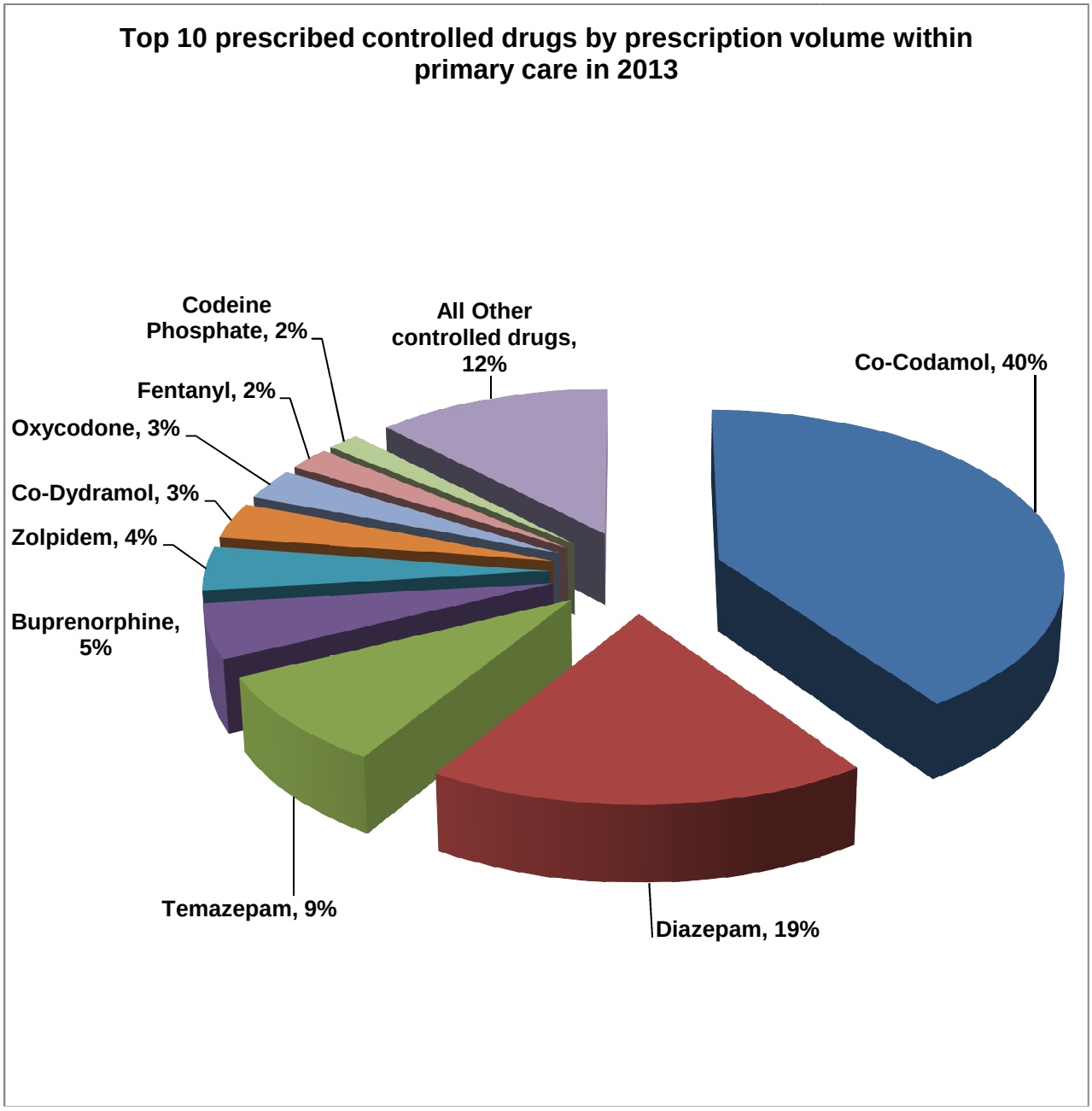
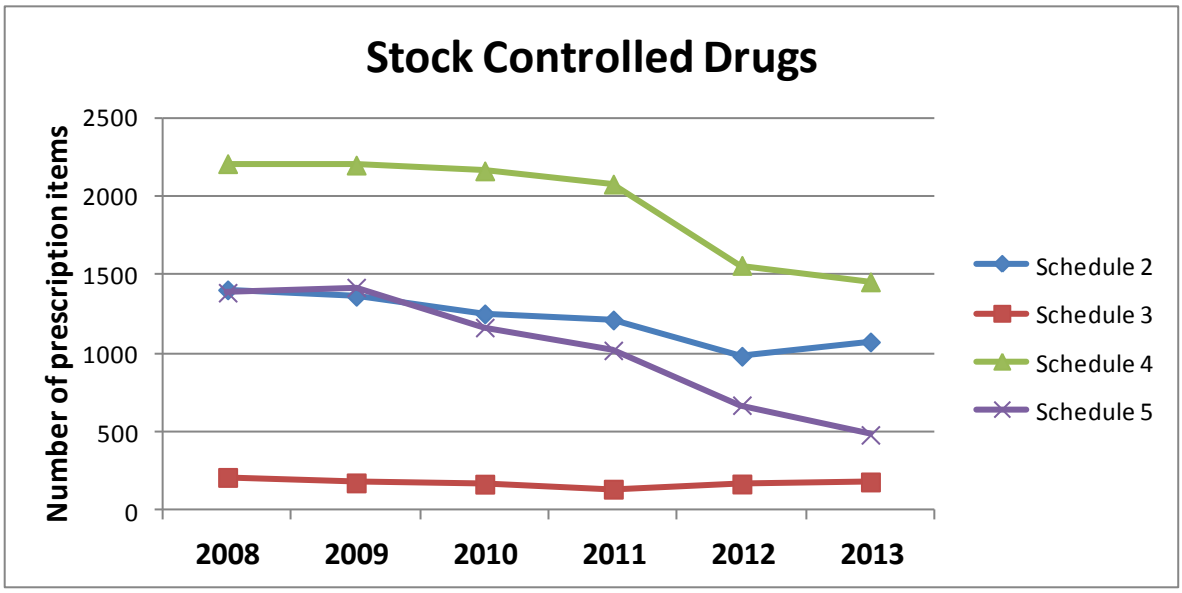


Chart 3


Top 10 prescribed controlled drugs by prescription volume within primary care in 2013
Codeine Phosphate, 2%
All Other controlled drugs, 12%
Co-Codamol, 40%
Fentanyl, 2%
Oxycodone, 3%
Co-Dydramol, 3%
Zolpidem, 4%
Buprenorphine, 5%
Temazepam, 9%
Diazepam, 19%

Controlled Drugs ordered by and supplied to General Practitioners (GPs)

Chart 4



This chart depicts the trends in stock ordering of controlled drugs over the past 6 years. The overall trend is downwards which reflects the work that the HCSB has done with practices, through training, visits and newsletters, to encourage a more rationalised approach to the CDs that GPs carry as stock.

Chart 5

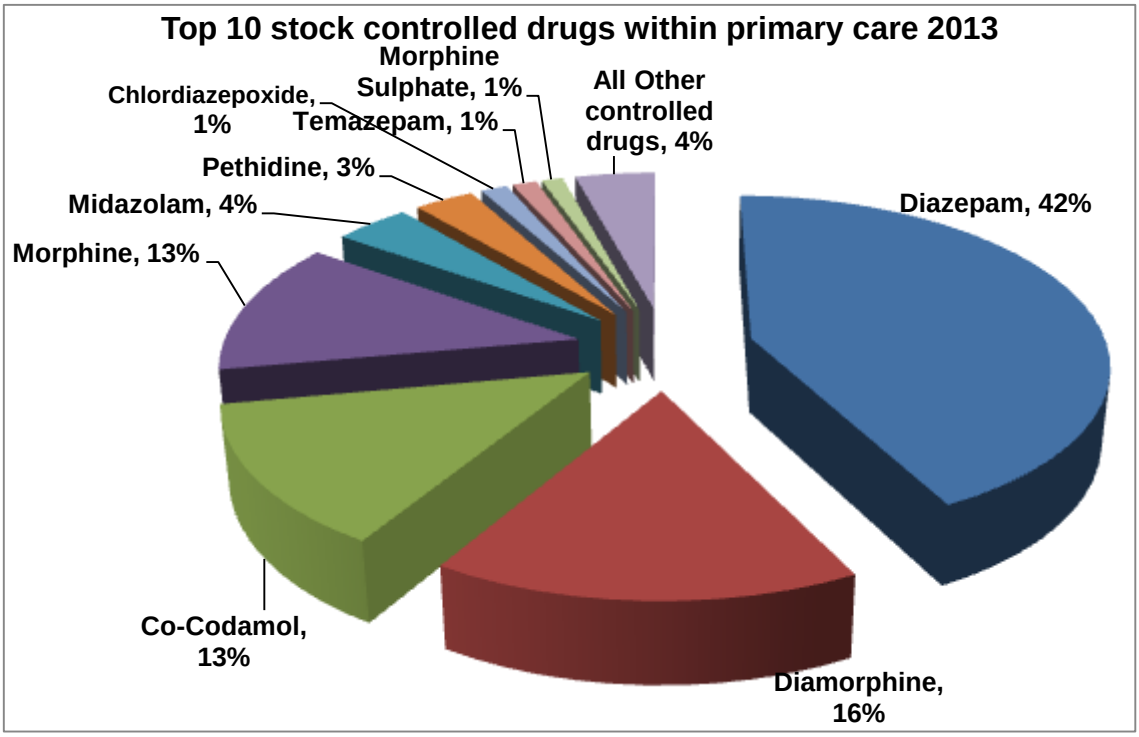
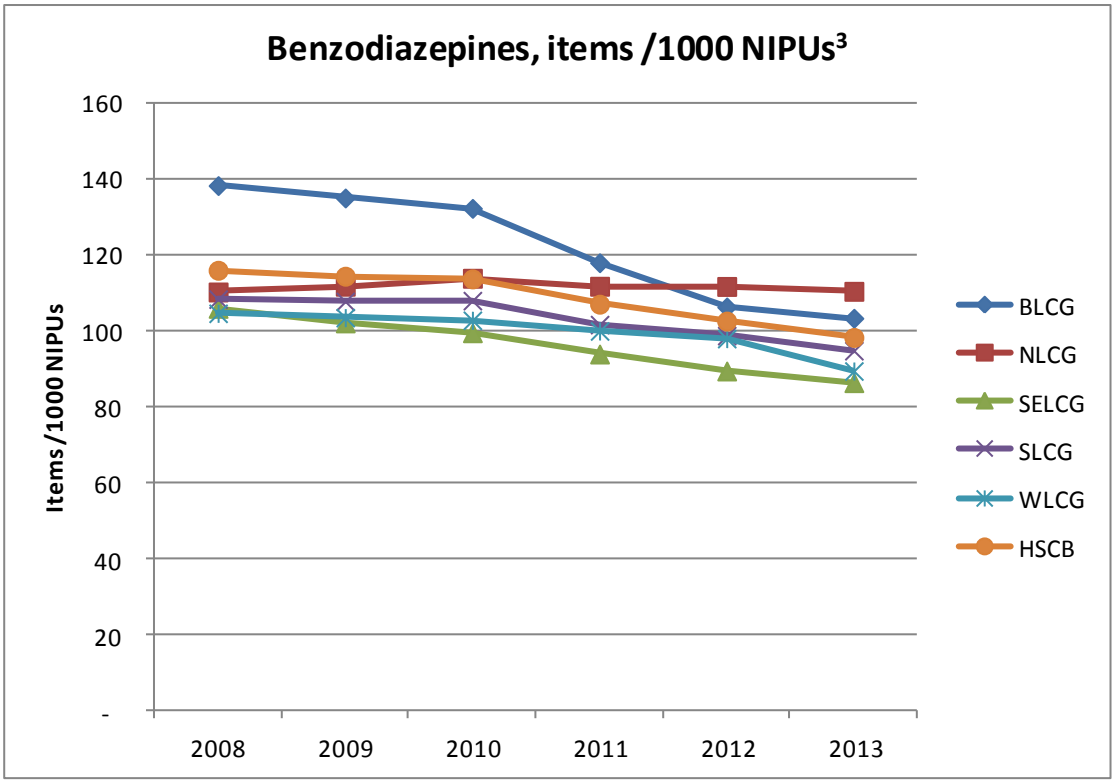


Chart 6



This chart depicts the overall prescribing volume of benzodiazepines in terms of NIPUs[3] for each of the five Local Commissioning Groups (LCGs), the Belfast; Northern; South Eastern; Southern and Western Local Commissioning Groups. LCGs are part of the HSCB and are co-terminus with their respective Health and Social Care Trust area. They work alongside other HSCB staff to commission services for the delivery of health and social care of their local population.

It is reassuring to see that the number of items / 1000 NIPUs continues to fall and reflects the work being done at HSCB and practice level to reduce prescribing of these drugs.

3. Northern Ireland Prescribing Units (NIPUs) are used to standardise for difference between practice in order to make valid comparisons with local and national average.NIPUs standardise for differences between practices in terms of patient list size, age/sex structure and additional needs.

Health and Social Care Trusts

There are 6 Health and Social Care (HSC) Trusts in Northern Ireland. Five of these are acute and community HSC Trusts and the sixth is the Northern Ireland Ambulance Service.

2. HSC Trusts (acute and community)

The five HSC (acute and community) Trusts in Northern Ireland are:

- Belfast HSC Trust
- Northern HSC Trust
- Southern HSC Trust
- South- Eastern HSC Trust
- Western HSC Trust

The most significant event in 2013-2014 was the controlled drugs review within the acute hospital sites by the Regulation and Quality Improvement Authority (RQIA). The purpose of the review was two-fold:

- To assess that systems and processes in place within Trusts for the safe and effective management of controlled drugs were robust and working effectively.

- To assess the effectiveness of communication and partnership working between relevant bodies within the Local Intelligence Network (LIN)

The review found that:

- All trusts had appointed appropriate Accountable Officers who had been provided with all necessary training.

- Robust processes were in place for auditing and monitoring of controlled drug use, and incident reporting mechanisms were well developed.

- Training in the management and use of controlled drugs was provided for relevant staff.

- Comprehensive systems were in place in pharmacies and wards to assure the security of controlled drugs.

- Systems were also in place to ensure security of controlled drugs when they were being transported to hospitals that did not have an onsite pharmacy.

This review concluded that following the fourth Shipman Report, robust systems were now in place for the management and use of controlled drugs in hospitals in Northern Ireland.

The review also made a series of fifteen recommendations to improve further what is already a comprehensive system. The full report is available at: http://www.rqia.org.uk/cms_resources/Management_of_Controlled_Drugs_FinalReport_120613_ISBN.pdf

Each Trust has developed an action plan following the review to take forward the recommendations.

3. Northern Ireland Ambulance Service HSC Trust

Intravenous morphine for administration by Northern Ireland Ambulance Service (NIAS) paramedics was introduced at the end of March 2011. The procedures relating to the storage, use and associated documentation of controlled drugs by ambulance staff were developed by NIAS in conjunction with the Medicines Regulatory Group (MRG) of the Department and the UK Home Office. The use of morphine by ambulance crews has seen significant clinical benefit for patients although the required documentation trail has impacted on paramedic workload, particularly at the start and finish of shifts. However, the procedures put in place were designed in such a way that adherence to them would offer staff a significant degree of protection in the event of any adverse incident relating to controlled drugs.

A small number of controlled drugs incidents have been recorded during the current reporting period. All incidents were investigated locally and, where appropriate regionally supported, as necessary, by MRG and no further concerns have been identified.

The MRG continues to perform unannounced inspections of all NIAS sites where controlled drugs are stored. No other significant issues were identified during these inspections. Where genuine errors have occurred in the recording of controlled drug stocks the robust procedures in place have allowed these to be identified and a rapid resolution achieved.

The current policy and procedures for the management of medicines by NIAS continues to be reviewed and will incorporate learning from our experience to date.

4. Hospices (Independent Hospitals)

All (4) Adult hospices in Northern Ireland plus Marie Curie Community Nursing Services and the Northern Ireland Children Hospices have appointed Accountable Officers.

One of their responsibilities is to submit "Occurrence Reports" detailing significant incidents involving controlled drugs. These are submitted quarterly to the Chair of the Local Intelligence Network (LIN) at the Department. Occurrence Reports are discussed at the next LIN meeting when action and learning points are shared.

As Accountable Officers we have a duty to inspect and review practices within our units. All the areas have had a pharmacy inspection by the MRG inspector and by the Regulation & Quality Improvement Authority (RQIA) pharmacy inspectors. All issues identified during the inspection process have been addressed by the individual organisations. This programme of audits and review is supported by an annual declaration and self-assessment.

All SOP's have been further developed and reviewed – these include stock checks and procedures governing all stages of the process from ordering through to the destruction of out of date stock.

A rolling education programme has been delivered to all staff to ensure that they understand the current regulations with regards to controlled drug management.

5. Independent Hospitals (other than Hospices)

The Independent Hospitals are regulated by RQIA. Controlled drugs are inspected by MRG and a CD Compliance Visit Report is issued and acted upon following the inspection.

There are many similarities between the arrangements in the Independent Hospitals and those adopted within an HSC secondary care environment; complexities of the arrangements vary depending on the number of beds and scope of clinical activities. Some of the Independent Hospitals do not have inpatient beds and interventions are day procedure only which requires a small range and stock of drugs. Some of the Independent Hospitals have onsite pharmacy and some use the services of the local community pharmacists to obtain CDs.

One significant feature of the Independent Hospitals is that doctors, with a few exceptions, are predominantly self employed clinicians and not employees of the hospital. As clinical workload can vary with waiting list initiative work and deadlines, bank nursing staff may also be used which can create a unique set of pressures for the Accountable Officer in relation to ensuring adherence with the organisational SOPs.

The Independent Hospitals have benefitted from the expertise of the Trust Accountable Officers taking regard of Trust Policies and Procedures when developing and reviewing their own SOPs.

Nurses receive medicines management training and clinicians are required to adhere to hospital policies and procedures as part of their practising privileges.

Whilst there are differences of scale and complexity, the core responsibilities of the Accountable Officer remain the same and each Accountable Officer must ensure that their Independent Hospital is operating its CD activities safely and in accordance with legislation.

The LIN meetings have been well attended by the Accountable Officers from the Independent Hospitals. The meetings have provided networking opportunities and have enabled sharing of CD concerns between agencies to promote and disseminate learning. This has ensured timely awareness of concerns regarding clinical staff who may work across a number of sites, including HSC and private practice, facilitating robust patient protection measures.

6. The Department of Health, Social Services and Public Safety

a. Community Pharmacies

A declaration and self-assessment form is issued to all community pharmacies annually. The self-assessment covers all aspects of the management of controlled drugs including specific written SOPs, staff training, prescribing patterns, diversion, complaints, transport, labelling, date checking and audit checks. The declaration confirms that the pharmacist, to the best of their knowledge and belief, is complying with the legal requirements in relation to controlled drugs. The declaration and self-assessment is reviewed by MRG Inspectors during pharmacy inspection visits. A Memorandum of Understanding in place between the Department and HSCB allows the formal transfer of information

relating to controlled drugs between both organisations. Inspection software has been modified recently to facilitate communication with the HSCB Business Services Organisation in respect of receipt by the Department of enhanced controlled drug data for use during community pharmacy inspections. To date, a pilot of information exchange has been successful. A risk-based inspection process was introduced in April 2011 for the inspection of community pharmacies. In relation to controlled drugs, the inspection process covers: maintenance of the controlled drugs register, safe custody of controlled drugs, diversion of controlled drugs, SOPs for the management of controlled drugs, disposal of out of date and returned controlled drugs, stock audits and a review of the annual declaration and self-assessment form. Any action points are agreed and the completed inspection report is signed by the Inspector and the pharmacist and a copy forwarded to the pharmacist. Inspections are conducted within a (maximum) 36 month cycle and are prioritised following the risk-based inspection. A quarterly report is forwarded to the HSCB Accountable Officer detailing the pharmacies inspected, any controlled drug issues which have arisen and the actions taken to resolve these issues.

b. NIAS HSC Trust

The routine inspection of NIAS stations was introduced in 2011 to review the management of morphine held by the stations. The inspections are carried out by MRG officers who examine both the station records and the personal records of paramedics. These records are used to provide an audit trail for morphine within the station. In addition there is a detailed reconciliation of the stock held by the station. The inspection report is signed by the Station Officer and the Inspector and a copy forwarded to the Station Officer and the NIAS Accountable Officer. Any issues arising are resolved in conjunction with the Station Officer and the NIAS Accountable Officer. Inspections are carried out on a 24 month cycle and are prioritised following the risk-based inspection.

c. Trust Pharmacies

Medicines Regulatory Group (MRG) inspectors conduct a cycle of compliance visits to ensure that management of controlled drugs in the Trust pharmacies complies with legislation and good practice. The previous cycle of visits which occurred in 2011/2012 will be repeated during 2014. MRG continues to cooperate with the “Secured by Design”

expert Police Officer, referring Trust Pharmacy enquiries in respect of security arrangements when refurbishment of premises is undertaken.

d. Hospices

Again, a cycle of compliance visits by MRG inspectors takes place on a 36 month basis at these facilities. Routine inspections are not due again until 2015. Interim visits are made, when requested by Hospice staff, to witness the destruction of unwanted or date-expired Schedule 2 controlled drugs.

e. Contract Research Organisations

Compliance visits by MRG inspectors, in relation to Misuse of Drugs legislation and associated good practice for the management of controlled drugs, are conducted at two facilities conducting Phase I-II clinical trials. The next routine inspections in the cycle are due at the end of 2014/beginning 2015.

f. Authorised Witnesses

Misuse of Drugs legislation requires that date-expired or otherwise unwanted schedule 2 controlled drugs stock be destroyed only under the supervision and direction of a witness authorised by the Department. A programme for the training and authorisation of witnesses in Trusts and the larger community pharmacy chains continues to be managed by MRG. A refresher course for authorised witnesses was held during the reporting period.

7. The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) routinely monitors the management of controlled drugs in relevant registered facilities, through its regulatory activity. Concerns in relation to the management of controlled drugs are discussed with registered providers and when appropriate are referred to the Accountable Officer in the relevant Trust. This has occurred once in the past year.

In June 2013 RQIA published an independent review of the management of controlled drug use in Trust hospitals.

RQIA evidenced that:

- Robust processes were in place for auditing and monitoring of controlled drug use, and incident reporting mechanisms were well developed.

- Training in the management and use of controlled drugs was provided for relevant staff, though consideration should be given to the need to increase staff awareness in the potential for abuse of controlled drugs in hospital settings.

- Comprehensive systems were in place in both pharmacies and wards to assure the security of controlled drugs. Systems were also in place to ensure security of controlled drugs when they were being transported to hospitals that did not have an onsite pharmacy.

- Practice has improved as a result of the ability to share information regarding use and possible abuse of controlled drugs.

RQIA considers that following the Fourth Shipman report, The Regulation of Controlled Drugs in the Community, robust systems are now in place for the management and use of controlled drugs in hospitals in Northern Ireland.

The review makes recommendations to improve further what is already a comprehensive system and is available on the RQIA website www.rqia.org.uk

Appendix 1

Background to the introduction of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

As a result of the actions of Harold Shipman an Inquiry, chaired by Dame Janet Smith DBE, was established which published 6 reports between 2002 and 2005? In the Inquiry's Reports Dame Janet Smith considered the systems for the management and regulation of controlled drugs, together with the conduct of those who operated those systems.

The Inquiry identified some key strengths within the arrangements which already existed in Northern Ireland. These included an acknowledgement of the benefits of the centralised arrangements which were integrated within the Department of Health, Social Services and Public Safety ("the Department") providing expertise of a multi-disciplinary nature and integration and collaboration with other professional bodies and investigation/enforcement authorities.

The significant changes which have since been made in both governance and legislation surrounding the management and use of controlled drugs have sought to build on these existing governance arrangements.

Legislative changes made include:

- Introduction of Health Act in 2006
- Amendments to Misuse of Drugs Regulations (Northern Ireland) 2002
- Introduction of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (the Regulations)

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1 October 2009 and apply to all healthcare settings and individual practices where controlled drugs are used covering activities such as prescribing, administering, storage, transportation and disposal.

These arrangements were designed to:

- Improve systems for managing and identifying concerns about controlled drugs
- Provide comprehensive and co-ordinated arrangements for monitoring and inspecting
- Establish a mechanism to support collaboration and information sharing

Underpinning these improvements was the determination that they would not compromise clinical care and patients' access to this care.

Accountable Officers

The Regulations identified the organisations (Designated Bodies) which were required to nominate individuals, known as Accountable Officers, who would be responsible for the management and use of controlled drugs in their organisation. The Designated Bodies (DBs) prescribed by the legislation are as follows:

- the Board (HSCB)
- a HSC Trust
- Northern Ireland Ambulance Service (NIAS)
- an Independent Hospital.

Accountable Officer Website

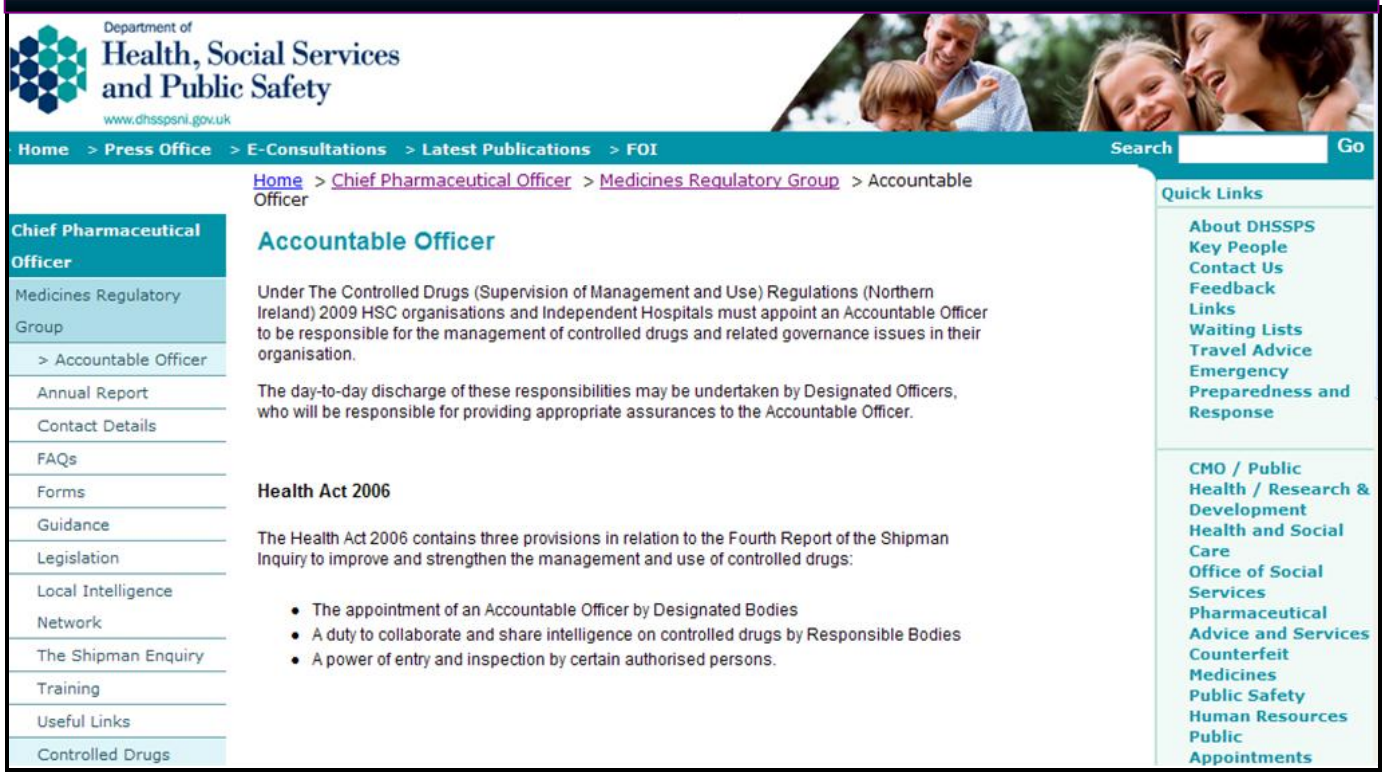
A section of the Pharmaceutical Advice and Services Departmental website has been dedicated to support the work of the Accountable Officers.

Within the contact details section, the name, address, telephone number and e-mail address is listed for each Accountable Officer and for the nominated representative for each Responsible Body.

A range of training materials have also been provided.

These can be found at: www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm

Where can I find information about Accountable Officers and the legislation?



The Local Intelligence Network

The concept of a Local Intelligence Network (LIN) was introduced to increase collaboration and promote information sharing between healthcare organisations, amongst others, about the use of controlled drugs and about individuals who give cause for concern.

The Northern Ireland Local Intelligence Network

There is a single LIN within Northern Ireland which meets quarterly.

The LIN is attended by Accountable Officers, representatives of the regulators, the Police, the Department and the Counter Fraud Unit of the Business Services Organisation (BSO), collectively known as Responsible Bodies.

Accountable Officers submit their quarterly Occurrence Report to the Chair of the LIN and concerns arising from these reports are shared within the confines of the confidential LIN meeting. Organisations can share well-founded concerns and, wherever possible, learn from these concerns. Designated Bodies are also encouraged to share good practice within this arena. The LIN is chaired by the Department. Terms of Reference can be accessed at the following link: www.dhsspsni.gov.uk/lin-terms-of-reference.pdf

Guidance

The Department developed a range of guidance documents to promote the safe and effective use of controlled drugs in healthcare organisations. These include guides to good practice which were developed for the secondary care sector in 2009 (updated in August 2012) and the primary care sector in 2010 (updated in May 2013). These provide background to the Regulations and take account of legislative changes and developments in professional practice and accountability which have arisen as a result of the Shipman Inquiry's Reports.

Guidance on 'Managing and Sharing Concerns':www.dhsspsni.gov.uk/managing-and-sharing-concerns.pdf and 'Safer Management of Controlled Drugs - A Guide to Strengthened Governance Arrangements in Northern Ireland were revised in September 2013.

All guidance documents can be found on the Accountable Officer website.

Appendix 2

Number of Meetings attended by Individual Bodies (out of a possible 5)

Designated Bodies	
Name	**Number of Meetings Attended**
Belfast HSC Trust	5
Northern HSC Trust	5
Southern HSC Trust	5
South Eastern HSC Trust	5
Regional HSC Board	5
Foyle Hospice	5
Kingsbridge Clinic	5
Marie Curie Hospice	5
Northern Ireland Hospice	5
Hillsborough Clinic	5
Fitzwilliam Clinic	4
Western HSC Trust	4
North West Independent Hospital	4
Northern Ireland Ambulance Service	3
St John's Hospice Newry	3
Northern Ireland Children's Hospice	3
Ulster Independent Clinic	3
Marie Curie Community Nursing Services*	2

Responsible Bodies	
Name	**Number of Meetings Attended**
Nursing & Midwifery Council	4
Department	4
Police Service of Northern Ireland	4
Regulation & Quality Improvement Authority	4
General Medical Council	3
Counter Fraud Unit of BSO	2
Health and Care Professions Council	2
Pharmaceutical Society of Northern Ireland	2

* Joined June 2013 - attendance only possible at 4 meetings