The Regulation and Quality Improvement Authority

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Independent Review of the Management of Controlled Drug Use in Trust Hospitals

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The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating and inspecting the quality and availability of health and social care (HSC) services in Northern Ireland. RQIA's reviews are designed to identify best practice, to highlight gaps or shortfalls in services requiring improvement and to protect the public interest. Our reports are submitted to the Minister for Health, Social Services and Public Safety, and are available on the RQIA website at www.rqia.org.uk.

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1. Executive Summary

This review considers the arrangements in place for the effectiveness of the management of controlled drug use in health and social care (HSC) trust hospitals. The Regulation and Quality Improvement Authority (RQIA) selected this topic for review, following a public consultation exercise.

Evidence was collected for the review using a range of methods including: completion of a self-assessment questionnaire by HSC trusts; validation meetings with trust senior staff, which included representatives from pharmacy, nursing and medicine; inspections of wards carried out by RQIA pharmacy staff; and a questionnaire provided to members of the Northern Ireland Local Intelligence Network.

The review found that all trusts had appointed appropriate Accountable Officers who had been provided with all necessary training. However, awareness of the role of the Accountable Officer among ward staff and junior medical staff in all trusts could be improved.

In all trusts 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. 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.

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

This review makes recommendations to improve further what is already a comprehensive system.

2. Introduction and Background

2.1 Controlled Drugs

Controlled drugs are drugs which are defined by the Misuse of Drugs Act 1971[1] as dangerous or otherwise harmful, and have the potential for abuse or misuse.

Controlled drugs have legitimate medical uses, and the legislation that governs their use is designed not to interfere with a patient receiving the most appropriate treatment. Doctors and dentists, as well as specified groups of non-medical prescribers are therefore allowed to prescribe and administer a wide range of controlled drugs.

Controlled drugs are an essential part of modern clinical care and can be used in a wide variety of clinical settings, for example:

- relief of acute pain after a heart attack or fracture;
- relief of chronic pain;
- palliative care in patients with terminal cancer;
- treatment of drug dependence;
- anaesthesia.

Controlled drugs also include benzodiazepines (tranquillisers and sleeping tablets), anabolic steroids and growth hormones.

Strict legal controls apply to controlled drugs to protect patients and the public and to prevent them being misused, obtained illegally or causing harm. These include controls which govern how these medicines may be:

- stored;
- produced;
- supplied;
- prescribed.

The Misuse of Drugs Regulations[2] divide controlled drugs into five schedules. The schedule into which a controlled drug is placed is based on its benefit when used in medicinal treatment, balanced against its harm if misused (see Appendix A).

[1] http://www.legislation.gov.uk/ukpga/1971/38/contents

[2] . The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 http://legislation.gov.uk.nisr/2002/1/contents/made

2.2 Controlled Drugs Legislation

The Misuse of Drugs Act 1971 and its regulations provide the statutory framework for the control and regulation of controlled drugs. The Act makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. Northern Ireland legislation is set out in The Misuse of Drugs Regulations (Northern Ireland) 2002, as amended.[3]

The Fourth Report of the Shipman inquiry[4] identified a number of serious shortcomings across the UK in the systems used for the management of controlled drugs and made recommendations to improve their management. The Northern Ireland response to the fourth report is set out in Improving Patient Safety- Building Public Confidence (November 2006).[5]

In response to recommendations made by the Shipman inquiry, the Health Act 2006[6] included measures to improve and strengthen the management and use of controlled drugs.

The Northern Ireland Regulations made under the Health Act are the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[7], 1 October 2009.

The new procedures contained in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 were designed to strengthen existing arrangements, by being integrated within the overall framework for improving quality in healthcare. They were intended to encourage good practice in the management of controlled drugs, as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients.

Safer Management of Controlled Drugs – A guide to good practice in secondary care was first published by DHSSPS in August 2009[8] and equivalent guidance for use in primary care was first published in August 2010.

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[3] A copy of this legislation can be found at http://legislation.gov.uk/nisr/2002/1/contents/made

[4] The 4th Report of the Shipman Inquiry – The Regulation of Controlled Drugs in the Community http://webarchive.nationalarchives.gov.uk/20090808154959/http://www.the-shipman-inquiry.org.uk/reports.asp

[5] www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf

[6] www.lawontheweb.co.uk/.../National_Health_Service_Act_2006

[7] The Controlled Drugs (Supervision of Management and Use)Regulations(Northern Ireland)2009http://www.opsi.gov.uk/sr/sr2009/nisr 20090225en1

[8] Safer Management of Controlled Drugs A guide to strengthened governance arrangements in Northern Ireland http://www.dhsspsni.gov.uk/safer-man-of-ctld-dgs-a-gd-to-str-gov-agts-ni.pdf

Safer Management of Controlled Drugs – A guide to strengthened governance arrangements in Northern Ireland was produced by DHSSPS in 2009 and revised in March 2011.

2.3 Systems Arising from Legislation

2.3.1 Designated Bodies and Responsible Bodies for Controlled Drug Management and Use

The legislation defined certain organisations as either Designated Bodies or Responsible Bodies.

In the legislation, Designated Bodies are defined as 'those that are directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health and social care services), or otherwise carrying on activities that involve or may involve the supply or administration of controlled drugs'.

Designated Bodies are accountable for the monitoring of all aspects of the use and management of controlled drugs by all health care professionals whom they employ; with whom they contract; or to whom they grant practising privileges.

Designated Bodies in Northern Ireland include:

- Health and Social Care Board (HSC Board);
- Health and Social Care Trusts;
- Northern Ireland Ambulance Service Health and Social Care Trust (NIAS);
- Independent Hospitals.

The legislation also identifies a number of organisations as Responsible Bodies, some of whom may not be directly involved in the management and use of controlled drugs. Responsible Bodies have a duty of cooperation and sharing of information in relation to the management and use of controlled drugs.

Responsible Bodies in Northern Ireland include:

- Designated bodies as above;
- DHSSPS;
- The Regulation and Quality Improvement Authority (RQIA);
- Police Service of Northern Ireland (PSNI);
- Counter Fraud Unit , Business Services Organisation (BSO);
- Regulatory bodies including:
  - Pharmaceutical Society of Northern Ireland;
  - General Medical Council;
  - General Dental Council;

- Nursing and Midwifery Council;
- The Health Professions Council.

2.3.2 Appointment of an Accountable Officer

Designated bodies are required to nominate and appoint an Accountable Officer to be responsible for the monitoring of the safe management and use of controlled drugs within the organisation, and to take appropriate action where necessary.

The regulations set out the responsibilities of the Accountable Officer. They should hold a senior post within the organisation, be a fit, proper and suitably experienced person who does not routinely supply, administer or dispose of controlled drugs as part of their duties.

2.3.3 Role of the Accountable Officer

- Ensure that safe systems are in place for the management and use of controlled drugs – this includes ensuring that Standard Operating Procedures (SOPs) are in place for all activities that involve controlled drugs.
- Monitor and audit the management and use of controlled drugs.
- Investigate concerns and incidents relating to controlled drugs.
- Ensure that relevant individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive adequate and up to date training.
- Collaborate with other responsible bodies to share information.

2.3.4 Sharing of Information

Following publication of The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, DHSSPS directed Accountable Officers to establish a Local Intelligence Network (LIN) for sharing information regarding the management and use of controlled drugs. Responsible Bodies and Designated Bodies participate in a single LIN for Northern Ireland.

The LIN was designed to enable timely and appropriate sharing of information. It enables agencies that have concerns about the activities of any healthcare professional or organisation, to liaise at an early stage with other local agencies that may be affected or have related information.

2.3.5 Routine Periodic Inspections

In partnership with other regulatory bodies, the Medicines Regulatory Group (MRG) of the DHSSPS is responsible for medicines control in Northern Ireland. This includes the monitoring of the production, import/export, possession, supply and administration of controlled drugs and other medicinal products, and ensures compliance with the legislative requirements of medicines control. Compliance is achieved through a system of unannounced

and pre-arranged inspections, follow-up visits, and investigation and enforcement activities.

RQIA is empowered under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003[9] to inspect establishments, including independent hospitals and clinics, nursing, residential and children's homes. Medicine inspections of regulated services are routinely undertaken by RQIA pharmacy inspectors. These examine arrangements for the management of medicines, and steps being taken to improve the standards in place for their management.

Inspections cover a range of matters including:

- record-keeping;
- storage and use of controlled drugs and;
- dealing with concerns and incidents relating to the management of medicines, including controlled drugs.

For those premises already inspected by MRG and RQIA, the Accountable Officer does not have a duty to undertake periodic inspections. However, the Accountable Officer may undertake additional inspections to give assurance that controlled drugs are being managed and used safely.

2.3.6 Standard Operating Procedures

Standard operating procedures are one of the practical measures that help to ensure good practice in the management of controlled drugs throughout the health and social care system. Legislation requires that Designated Bodies have adequate and up-to-date Standard Operating Procedures (SOPs) in place covering:

- who has access to controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise;
- record keeping.

2.3.7 Rationale for the Review

Safer Management of Controlled Drugs - A Guide to Good Practice in Secondary Care (Northern Ireland) sets out how changes in governance arising from the new legislation apply to the management and use of controlled drugs in secondary care settings. It sets out the principles and

[9] http://www.legislation.gov.uk/nisi/2003/431/contents/made

processes underpinning good practice in medicines management in relation to controlled drugs. This framework is designed to ensure that controlled drugs are prescribed and managed safely and securely, in accordance with legislation, professional standards and best practice guidance.

MRG conducts controlled drug inspections in all trust hospital pharmacies. However, neither MRG nor RQIA carry out inspections at ward level in secondary care hospitals.

It is important, therefore, to ascertain the level of compliance with DHSSPS guidance relating to the management of controlled drug use in secondary care. It is also important to assess the effectiveness of the partnership working arrangements that have been put in place to ensure the effective management of controlled drugs.

This review assesses the arrangements in place for the effectiveness of the management of controlled drug use in HSC trust hospitals. It also aims to provide assurance that these arrangements are robust and adhered to by all staff involved in the use of controlled drugs.

3. Terms of Reference

1. To assess the organisational governance arrangements in place in Health and Social Care Trusts for the management of controlled drugs in secondary care.

2. To assess the quality and effectiveness of Standard Operating Procedures in place in trusts in relation to the management and use of controlled drugs in secondary care.

3. To assess the effectiveness of these arrangements within Health and Social Care Trusts at clinical practice levels.

4. To assess the effectiveness of communication and partnership working between Responsible Bodies in ensuring the effective management and use of controlled drugs in relation to secondary care.

3.1 Exclusions

This review did not assess arrangements in place for the management and use of controlled drugs in:

- Primary care;
- Independent Hospitals;
- Hospices;
- Northern Ireland Ambulance Service Health and Social Care Trust (NIAS);
- Operating Theatres;
- Community Settings (including controlled drug use in patients' homes).

Independent hospitals and Hospices are regulated services and as such are subject to registration and inspection by RQIA. Medicines management, including the arrangements for controlled drugs, is assessed as part of RQIA's inspection programme.

The Northern Ireland Ambulance Service was reviewed by RQIA in 2010 (report published February 2011)[10]. Its management of controlled drugs was reported on as part of that review. No major issues in medicines management including the management of controlled drugs were identified by the review. Additionally as controlled drug licence holders, each NIAS station is subject to inspection by MRG.

As part of RQIA's Three Year Review Programme 2012-15[11], a review will be carried out in the acute sector in relation to theatre practice. This will include an assessment of the management of controlled drugs in operating theatres.

[10] http://www.rqia.org.uk/publications/rqia_reviews/rqia_reviews_2010.cfm

[11] http://www.rqia.org.uk/publications/corporate_documents.cfm

RQIA's review programme will also include a review of medicines management in primary care. This review will include the arrangements for management and use of controlled drugs in primary care and if appropriate, an assessment of the management of controlled drug use in the community.

This review, however, includes an assessment of the effectiveness of communication between hospital and community organisations as part of the Local Intelligence Network.

4. Methodology

Key stages of the review:

- HSC trusts were asked through self-assessment, to provide information regarding the processes in place for governance of controlled drug use. This included the role of the Accountable Officer, development of Standard Operating Procedures, monitoring of controlled drug use and arrangements for information sharing with the LIN.

- Self-assessments were also provided for completion by trust pharmacies and wards that used controlled drugs. A separate section was provided for those sites that did not have their own pharmacy.

- A short self-assessment was provided to members of the LIN asking them to comment on its effectiveness and suggestions for improvement.

- Inspections were carried out in a number of hospital wards in each trust to assess the effectiveness of governance arrangements and the appropriate use of Standard Operating Procedures. A patient journey approach was taken, charting the progress of a controlled drug from when it arrived in the pharmacy until the time it was administered to the patient.

- Validation meetings took place with members of trust senior teams, with representation from nursing, pharmacy and medicine.

5. Controlled Drug Use in Northern Ireland

5.1 Western Health and Social Care Trust (Western Trust)

Controlled drug use in the Western Trust occurs in the following sites:

- Altnagelvin Hospital;
- South West Acute Hospital;
- Tyrone County Hospital;
- Tyrone and Fermanagh Hospital;
- Waterside Hospital, Lakeview and Grangewood.

Pharmacies are sited at Altnagelvin, South West Acute and Tyrone County hospitals, which dispense controlled drugs to all other hospital sites. There are 57 pharmacists employed across these sites.

In 2011-12 the number of controlled drugs packs supplied in the Western Trust was:

- 12,600 packs Schedule 2 controlled drugs;
- 36,908 packs Schedules 3-5 controlled drugs.

5.2 Southern Health and Social Care Trust (Southern Trust)

Controlled drug use in the Southern Trust occurs in the following sites:

- Craigavon Area Hospital;
- Daisy Hill Hospital;
- Lurgan Hospital;
- St. Luke's Hospital;
- South Tyrone Hospital.

Trust pharmacies are sited at Craigavon Area and Daisy Hill hospital, which dispense controlled drugs to all the hospital sites within the trusts. There are 62 pharmacists and 49 pharmacy technicians employed throughout the trust.

In 2011-12 the number of controlled drugs packs supplied in the Southern Trust was:

- 13,567packs Schedule 2 controlled drugs;
- 37,149 packs Schedule 3-5 controlled drugs.

5.3 South Eastern Health and Social Care Trust (South Eastern Trust)

Controlled drug use in the South Eastern Trust occurs in the following sites:

- Ards Community Hospital;
- Bangor Community Hospital;

- Downe Hospital;
- Lagan Valley Hospital;
- Thompson House;
- Ulster Hospital.

There are 62 pharmacists and 39 pharmacy technicians employed throughout the trust.

In 2011-12 the number of controlled drugs packs supplied in the South Eastern Trust was:

- 12,493 packs Schedule 2 controlled drugs;
- 56,837 packs Schedule 3-5 controlled drugs.

5.4 Belfast Health and Social Care Trust (Belfast Trust)

Controlled drug use in the Belfast Trust occurs in the following sites:

- Royal Victoria Hospital;
- Belfast City Hospital;
- Royal Belfast Hospital for Sick Children;
- Royal Jubilee Maternity Services;
- Knockbracken;
- Mater Hospital;
- Muckamore Abbey Hospital;
- Musgrave Park Hospital.

There are 240 pharmacy staff employed throughout the trust (excluding the regional service).

In 2011-12 the number of controlled drugs packs supplied in the BHSCT was:

- 29,970 packs of Schedule 2 controlled drugs;
- Schedule 3-5 figures are not currently available.

5.5 Northern Health and Social Care Trust (Northern Trust)

Controlled drug use in the Northern Trust occurs in the following sites:

- Antrim Area Hospital;
- Causeway Hospital;
- Dalriada;
- Holywell Hospital;
- Inver;
- Mid Ulster Hospital;
- Robinson Hospital.

There are 225 pharmacy staff employed across the trust.
In 2011-12 the number of controlled drugs packs supplied in the Northern Trust was:

- 23,202 Schedule 2 controlled drugs;
- 42,048 Schedule 3-5 controlled drugs.

6. Findings

6.1 Term of Reference One

To assess the organisational governance arrangements in place in trusts for the management of controlled drugs in secondary care.

6.1.1 Appointment of Accountable Officers

The Accountable Officer (AO) is the person within the trust who has organisational responsibility for controlled drugs.

All trusts had appointed an experienced pharmacist into the post of AO. In all trusts the AO was the head or director of pharmacy and medicines management. In accordance with legislation the AO did not routinely supply, administer or dispose of controlled drugs. The AOs advised the review team that, in exceptional circumstances, they may be directly involved. However, these circumstances were rare and considered by the review team to be appropriate.

All AOs reported that they had received appropriate training, both on appointment and on an ongoing basis. All AOs reported that they had been provided with resources by the trusts to allow them to carry out their role. In three trusts (Northern, South Eastern and Western), funding was being sought for additional pharmacy support, at an appropriate level, to assist the AO in meeting their legislative responsibilities.

Recommendation 1

Trusts should review the arrangements to support Accountable Officers to ensure that they are provided with sufficient resources to carry out their role.

6.1.2 Governance Structure

Governance is the system by which an organisation is directed and controlled, at its most senior levels, in order to achieve its objectives and meet the necessary standards of accountability, probity and openness.

The Chief Executive of each trust has overall responsibility for the safe and secure handling of all medicines as part of the controls assurance medicines management framework. The AOs are accountable to the senior executive management team within their own organisation for implementing requirements arising from the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 which ensure that systems of control for the safe and secure handling of controlled drugs are in place.

Trusts provided evidence of how the AO fits into the overall trust governance structure and evidence that clearly defined reporting mechanisms were in

place. In all trusts the AO reports directly to a member of the senior executive management team, either the Director of Acute services, Director of Cancer services or Medical Director. All AOs are members of committees responsible for supporting medicines governance. They all had a place on their trust's drug and therapeutics committee (or similar). This committee is accountable to the trust's senior management team and the Trust Board, usually via the Medical Director.

In all cases there was evidence of a good working relationship between the AO and the trust's Responsible Officer (RO). This ensured that information held by the AO, where necessary, would feed into the revalidation process for doctors.

Areas of good practice were noted in the Western Trust. The trust's Governance Committee is chaired by the trust Chairman, with membership including the Chief Executive and members of the Trust Board. Although not a legal requirement, the AO provides this committee with a trust specific annual report, alongside the annual report from the AOs in Northern Ireland. The trust also has a Medicines Governance Working Group and controlled drugs management is a standing agenda item, with the AO attending every three months.

The Governance Committee meetings are also attended by the Postgraduate Dean who has responsibility for junior doctor training. In this way, any controlled drug issues involving doctors in training can be readily addressed.

In the other four trusts there was no direct controlled drugs report provided by the AO to the Trust Board. The review team considered that a formal report to Trust Boards would emphasise the importance of controlled drugs governance which includes the role of the Accountable Officer.

Recommendation 2

Trusts should consider whether an annual controlled drugs report should be provided by the Accountable Officer to Trust Boards.

6.1.3 Staff Awareness of the Role of the Accountable Officer

All trusts have medicines management/controlled drugs policies in place. However, not all policies reference the role of the AO. The trusts provided evidence that when controlled drugs legislation was implemented, information regarding the role of the AO was disseminated within senior management and within human resources directorates. There was also good evidence of awareness of the role of the AO among pharmacy staff.

Evidence was provided of controlled drugs training programmes for nursing staff and junior medical staff. This training had information on the role of the AO, though there was some doubt as to its effectiveness.

During ward inspections, staff knowledge of the AO was assessed. It was evident that staff at this level were not aware of the name or the role of the AO within the organisation, or their responsibilities in regards to controlled drugs.

Knowledge of the role of the AO was considered to be particularly important in the case where a member of staff did not feel comfortable reporting an issue through line management structures, due to the nature of an incident involving controlled drugs or the personnel involved. In these circumstances reporting could be direct to the AO. Effective staff training and communication should continue to emphasise the importance of the role of the AO.

Recommendation 3

Trusts should ensure that relevant staff at all levels in the organisation are aware of the role of the Accountable Officer.

6.1.4 Investigation of Incidents and Concerns

All trusts have robust incident reporting mechanisms in place. All incidents are recorded on the trust risk management system DATIX. There are arrangements in place to ensure that incidents involving controlled drugs are reported to the AO.

The AO also receives information from any complaints regarding controlled drugs. In most trusts, the AO is contacted by the senior case managers in human resources if a case involves medicines.

Other staff members such as directors, assistant directors, ward managers, pharmacists or medical staff may contact the AO where they have a concern. Ward inspections provided further evidence that incident reporting mechanisms were understood by ward staff. However, staff were not always aware that if the incident involved controlled drugs that the AO should receive this information.

Trusts were asked to outline their procedure for the escalation of an immediate concern involving controlled drugs. There was evidence that robust processes involving the AO were in place in each trust. There were also appropriate processes in place for the involvement of other bodies such as DHSSPS and the Police Service of Northern Ireland (PSNI), where required. Incidents are also shared with the LIN for information and to facilitate sharing of any learning. Incident reports form part of each trust's quarterly LIN occurrence report.

During validation meetings with staff, all trusts provided examples of incidents involving controlled drugs. The review team considered that these had been dealt with appropriately.

Good practice was outlined in the Southern Trust where near misses are also reported and recorded. These near misses are assessed by a governance

pharmacist in terms of what could have happened and its potential impact. Preventive measures are then put in place.

In all cases, in line with legislation, the AO keeps a record of all incidents and actions taken.

A large percentage of incidents involve Schedule 3, 4 and 5 controlled drugs. However, a large proportion of monitoring of controlled drug use focuses on Schedule 2 drugs, as when they are abused, they are potentially more harmful than drugs in other schedules.

Pharmacists can add additional controls on any controlled drug above what is required in legislation. They may ask wards to place certain Schedule 3, 4 or 5 drugs in a controlled drug cabinet. Also, they may monitor more closely usage of certain Schedule 3, 4 and 5 drugs. An area of good practice in the majority of trusts is the development of drugs of potential abuse reports, which include all schedules of controlled drugs. These are routinely sent to all ward sisters and ward pharmacists.

However, all trusts indicated that more work was required in the monitoring of Schedule 3, 4 and 5 controlled drugs as a number of incidents involved drugs contained in these schedules.

Discussion took place with trust senior management teams around staff awareness of controlled drugs incidents and what should be reported. The review team was advised of some reluctance to report a colleague even though it may be in an individual's best interests. It was also clear that nursing staff were better at reporting concerns than medical staff. It was not clear that staff were aware of the scale of the potential for misuse of controlled drugs, or what they should be looking for in relation to indications of controlled drug misuse.

To address this issue, the Southern and Western Trusts had organised controlled drugs awareness sessions which were provided by the police service or fraud prevention/pharmacy staff. These sessions explored the potential for misuse of controlled drugs within hospital settings. They also included information on indicators of drug abuse and what to look for within the hospital setting.

Recommendation 4

All trusts should continue to develop their monitoring processes for Schedule 2, 3, 4 and 5 drugs.

Recommendation 5

Trusts should ensure that all relevant staff have an awareness of the potential for controlled drug abuse in the hospital setting and also indicators of abuse.

6.1.5 Monitoring and Auditing of Controlled Drug Use

All trusts have systems in place for the monitoring and auditing of controlled drugs at pharmacy and ward level. Where appropriate, each ward has a list specifying which controlled drugs should be held as stock, and this list is regularly reviewed.

Regular medicines reconciliation checks should be carried out to ensure that nursing staff know when to order new stock and rotate stock so that it does not become out-of-date.

Quarterly pharmacy audits of wards are part of trust controls assurance standards for medicines management. The purpose of ward pharmacy audits is to ensure that:

- all controlled drugs are accounted for;
- usage appears to be appropriate;
- staff are adhering to policy and procedure in relation to supply, storage and record keeping.

In the Western Trust, discharge prescriptions are checked by a pharmacist, and any concerns relating to controlled drugs raised with the AO. Clinical pharmacists review patient kardexes at ward level, and ward pharmacists carry out quarterly medicines management checks.

All concerns relating to the administration of controlled drugs are raised with ward managers and highlighted to the AO. Monthly drugs of potential abuse reports are reviewed quarterly by pharmacists with ward managers and concerns are forwarded to the AO. Regular pharmacy and ward stock checks are carried out and an annual controlled drug audit is carried out in its maternity services. Omitted doses of medicines are audited by nursing staff as part of National Patient Safety Association (NPSA) missed dose recommendations.

In the South Eastern Trust, all discharge prescriptions are checked by a pharmacist, and patient kardexes are regularly reviewed during inpatient stays. Drugs of potential abuse reports are reviewed on a regular basis. All areas using controlled drugs undergo quarterly audits of controlled drugs, conducted by ward pharmacists, with the results forwarded to the AO.

Audit findings are forwarded to clinical managers for discussion at ward managers' meetings where action plans are drawn up to address deficiencies in practice. Results of three monthly controlled drugs checks are also discussed at the controls assurance medicines management subgroup.

Rolling programmes of controlled drug checks are carried out in pharmacies and in wards where there are a minimum of twice daily stock checks.

In the Belfast Trust discharge prescriptions are checked by a pharmacist, and patient kardexes are regularly reviewed during inpatient stays, where there are clinical pharmacists. There are quarterly controlled drug checks carried out in pharmacies, and quarterly audits of controlled drugs are conducted by ward pharmacists, and the results for all sites forwarded to the AO.

In the Northern Trust routine stock checks are carried out in pharmacies and quarterly checks are carried out in wards. Twice daily stock checks are carried out by ward staff. There is a rolling audit programme which includes omitted and delayed dose audits as part of National Patient Safety Agency (NPSA) recommendations.

In the Southern Trust there are quarterly controlled drug audits carried out by pharmacists. Monthly drugs of potential abuse reports are produced and reviewed by pharmacists and ward managers. Clinical checks of prescriptions and medicine kardexes are carried out by dispensary and ward pharmacists.

Ward inspections confirmed that a regular programme of controlled drug audits is conducted by pharmacy staff. Where possible, audits are completed by a pharmacist who is not the designated ward pharmacist. Ward staff are given feedback on audit outcomes and, where necessary, action plans are drawn up.

Pharmacy staff reported that completing the necessary audit programme was a challenge. However, inspection of ward records provided evidence that ward controlled drug records and stocks are kept under regular scrutiny.

Wards have a twice daily handover of the responsibility for controlled drugs held on the ward. This involves the handover of the ward controlled drug key and is usually done following the twice daily stock checks performed at each staff handover. These handovers and stock checks should be signed off by an appropriate member of staff from each shift. Ward inspections noted that these handovers were not always being signed off by members of both shifts. Trusts should ensure that handovers should be conducted in line with Standard Operating Procedures.

An area of good practice was noted in parts of the Southern Trust, where nursing staff are periodically observed by a nursing sister when recording and administering controlled drugs. This is another measure of assurance and compliance with SOPs. All trusts should consider implementing this in the future.

Recommendation 6

Trusts should ensure that ward handovers for controlled drugs are conducted in line with Standard Operating Procedures.

Recommendation 7

Trusts should consider carrying out observation audits of controlled drug management.

6.1.6 Staff Training

Accountable Officers have a responsibility to ensure that relevant individuals involved in the management and use of controlled drugs receive appropriate training.

All trusts have systems in place for training of pharmacy, nursing and medical staff. Formal induction programmes are in place for pharmacy and nursing staff. Medicines management, specifically management of controlled drugs, forms part of staff induction. All pharmacy and ward staff receive training on standard operating procedures.

Ward inspections provided evidence of staff training for nursing staff which is maintained as part of their continuing professional development.
This included:

- awareness of policies (signature sheet held on wards);
- medicines study days;
- staff induction to ward procedures;
- regular staff meetings where learning from incidents is shared;
- SOPs training (staff signature sheet held on wards);
- informal training by ward pharmacists;
- email safety alerts.

All nursing staff have mandatory medicines management training every three years, which has a controlled drugs component. All trusts have in place or are rolling out a programme of nurse competency audits. These cover six competencies in relation to controlled drugs:

- ordering of controlled drugs;
- receipt of controlled drugs;
- administration of controlled drugs;
- return of controlled drugs to pharmacies;
- disposal of controlled drugs at ward level;
- prescribing of controlled drugs (only applies to qualified nurse prescribers with a certificate of competence approved by the AO).

In all trusts there are mentoring and preceptorship programmes for nurses.

Training in medicines management forms part of junior doctor induction.
It was not clear that the training contained sufficient detail in the management, awareness and use of all schedules of controlled drugs. It was also unclear

whether robust ongoing training in controlled drug management and use was being provided for all doctors.

Examples of good practice were seen in the Belfast Trust where the lead controlled drugs pharmacist has developed a workshop for assistant service managers/ward sisters/charge nurses and clinical pharmacists.
The workshop will be rolled out across all Belfast Trust sites.

In the South Eastern Trust, the controls assurance medicines management subgroup has prepared and issued an anonymised questionnaire, to identify any additional nursing training needs.

Where a ward has a designated pharmacist or a named pharmacist, processes were more robust and good practice in relation to controlled drugs appeared to be more ingrained. In these cases more informal training and immediate advice is provided which meets the individual needs of the ward in terms of controlled drugs management. A lunch and learn session has been organised to raise awareness of areas identified by the questionnaire.

Recommendation 8

Trusts should assure themselves that appropriate training is provided for medical staff in the use and management of all schedules of controlled drugs.

Recommendation 9

Trusts should work towards providing appropriate pharmacy resource into all wards that use controlled drugs.

6.1.7 Non-Medical Prescribers

Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002[12] introduced on 10 May 2012 allow a nurse independent prescriber and a pharmacist independent prescriber to prescribe controlled drugs.

The amendments provide that pharmacist independent prescribers, as defined in the amendment, and nurse independent prescribers, may prescribe (with specified restrictions), any controlled drug in Schedule 2, 3, 4 and 5 of the 2002 Regulations, as amended.

Non-medical prescribing must take place within a system of standards, guidance and monitoring. It must take place within a robust governance system that includes the role of the Accountable Officer.

[12] http://www.dhsspsni.gov.uk/circular_the_misuse_of_drugs__amendment__regulations__northern_ireland__2012.pdf

In the Belfast Trust, the controlled drug policy has not yet been updated to reflect non-medical prescribers, and the intention is to include them in the general monitoring process. A central register of all non-medical prescribers will be developed.

The South Eastern Trust has developed a policy for non-medical prescribers who will be required to be on a trust register and include controlled drugs on their parameters of prescribing if they are to be considered competent to prescribe.

Pharmacist independent prescribers must complete the Northern Ireland Centre for Pharmacy Learning and Development (NICPLD) distance learning package for controlled drugs.

A non-medical prescribers' subgroup has been set up to consider how pharmacy and nursing non-medical prescribers will be audited.
Primary care prescriptions issued by non-medical prescribers who prescribe controlled drugs are received regularly from the Health and Social Care Board and checked against the prescriber's agreed parameters of prescribing.

In the Southern Trust, the only non-medical prescribers who can prescribe controlled drugs are those involved in palliative care, emergency department and cardiac emergency nursing. All non-medical prescribers must provide the AO with evidence of having successfully completed a course on controlled drug prescribing. They must also provide a list of drugs that they are competent to prescribe, signed by their mentor. A register will also be held.

In the Western Trust, all new non-medical prescribers apply to the trust non-medical prescriber working group for inclusion on the trust register. Details of their parameters of prescribing are certified by their manager and lead clinician. The AO meets with all applicants who must present evidence of completion of the Northern Ireland online controlled drug course.

At present, only non-medical prescribers who work in accident and emergency or palliative care can prescribe controlled drugs. Further governance arrangements are being put in place to support future roll out in line with the legislation.

In the Northern Trust at the time of the review there was no approved policy involving controlled drug prescribing for non-medical prescribers, and so they are not authorised to prescribe.

All trusts are at different stages in their development of non-medical prescribing procedures, with some at an early stage of development.

Recommendation 10

Trusts should continue to develop their policies for non-medical prescribing of controlled drugs, which should include processes for monitoring and audit.

6.1.8 Conclusions

All trusts had appointed appropriate people to fulfil the role of AO. AOs considered that they had received sufficient training, both on appointment and on an ongoing basis.

In three trusts the AOs reported that they would need extra staff resource to continue to meet their statutory responsibilities.

All trusts provided clear governance structures for AOs, and there was evidence in all trusts of a good working relationship between AOs and ROs. Consideration should be given to providing a controlled drug report direct to trust boards.

Senior staff in trusts were aware of the identity of the AO and their roles, but it was not clear that ward staff had the same level of awareness.

All trusts had robust systems in place for dealing with incidents. It was clear that all necessary information regarding controlled drugs was being passed to the AO. A large percentage of incidents involved Schedule 3, 4 and 5 controlled drugs. Trusts should continue to develop their monitoring processes in this area.

Staff awareness of the potential for controlled drug abuse in hospital settings should also be developed further.

All trusts had comprehensive systems in place for monitoring and auditing of controlled drug use, both in pharmacies and wards. Ward handovers for controlled drugs should be conducted in line with Standard Operating Procedures.

All trusts have systems in place for training staff involved in the ordering and administration of controlled drugs. It was noted that as a result of informal training and immediate advice, systems were more robust in those wards that had direct pharmacy input. Trusts should aim to provide appropriate pharmacy input into all wards that use controlled drugs.

Trusts are at different stages of development of policy and procedure with respect to non-medical prescribers and they should continue to develop processes in this area.

6.2 Term of Reference Two

To assess the quality and effectiveness of Standard Operating Procedures in place in trusts in relation to the management and use of controlled drugs in secondary care.

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 set out that Accountable Officers must ensure that their organisations have adequate and up-to-date Standard Operating Procedures (SOPs), in relation to the management and use of controlled drugs.

A SOP is a working document. It details the current agreed working practice applicable to the management of controlled drugs in an individual setting. SOPs are needed for every stage of a controlled drug's journey, from procurement, safe storage, supply and administration, to destruction. They should be accessible to staff at all times.

SOPs were submitted as part of the information requested at the beginning of the review. Awareness and use of SOPs was assessed during visits to wards and pharmacies.

All trusts had pharmacy SOPs in place and all authorised personnel had been trained in their use. Compliance was demonstrated by means of a signature sheet.

All trusts have SOPs in place for the management of controlled drugs. All trusts have SOPs at pharmacy level, and all trusts with the exception of the Northern Trust have SOPs at ward level. The Northern Trust has a controlled drug section in its nursing medicines management policy, and is in the process of developing SOPs for wards that use controlled drugs.

Ward inspections confirmed that SOPs were in place both in hard copy and also on trust intranets.

Each trust pharmacy is inspected on a two yearly cycle, by the Medicines Regulatory Group of DHSSPS. Trust wards and facilities are audited against their SOPs by trust pharmacists who visit each area once every three months and complete a standard controlled drug audit proforma with the ward manager.

All SOPs are reviewed every two years, or sooner if legislation or practice changes, or if an incident report has indicated that a change to procedure is necessary. The review normally takes into account changes in legislation, practice and learning from incidents and audits.

In four trusts, ward SOPs had been developed by pharmacy staff and then disseminated to the areas where controlled drugs were being used.

The Western and Belfast Trusts reported that initially SOPs had been developed by a multidisciplinary group, chaired by the principal pharmacist. In a number of instances the review of ward SOPs is being carried out by pharmacy staff and not on a multidisciplinary basis.

It is important that development and review of SOPs should be multidisciplinary, involving both nursing and medical staff where appropriate. Multidisciplinary input ensures that procedures are workable at the level at which they are used, and are more likely to be adhered to.

Recommendation 11

Trusts should ensure multidisciplinary input when developing and reviewing Standard Operating Procedures.

6.3 Term of Reference Three

To assess the effectiveness of these arrangements within trusts at clinical practice levels.

Two specific procedures were considered by the review team:

- destruction of controlled drugs;
- arrangements for patients own controlled drugs.

6.3.1 Destruction of Controlled Drugs

Guidance on destruction of controlled drugs has been provided to pharmacies by the Medicines Regulatory Group.

All trusts had SOPs in place for dealing with the destruction of controlled drugs.

As set out in legislation, all trusts had in place witnesses, authorised and trained by MRG, for the destruction/disposal of controlled drugs in the trust pharmacy.

Ward staff identify drugs that need to be returned to the pharmacy.
A pharmacist, in conjunction with a competent registered nurse, makes a note of the return in the ward requisition book, and also ensures that it is signed and dated.

Expired controlled drugs from pharmacy stock are destroyed by a pharmacist in the presence of an Authorised Witness on a regular basis, with appropriate records kept of each item destroyed.

In all trusts the procedure at ward level is that only small amounts of controlled drugs may be destroyed. Larger quantities of controlled drugs are returned to the pharmacy along with the appropriate paperwork for their safe

disposal. Where hospitals have a formal agreement with Northern Ireland Water, partially used or broken ampoules may be disposed of at ward level by flushing the contents away. Destruction of a single tablet is usually through being crushed on a paper towel and placed in the burn bin. All such destructions are witnessed by a registered nurse and recorded in the ward control drug record book.

6.3.2 Arrangements for Patients Own Controlled Drugs

Often patients, on admission, will bring their own medicines with them and these may include controlled drugs. The methods of dealing with these drugs varied across trusts and within different hospitals and wards.

In many instances patients' own controlled drugs are sent home at an early stage with the family. In this case there is no assurance that the drugs are properly handled, and there is potential for abuse.

In other wards, patients' own controlled drugs are kept securely in the controlled drug cabinet, and a separate register is kept. Some trusts have issued a standardised red patients' own drug record book. These drugs are separated from ward stock within the controlled drug cabinet by being placed on a separate shelf, or in a sealed envelope that may have an additional tamper proof seal, and are clearly marked with the patient's name. These drugs then form part of the twice daily stock check until the patient is discharged. This process provides greater assurance that drugs are properly handled and are available for the patient on their discharge, if appropriate.

In discussion with trusts, it was considered that further local development of existing regional guidance on how to deal with patients' own controlled drugs would be helpful.

Recommendation 12

Trusts should consider further local development of existing regional guidance to provide assurance that patients' own controlled drugs are being dealt with appropriately.

6.3.3 Security of Controlled Drugs

(a) Storage of Controlled Drugs and Controlled Drugs Stationery

(i) Pharmacy

In all trusts, controlled drugs are stored securely within the pharmacy site in line with best practice and legislative requirements.

Access is carefully controlled and restricted to staff approved by pharmacy managers. Security systems are well established and robust.

Controlled drug stationery and controlled drug registers are stored securely.

Controlled drugs checks are carried out in pharmacies either daily, weekly or monthly, depending on the rate of usage of the particular controlled drug.

(ii) Wards

In all trust wards controlled drugs are held within secure cabinets in line with good practice and legislative requirements. Access to keys to the controlled drug cabinets is restricted to appropriate personnel and robust systems are in place for retention/ handover of keys.

(b) Requisitioning of Controlled Drugs

In the Belfast Trust, the senior nurse or midwife is responsible for the ordering of controlled drugs. The task may be delegated but responsibility remains with the senior member of staff on a ward.

On receipt at the pharmacy, the documents are checked to ensure that they have been correctly completed. An authorised signatory list should be available should it be necessary to validate the signature of the person requisitioning the controlled drug order. It was not clear if this list was available on all sites in the trust. The pharmacy requires trust photographic identification to be produced by the trust messenger at collection. It is good practice that where possible the same person does not requisition and collect a controlled drug.

As soon as possible after delivery/collection, the senior nurse/midwife should check the controlled drug against the original requisition, to ensure that the correct drug and quantity have been supplied. If there are any discrepancies, the person performing the check should immediately contact the pharmacy. A duplicate requisition is returned to the pharmacy. Receipt of the controlled drug should be recorded in the appropriate page of the ward controlled drug record book (CDRB).

In the Southern Trust, ordering of controlled drugs is restricted to a nurse/midwife deemed suitable by the ward manager. Agency staff cannot order controlled drugs.

The pharmacy retains an authorised signatory list and on receipt of the requisition at the pharmacy the signature is checked for authenticity. The trust also has a policy that the same person cannot both order and collect controlled drugs.

All staff must carry photographic identification when collecting controlled drugs.

On receipt of a controlled drug at ward level, the responsible nurse, in the presence of the messenger, enters the necessary information in the ward CDRB. This is signed by the receiving nurse and also the messenger.

In the South Eastern Trust, the ward sister in each case authorises a list of staff who can order controlled drugs. A list of authorised signatories is held at both ward and pharmacy level.

The pharmacy checks that the requisition has been signed and dated by the senior nurse who should be on the authorised signatories' sheet retained in the pharmacy. All staff that collect controlled drugs must have photographic identification and their signature and details are recorded in the ward CDRB.

On receipt of a controlled drug on a ward, the nurse/midwife who accepts the delivery must sign the controlled drug delivery record. As soon as possible after delivery the senior registered nurse, or midwife in charge should check the controlled drugs against the original requisition to ensure that the correct drug and quantity have been supplied. The check should be carried out in the presence of another member of staff to witness the checking process and protect against any potential allegations of missing drugs.

In the Northern Trust, only registered nurses/midwives with appropriate experience are permitted to order controlled drugs. Controlled drug requisitions must be written in designated Northern Trust requisition books, completed by the ward manage/nurse in charge. A list of signatures is retained in the pharmacy in order to check the validity of a requisition.

There is no list of personnel authorised to collect controlled drugs. For ward staff, identification badges must be checked before release of a controlled drug. The pharmacy department also retains a list of porters for who controlled drug collection and delivery forms part of their duties. A list of trust transport drivers is also retained for those orders coming from another hospital.

On some sites there is a policy that the same person that orders a controlled drug does not also collect it, however, it was noted that is not strictly adhered to at all locations.

In the Western Trust, only registered/nurses/midwives that have been assessed as competent are permitted to requisition controlled drugs. Each ward manager supplies to the pharmacy department signature lists of registered nurses who are able to order controlled drugs. The signature on the requisition must match that on the signature list before the controlled drug is supplied.

Ward staff tend to be known by pharmacy staff, however, if there is any doubt of identity, identification cards must be produced. The name of the person collecting the controlled drug is entered into the controlled drug register.

Two nurses verify the amount received, type and dose of drug and requisition number into the ward CDRB. They also record and sign for the total stock balance.

There is no policy within the trust to say that the same person cannot requisition and collect a controlled drug. However in all trusts almost all controlled drugs are delivered to wards as opposed to being collected by a member of staff.

In discussions with trust senior teams, one of the challenges facing any hospital is maintaining an accurate and up to date list of authorised signatories. The list is an important part of the security surrounding the collection of controlled drugs and so the list must be current. This is a matter that could be considered at a regional level.

Recommendation 13

Trusts should establish methods of maintaining accurate lists of authorised signatories for controlled drugs.

Standard Operating Procedures are in place in all trusts for the ordering from pharmacy, and collecting from pharmacy of controlled drugs by ward staff or other members of staff, such as porters. It is important that the same person who orders the controlled drug is not also the person who collects it from pharmacy.

In all cases identification should be checked before the drug is released.
It was not clear that in all cases the SOPs included arrangements to ensure that the same person did not both order and collect a controlled drug.
The process should also be subject to audit.

Recommendation 14

All trusts should assure themselves that robust processes are in place regarding ordering, collecting and receiving a controlled drug.

(c) Hospitals Without Onsite Pharmacy

A number of wards in hospitals which do not have an onsite pharmacy use controlled drugs. It is important that these hospitals and the pharmacy providing their supply of controlled drugs have robust SOPs in place, particularly in relation to transport and disposal/destruction.

In the Belfast Trust, controlled drugs are transported securely in line with legislative and good practice requirements.

In wards, when drugs are received they are immediately entered into the ward CDRB, checked and signed by two registered nurses. The requisition number

and pharmacy from which the drug was obtained are also recorded in the CDRB.

Only partially used or damaged Schedule 2 controlled drugs are destroyed at ward level. This is documented in the ward CDRB and witnessed by two registered nurses. All other controlled drugs are returned to pharmacy for destruction, using completed documentation in the controlled drug order book.

The Northern Trust has four sites using controlled drugs that do not have a pharmacy onsite and transport to these sites is carried out in line with legislative and best practice requirements. All controlled drugs are returned to pharmacy for destruction.

In the South Eastern Trust there are five sites using controlled drugs that do not have an onsite pharmacy. Transport to these sites is carried out in line with legislative and best practice requirements.

On delivery, the order is checked by two registered nurses, details recorded in the ward CDRB, and the new stock added to the existing balance.

Only small amounts of controlled drugs should be destroyed at ward level. All destruction must be documented in the controlled drug record book and witnessed by two registered nurses. Both persons should sign the controlled drug record book, stating the amount destroyed and the date of destruction.

In the Southern Trust, there are three sites using controlled drugs which do not have an onsite pharmacy and transport to these sites is carried out in line with legislative and good practice requirements.

On receipt on the ward the delivery is checked that the correct drug, quantity and strength have been supplied. The controlled drugs register is then completed and witnessed by a second member of staff.

All unused and out-of-date controlled drugs are returned.

In the Western Trust, there are four hospital sites using controlled drugs that do not have a pharmacy, and transport to these sites is carried out in line with legislative and best practice requirements.

On receipt of controlled drugs, which are transported in locked containers, two designated staff members check that the correct drug and quantity of drug has been supplied. An appropriate entry is made in the ward CDRB and signed by both staff members.

All unused or out-of-date controlled drugs are returned to the pharmacy for destruction.

All trusts have robust auditable processes in place for the transport and return of controlled drugs from those sites which do not have a pharmacy.

6.3.4 Conclusions

All trusts had or were in the process of finalising SOPs in both pharmacies and wards. Trusts should continue to ensure that SOPs are updated with input from all relevant disciplines.

All wards and pharmacies had robust procedures in place for destruction of controlled drugs. Consideration should be given to development of guidance in relation to management of patients' own controlled drugs.

All trusts had robust systems in place for security of controlled drugs and controlled drug stationery in pharmacies and wards.

Assurance should be sought that accurate lists of authorised signatories for controlled drugs are maintained and that the same person does not both order and collect a controlled drug.

Comprehensive systems are in place to assure the safety and security of controlled drugs when they are being transported to those hospitals which do not have a pharmacy.

6.4 Term of Reference Four

To assess the effectiveness of communication and partnership working between Responsible Bodies in ensuring the effective management and use of controlled drugs in relation to secondary care.

A short questionnaire was sent to all members of the Local Intelligence Network (LIN).

6.4.1 Local Intelligence Network

Controlled drugs legislation includes a legal duty of collaboration regarding the use of controlled drugs. A single LIN has been established in Northern Ireland.

The role of the LIN is to share information about incidents and concerns relating to use and possible abuse of controlled drugs, including potential or actual systems failures.

According to its original terms of reference the LIN in Northern Ireland will:

- agree local principles for sharing controlled drug intelligence between agencies;
- actively share intelligence regarding use and possible abuse of controlled drugs;
- agree guidance on operational matters;
- constitute incident panels as appropriate;

- collaborate with cross-border groups in relation to controlled drug issues and be represented at cross-border meetings;
- take regard of incidents and concerns and their outcomes to promote best practice with respect to monitoring processes/audits of controlled drug management, training provision and policy development.

Membership of the LIN in Northern Ireland includes, but is not limited to:

- HSC Board;
- HSC trusts;
- Northern Ireland Ambulance Service HSC Trust;
- Independent Hospitals;
- Counter Fraud Unit of BSO;
- DHSSPS;
- RQIA;
- Police Service of Northern Ireland;
- Pharmaceutical Society of Northern Ireland;
- Nursing and Midwifery Council;
- General Medical Council;
- General Dental Council;
- Health and Care Professions Council.

AOs submit a quarterly Occurrence Report sharing their concerns within the confines of the confidential LIN meeting. Organisations can learn details of individual concerns and, wherever possible, share in the learning which has arisen from these concerns. Designated Bodies are also encouraged to share good practice within this forum.

6.4.2 Questionnaire Responses

Operation of the LIN

The LIN is at present chaired by DHSSPS. Members of the LIN indicated that they were content with this arrangement. This was supported by trust senior teams during trust validation meetings.

Responses indicated that information sent out from chair/deputy chair is well organised and sent in a timely way. All members agreed that the chair and deputy-chair of the LIN have a professional approach, are expert in their field, focused on their roles and are supportive to AOs.

There is a high attendance rate at the LIN meetings.

AOs have met individually with the chair of the LIN, who has provided them with training and support for their AO responsibilities.

Small working groups have been beneficial in building up relationships and understanding of roles and legislation.

The AOs of Northern Ireland produce an annual report, which can be accessed on the DHSSPS website.

Sharing of Information

The LIN continues to develop robust and consistent arrangements for both receiving and sharing information. In line with the terms of reference for the LIN, there is active sharing of information regarding use and possible abuse of controlled drugs.

Members share information highlighted in occurrence reports. Learning from any incidents with updates relating to previous concerns is also shared with the members of the LIN. There may be occasions when individual AOs may contact each other outside the LIN to discuss a particular concern.

Each member of the LIN (two per meeting) takes turns in presenting information on their organisation and their specific role. This has been helpful for the members as it informs them of the knowledge and expertise of others and has been highly interactive and informative.

This forum, with the focus on controlled drugs, has given AOs a greater awareness of the importance of their role within the legislation. Sharing of information regarding cases of abuse/potential abuse of controlled drugs has allowed AOs to look at the appropriateness of their own systems and make changes where required.

As the LIN has developed, more robust links at higher strategic levels have developed to highlight and support the role of the LIN and the AO.
For example, relationships have developed with the Business Services Organisation (BSO) Department of Legal Services which members have found to be invaluable.

A challenge for the LIN is around confidentiality of information and whether the names of individuals involved in the abuse of controlled drugs be shared with the other members of the LIN. A policy should be developed by the LIN that balances public safety against the rights of an individual to confidentiality of personal information.

Recommendation 15

Each trust should confirm its policy for dealing with sharing of personal information where it is felt to be appropriate.

6.4.3 Conclusion

Responses from all members of the LIN agree that practice has improved as a result of sharing information regarding incidents, learning from incidents and discussion of best practice. The review team felt this was supported by validation meetings with senior trust staff.

The review team also considered that a major benefit of the LIN is that organisations are now enabled to raise concerns about the activities of any health care professional or organisation. These are then shared at the earliest stage with other agencies who may also be affected or who may have additional information.

7. Summary Conclusions

The aim of this review was to assess the arrangements in place for the management of controlled drug use in hospitals in Northern Ireland in relation to regulations put in place following the Fourth Report of the Shipman Inquiry, The Regulation of Controlled Drugs in the Community.

All trusts have appointed Accountable Officers and it is clear where they fit into overall trust governance processes. Consideration should be given to a formal controlled drug report being provided for each trust board.
All Accountable Officers have received necessary training.

In two cases the Accountable Officers considered that appointment of a designated officer was needed in order for them to fully discharge their responsibilities in relation to controlled drugs.

There was good awareness of the role of the Accountable Officer among senior trust staff and within pharmacy staff. However, awareness should be improved among ward staff and junior medical staff and this could be addressed through training.

Robust incident reporting mechanisms were in place, and trusts provided examples of incidents involving controlled drugs that had been identified and dealt with appropriately. In all trusts a large proportion of incidents involved Schedule 3, 4 and 5 drugs. All trusts were aware of the need for increased monitoring in these areas. Trusts should also consider the need for further awareness training for staff in the potential for abuse of controlled drugs.

All trusts had developed detailed standard operating procedures for management of controlled drugs in pharmacies. All trusts, with the exception of the Northern Trust, had developed detailed standard operating procedures for use in wards that use controlled drugs. The Northern Trust was in the process of developing its ward procedures.

All trusts had systems for monitoring and auditing of controlled drug use.

All trusts had developed medicines management training programmes for staff, which contained modules regarding use of controlled drugs. These sections should in future have more emphasis within the total programme of medicines management. It was clear that in those wards with a designated pharmacist, awareness and training in the area of controlled drug management were of a high standard.

Systems to assure the security of controlled drugs were robust at both pharmacy and ward level and there were also robust systems in place to assure the security of controlled drugs on transport to hospitals that did not have their own pharmacy.

Members of the LIN have reported and the review team agreed that 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 have now been put into place for the management and use of controlled drugs in hospitals in Northern Ireland.

8. Summary Recommendations

Recommendation 1
Trusts should review the arrangements to support Accountable Officers to ensure that they are provided with sufficient resources to carry out their role.

Recommendation 2
Trusts should consider whether an annual controlled drugs report should be provided by the Accountable Officers to Trust Boards.

Recommendation 3
Trusts should ensure that relevant staff at all levels in the organisation are aware of the role of the Accountable Officer.

Recommendation 4
All trusts should continue to develop their monitoring processes for schedule 3, 4 and 5 drugs.

Recommendation 5
Trusts should ensure that all relevant staff have an awareness of the potential for controlled drug abuse in the hospital setting and also of indicators of abuse.

Recommendation 6
Trusts should ensure that ward handovers for controlled drugs are conducted in line with Standard Operating Procedures.

Recommendation 7
Trusts should consider carrying out observation audits of controlled drug management.

Recommendation 8
Trusts should assure themselves that appropriate training is provided for medical staff in the use and management of all schedules of controlled drugs.

Recommendation 9
Trusts should work towards providing appropriate pharmacy resource into all wards that use controlled drugs.

Recommendation 10
Trusts should continue to develop their policies for non – medical prescribing of controlled drugs which should include processes for monitoring and audit.

Recommendation 11
Trusts should ensure multidisciplinary input when developing and reviewing Standard Operating Procedures.

Recommendation 12
Trusts should consider further local development of existing regional guidance to provide assurance that patients' own controlled drugs are being dealt with appropriately.

Recommendation 13
Trusts should establish methods of maintaining accurate lists of authorised signatories for controlled drugs.

Recommendation 14
All trusts should assure themselves that robust processes were in place regarding ordering, collecting and receiving a controlled drug.

Recommendation 15
Each trust should confirm its policy for dealing with sharing of personal information when it is felt to be appropriate.

Appendix A

Controlled Drugs Schedules

Schedule 1
These drugs have no recognised medicinal use and include cannabis, cocoa leaf, lysergic acid diethylamide (LSD) and mescaline. The production, possession and supply of these drugs are limited to research or other special purposes.

Schedule 2
Drugs include diamorphine (heroin), morphine, pethidine, amphetamines and cocaine. They are subject to safe custody requirements and must be stored in a locked receptacle, usually in an appropriate controlled drug cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug, or a person authorised by the person. A register must be kept for schedule 2 CDs which must comply with relevant regulations.

Schedule 3
The majority of Schedule 3 controlled drugs are exempt from safe custody requirements (including midazolam which was rescheduled on 1 January 2008 from Schedule 4) and may be stored with other medicines in the dispensary.

Some Schedule 3 drugs that do require safe custody are temazepam, buprenorphine flunitrazepam and diethylpropion.

Schedule 4
Relates to and includes drugs which are exempt from safe custody requirements, and the requirement to maintain a register. Examples are most of the benzodiazepines (except midazolam and temazepam), and most of the anabolic and androgenic steroids.

Schedule 5
Relates to and includes preparations of certain controlled drugs, which are exempt from full control, when present in medicinal products of low strengths as their risk of misuse is reduced.

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