Department of
Health, Social Services and Public Safety
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From: The Chief Pharmaceutical Officer
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[redacted]

Heads of Pharmacy and Medicines Management
Trust and Board

Our Ref: DH1/13/92475

Date: 8 April 2013

Dear Colleague

'USE AND CONTROL OF MEDICINES – Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services'

This communication is by way of notice of our intention **not** to publish a further edition of the above guidance. In the interim period since the publication of the last edition there has been a series of guidance issued in respect of legislation and best practice associated with the use and control of medicines. The latest edition of 'Use and Control of Medicines' is now out of date in some areas and should not be relied upon to give definitive direction to those employed in the Service. I am requesting, therefore, that you ensure that these updated guidance and regulations have been taken into account in your published Trust medicines policies.

We will be writing soon to advise you in respect of the development of a Northern Ireland medicines policy document which will reflect all the relevant publications to date. In the meantime it will be important for you to work together in order to promote a common medicines policy across all Trusts.

Yours sincerely

Dr Norman Morrow
Chief Pharmaceutical Officer

Royal Pharmaceutical Society of Great Britain

MAHI - STM - 089 - 3847

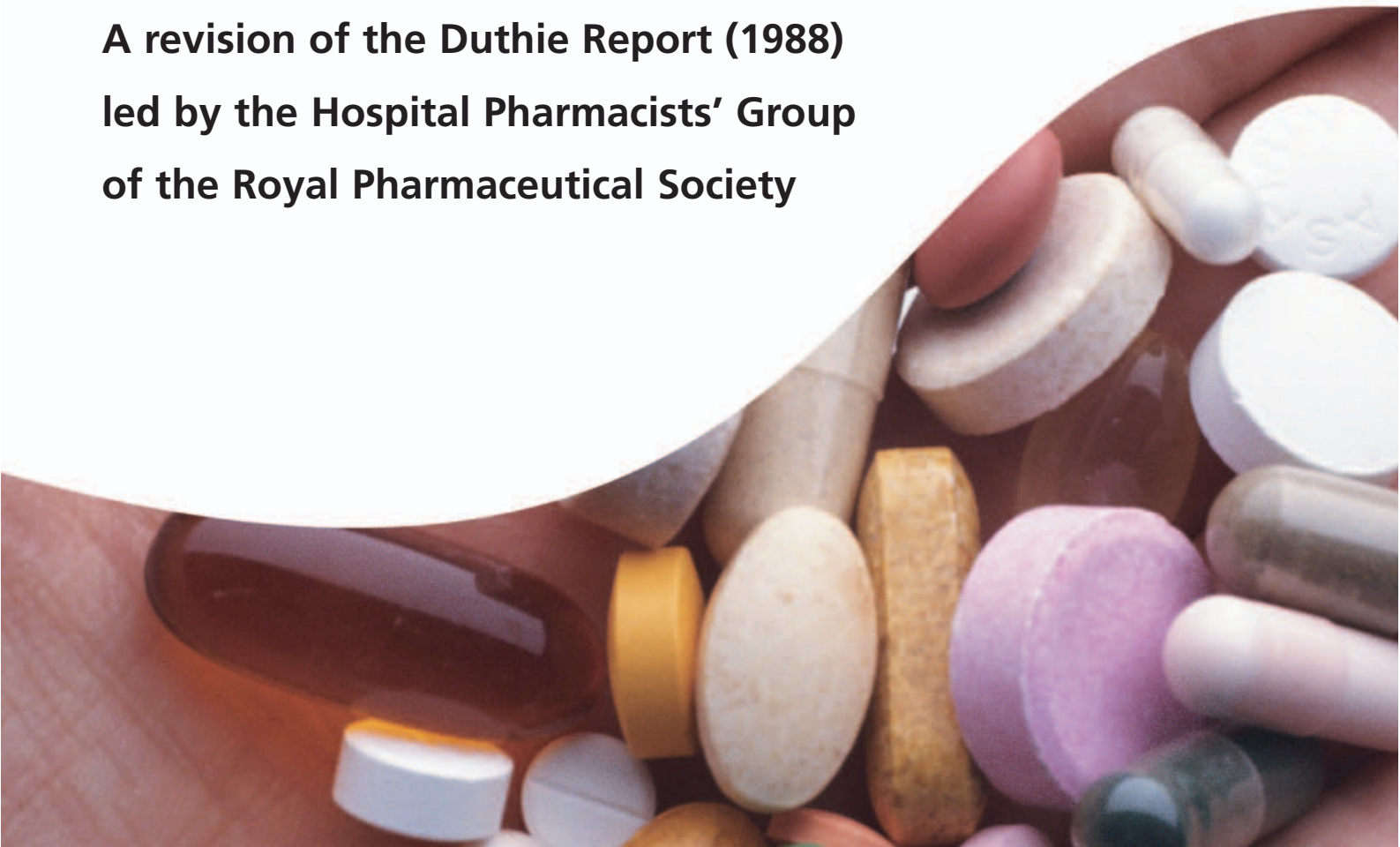
MMcG- 76

March 2005

THE SAFE AND SECURE HANDLING OF MEDICINES:

A TEAM APPROACH

A revision of the Duthie Report (1988) led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society



MAHI - STM - 089 - 3848

Preface

A prescribed medicine is the most frequent treatment provided for patients in the NHS. Medicines must be prescribed, dispensed and administered safely and effectively. And, equally important, their storage and handling within NHS organisations must be safe, secure and comply with current legislation.

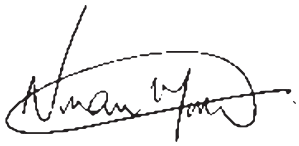
Comprehensive guidance on safe and secure handling of medicines was last issued to the NHS in 1988, in the report of a working group chaired by Professor R B Duthie. There have been many changes in legislation and practice since then, and the Royal Pharmaceutical Society of Great Britain has led a multi-disciplinary review to produce this updated report, in consultation with relevant stakeholders including medical and nursing organisations and the National Patient Safety Agency.

Thanks are due to the Royal Pharmaceutical Society and to the members of the working group who undertook the task of updating the report. We commend it to NHS organisations and to health professionals. We hope it will be a valuable resource to support the development of policy and good practice on handling and security of medicines within local arrangements for clinical governance and patient safety.

Jim Smith
Chief Pharmaceutical Adviser
for England

Carwen Wynne-Howells
Chief Pharmaceutical Adviser
for Wales

Bill Scott
Chief Pharmaceutical Officer
for Scotland



Norman Morrow
Chief Pharmaceutical Officer
for Northern Ireland

While the contents of this document have been approved for use in all four countries in the United Kingdom, there are some aspects that are not always appropriate for every country.

With the breadth of practice situations in the UK it might be appropriate for this guidance to be contextualised in each of the devolved administrations.

Editor's Note:
The Pharmaceutical Society of Northern Ireland (PSNI) has endorsed this report as good practice. They have produced their own guidance booklet in April 2004 - "Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services" This was issued by the Department of Health, Social Services and Personal Social Services. This was published in April 2004 (2nd Edition).

The Safe and Secure Handling of Medicines: A Team Approach

The Royal Pharmaceutical Society of Great Britain (RPSGB), with encouragement from the Department of Health, established its own multi-disciplinary working group to review and update the existing guidance on safe and secure handling of medicines. The working group was established under the chairmanship of Professor G B A Veitch, reporting to the Council through the Hospital Pharmacists Group. Its terms of reference were to revise and update the Duthie report. Details of the working group membership and schedule are given in Appendix 2.

Foreword

The revision of the Duthie report was undertaken to ensure that the guidance was updated to reflect changes in legislation and developments in practice since 1988. The fundamental reasons for the guidance have not changed – in the course of using medicines for therapeutic benefit it is important for institutions and health care professionals to

- comply with current legislation;
- follow guidance issued by the Health Departments for England, Wales, Scotland and Northern Ireland and other Government Departments e.g. Home Office;
- manage the risks to patients and staff arising from the use of medicines.

The clinical and economical use of medicines and the systems to address these issues are not covered by this document.

It is perhaps useful to clarify the products that are covered by this guidance. The term ‘medicines’ embraces all products that are administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function. It follows from this definition that infusions or injections of sodium chloride 0.9% and water for injection are included as are all medicinal products covered by the European Directive on Medicines.

This revised version of the Duthie report retains some elements of the original structure and also contains some new elements, such as the chapter concerned with self administration of medicines and Appendix 1 dealing with controlled drugs.

We have maintained one important feature of the original document, namely the self-contained chapters dealing with different types of working areas. For those concerned with only one sphere of activity, this structure makes the guidelines easy to use and avoids extensive cross-referencing.

This necessarily means that the guidelines may appear repetitious for the reader going from cover to cover.

We have used the term ‘patients’ throughout to refer to service users, otherwise known as clients, consumers or customers.

We recognise that the guidelines will be used in a number of institutions, both NHS and private, and for this reason we have referred to the relevant corporate body as ‘the organisation’ – to indicate NHS Trust, PCT or equivalent in Wales, Scotland, Northern Ireland, etc.

We have defined the terms and descriptions used in the glossary at the back of these guidelines.

There is relatively little legislation concerning the handling of medicines within the hospital service. Key legislation includes the Medicines Act, the Misuse of Drugs Act and its associated Regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations and the regulations relating to the disposal of hazardous waste. Bearing this in mind, the guidelines have been drafted, as far as possible; to say ‘should’ when recommending good practice and ‘must’ to indicate a legal requirement.

These guidelines have been drafted to reflect the current legislative framework and good practice. Inevitably, practice will continue to develop in line with social and technological developments and, on occasions, users of the guidelines may find points which, in their own area of activity, fit uneasily with their established practice. In such cases, we hope that the principles we have identified will enable them to devise safe and secure systems appropriate to their needs. There may also be local situations where new models of practice have been developed that are not specifically described here but for which a set of principles can be applied. For example, the issues concerning the handling of medicines in a Day Theatre would be similar to those in any other Operating Department and therefore the guidelines set out in Chapter 10 (Operating Departments) would be applicable.

Future editions of the guidelines will cover changes in the law.

Table of contents

Chapter 1

Background and Changing Environment

1.1.1 There have been four previous reports concerned with the control of medicines in hospitals: the Aitken Report of 1958, the Annis Gillie Report of 1970, the Roxburgh report of 1972 and the Duthie Report of 1988.

1.1.2 Since 1988 there have been changes in the structure, function, operational arrangements and the legal basis of activities within the NHS. These changes have prompted the need for up-to-date guidance on the safe and secure handling of medicines within the framework of developing NHS services.

1.2 Key factors in the current situation are:

- **Increasing emphasis on clinical governance.** Good Clinical governance demands clear lines of responsibility and accountability and clear policies for managing risk. Systems that ensure the safe and secure handling of medicines are essential elements of good clinical governance.

- **Growing awareness of medication errors.** There is growing awareness of medication errors and the establishment of the National Patient Safety Agency has demonstrated the NHS commitment to the development of safe systems of patient care.

- **Changing public expectations.** There has been a growth in the expectations by patients that their treatments will meet the highest standards.

- **Changing models of patient care.** These include reductions in the length of hospital stay, the growth of day procedures, the development of medical support units away from hospital centres and the growth of treatment at home. Patient self-administration of medicines and the continued use of patient's own medicines whilst in hospital represent further developments.

- **Technological advances.** Electronic data transfer, automation and robotic systems will become routine elements of systems for handling medicines in the near future. Computerised prescribing, automated dispensing and electronic recording of administration are already in

operation and will be widely implemented. Information technology developments allow rapid, economic procurement of medicines and rapid transfer of information between primary and secondary care.

- **Developing roles of healthcare staff, including pharmacy staff.** Agenda for Change, multi-skilling and the advent of non-medical, independent and supplementary prescribers are changing the ways in which healthcare staff are trained and practise.

1.3 The growth of drug misuse and drug-related crime means controlled access to the products and the safety of the staff involved in their control continues to be important.

Chapter 2

Approaches and Scope of the Guidance

2.1.1 This document only considers the processes associated with the physical handling of medicines. The clinical elements of the management of medicines (such as choice of medicine, dose, route of administration, frequency of administration and duration of treatment should be appropriate to the patient's condition, taking into account allergies, metabolic limitations, etc.) are beyond the scope of this guidance.

2.1.2 Application of this guidance is a multidisciplinary activity. In developing local procedures and policies, all staff groups undertaking the initiation of treatment and the handling of medicines should be involved. Appropriate use should be made of pharmaceutical advice.

It is not the intention of the document to provide detailed consideration of all possible circumstances that might apply when medicines are used. It provides the principles needed for controlling the activities of handling medicines. In support of these principles, guidance in respect of specific elements of practice is provided to enable staff to devise their own operational policies and procedures for the safe handling of medicines appropriate to local circumstances with due regard to the relevant legislation.

2.1.3 In addition to providing guidance for the development of appropriate policies and procedures, this document should be used as a tool for the auditing of safe and secure medicines handling within hospitals. In this context, the guidance should be used together with the Standards for Better Health Domain 1 - Safety.

2.1.4 The original guidance was based on the elements of a structured medicines trail. The trail covered all activities concerning medicines within the overall responsibility of the hospital concerned. This document uses a similar process and retains the focus on the aspects of responsibility, record keeping and reconciliation. A revised medicine trail is shown and the guidance is based on the stages shown within it. Transactions involving the physical handling of medicines and the control processes required for these have been addressed.

2.1.5 The document essentially deals with medicines and these are referred to throughout. However it is routine practice for other products such as disinfectants and diagnostic reagents to be supplied from the Pharmacy. Some of these may be used in ensuring the safe use of medicines and thus their control might be appropriately considered under the principles

outlined below.

2.1.6 In addition to receiving input from the members of the working group, material was received from a number of subgroups established to provide expert opinions on specialist topics. A final draft was also scrutinised by those shown in Appendix 2 .

Chapter 3

Achieving the Safe and Secure Management of Medicines

3.1 In any healthcare organisation the principles which govern the management of medicines must be applied to all the activities in which medicines or their administrative and legal control are concerned. The key principles are:

- compliance with current legislation;
- adherence to guidance issued by the Health Departments for England, Wales, Scotland and Northern Ireland and other national guidance e.g. NPC Guide;
- management of the risks to patients and staff arising from the use of medicines.

These principles should be applied to the management and physical handling processes involved in the initiation of treatment, prescribing, procurement, production, acquisition, storage, distribution, dispensing, preparation, administration to patients and the safe handling and disposal of any residual medicinal product.

3.2.1.1 It is the responsibility of the senior management of the organisation to establish, document and maintain an effective and economical system by which medicines are managed safely and securely to meet the patients' clinical needs. This should include formal performance reporting mechanisms and a commitment to promote awareness of the significance of the system within the organisation.

3.2.2 The senior management board of the organisation should designate an experienced, senior member of staff to be responsible for management of this system. This should normally be the senior pharmacist in the organisation.

3.2.3 Specific policies, incorporating references to relevant guidance and appropriate standards, should exist for each activity and should include:

- Detailed, approved, operational procedures (standard operational procedures, SOPs) to cover all facets of the activity.
- Defined responsibilities, competencies, training and performance standards of staff involved in the activity.

- Control of all materials, including equipment, containers, devices and packaging, used in the processes.

- Provision and use of suitable devices and clothing to protect the patient and staff engaged in processes from avoidable hazards.

- Provision, maintenance and correct performance of facilities and equipment, including disposables, for the whole range of activities carried out.

- Consistent approach to medicines' presentation including labelling. (see the labelling requirements of the RPSGB - Medicines, Ethics and Practice Guide)

- Full documentation of systems, processes and other related issues such as accidents, errors and client complaints related to the handling of medicines.

- Validation of all procedures.

- Routine audit of systems and consequent remedial action.

- Risk assessments for all procedures.

- Reference to other legislative requirements, where necessary, such as Control of Substances Hazardous to Health (COSHH) and ionising radiation regulations.

3.3 The paragraphs below are an aid to the completion or review of the procedures needed for the safe and secure management of medicines. The stages for a medicines trail and links between them are outlined in Section 4. This can be used as a guide to identify all the activities for which SOPs are required. The components and principles for development of comprehensive SOPs are described in Section 5. It is recognised that not all the elements or statements will be relevant to all activities, however, the principles may be used as a guide in development of new SOPs or for the review of existing SOPs.

Chapter 4

The Medicines Trail

4.1 Definition

The medicines trail (Figure 4.1, page 17) covers all the potential activities that are associated with a medicinal product, from the initiation of the patient treatment through a prescription or patient group direction to the administration of the medicine and the disposal of any waste material.

As this is a multistage process there is a need to introduce controlled links between the relevant stages. These links must be included to ensure full consideration of all aspects throughout the trail from the perspective of safe and secure handling.

Some of the activities will always be present in the treatment of an individual patient whilst others will only occur when certain medicines are used or when specific local circumstances exist.

4.2 Prescribing/ initiation of treatment

Definition: (In the strict, legal sense) - to order in writing the supply of a prescription only medicine for a named patient. (In the extended, commonly-used sense) – to authorise by means of a prescription the supply of any medicine (not just a prescription-only medicine).

Commentary:
A patient's treatment must be initiated through a formal process. This may be diagnosis and prescribing by a member of the medical staff (or any other authorised prescriber) or may be through an approved patient group direction. In certain life-threatening circumstances the process may not be formally initiated in full but retrospective records must be made to cover the treatment given.

Similarly, other activities involving products that are not directly associated with a specific patient, such as disinfection, should be undertaken using an approved procedure and the work carried out by competent members of staff. Appropriate steps must be implemented to control these procedures regardless of whether they are undertaken using a paper or electronic communication system.

There should be compliance with legal and professional requirements as well as local regulations and guidelines. Local guidelines will include any policies and procedures that limit the choice of medicines available, the length of prescribing period, the format and style of the information and the records made.

4.3 Procurement/acquisition of medicines

Definition: The activities through which a medicine is acquired for use in treating a patient

Commentary:
The medicine must be appropriate and legitimate for its intended use. Identification of potential sources of supply, specification of the medicine for its intended use, consideration of other issues such as lead times and shelf life as well as the method of procurement need to be considered.

Compliance with legal requirements, standing financial instructions, data controls etc. need to be included. In addition, policies are required to cover special products such as clinical trials medicines, medicines supplied on a "named patient" basis, imported medicines and medicines known to be used outside the indications listed on the marketing authorisation.

4.4 Manufacture /manipulation of medicines

Definition: The activity by which the medicine is made or subject to further change prior to being sent to the point of use.

Commentary:
Medicines may be produced or modified by the hospital or a third party prior to administration to a patient. This activity includes manufacturing of medicines from raw materials, repackaging of medicines into small packs from bulk supply, aseptic dispensing of parenteral nutrition solutions, reconstitution of injections, addition of parenteral medicines to intravenous solutions and the preparation of suspensions form tablets or capsules. (In some cases the point of manipulation may also be the point of issue/dispensing.)

These activities may be carried out in a suitably-equipped hospital pharmacy or contracted out to commercial manufacturers. Full controls of all the processes must be managed in order to sustain quality at the time of use.

4.5 Receipt of medicines

Definition: The formal activities undertaken when medicines are received by the organisation from any external source, or transferred from one location to another within the organisation. Storage of medicines in anticipation of latter stages in the trail is also included.

Commentary:
All medicines received by the organisation should be of the quantity and quality specified and suitable for the purpose for which they are intended. Quality issues should include confirmation of product identity and quantity, confirmation that deterioration through inappropriate storage, such as breakage of cold chain, has not occurred and confirmation of compliance with any legal and/or local requirements.

Patients' own medicines, which are brought into hospital to be used to continue their treatment, should be checked for quality and accuracy of the labelling. Records of medication brought into hospital by the patient need to be maintained, irrespective of whether it is used or not. Patients' own medicines, unless properly recorded, provide opportunities for diversion that would otherwise be difficult to trace.

Once received into the hospital, the physical condition and inventory records of medicines should be controlled. Consideration of environmental and security aspects of all storage locations should be included as well as the processes by which the records of the stock are maintained.

4.6 Issue to point of use/ dispensing or supply

Definition: The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used or supplied directly to the patient.

Commentary:
Medicines at this stage may be supplied as ward /department stock or as items for specific patients. In addition, direct issues to patients being discharged from hospital or to outpatients may be made.

Automated or robotic systems may be used to dispense medicines to minimise manual picking errors.

"One-stop" dispensing has been introduced in some hospitals. This combines the inpatient supply to individual patients with the discharge medication.

The majority of transactions at this stage will be undertaken by the Pharmacy Department.

4.7 Preparation/manipulation of medicines for administration

Definition: The activities associated with the preparation of the medicine for use. These include the calculation and selection of doses, the withdrawal of volumes from containers, the preparation of injections from vials/ampoules of dry powder and the preparation of complex admixtures.

Commentary:
Some form of manipulation of the medicine may be necessary immediately prior to its administration. This is particularly the case with parenteral medicines. The activities associated with this are fundamental in ensuring the correct medicine is administered to the patient. Although some of these activities may be undertaken at the bedside, many will be done in ward utility/clinical rooms or in special facilities with controlled environments.

Parenteral injections should be prepared aseptically in a controlled environment under pharmaceutical control, where possible. Centralised additive services are provided in a number of hospital pharmacy departments and should be used in preference to making additions on wards. In addition to the physical processes leading to safe and accurate dose administration there is a need to ensure that security and legal aspects are covered and that all appropriate records are kept.

4.8 Use of medicines/administration

Definition: The activities undertaken when a medicine is administered, i.e. given by introduction into the body, or by external application, to a patient.

Commentary:
This is the key activity in the medication use process and it is the point at which there are many opportunities for error. There may be considerable potential for deviation from the desired practice. Activities covered include identification of the patient, selection of the medicine, administration of the medicine and recording the medicine administered.

Electronic processes including optical readers that can identify the nurse/doctor, the patient and the medicine can reduce the risk of errors occurring. (see also chapter 6)

4.9 Removal/disposal of surplus/waste medicines from wards and departments

Definition: The activities associated with the removal and disposal of medicines that are no longer required or are no longer suitable for their intended use.

Commentary:
Procedures for safe removal and destruction of unwanted, damaged, out of date or part-used medicines are required from all locations where medicines are stored and administered. When carrying out these activities, safety, security, legal requirements and local environmental regulations must be considered for each product. Appropriate records should be made to complete the audit trail of the medicine from purchase (or, in the case of items received free-of-charge or patients own medicines, receipt) to destruction or reuse.

Procedures for the disposal of waste materials covered in this section may also be relevant in the earlier sections of the medicines trail, particularly manufacture, preparation and storage.

4.10 Removal/disposal of surplus/waste medicines or related materials from the hospital

Definition: The activities through which unwanted medicines or waste materials are removed from the hospital

Commentary:
This stage is primarily concerned with the safe and timely removal of surplus/waste medicines accumulated in any of the previous stages. It covers the removal of any medicine that has not been administered to a patient that is not to be retained in anticipation of such a use.

In some instances the medicines should be sent for appropriate waste disposal but in other instances, surplus medicines, which are still fit for use, may be transferred to another hospital where there is a demand.

There should be full compliance with local regulations and national regulations e.g. Waste Management Regulations, such as those issued by the water authorities, and all legal requirements should be met. In addition, appropriate records should be kept to complete the audit trail.

4.11 Links between stages

Definition: All activities associated with the transfer of information or materials between stages

Commentary:
There needs to be recognition that activities within and between stages will nearly always involve the transfer of information. Except where the same person initiates and administers treatment, there will be a need for communication with others. This communication may be confined to one location. An example would be where a prescription is written for a ward stock medicine to be administered by a nurse from the same ward. It is more likely that information will have to pass to another site such as to the pharmacy, for the supply to be made.

Particular care will be needed in those circumstances where the original document is not transferred with the request, such as when prescriptions are transcribed on to intermediate order sheets or where fax machines are used. Continuous control and security of the information and the method by which it is held are essential.

Examples of information transfer requiring particular attention include:

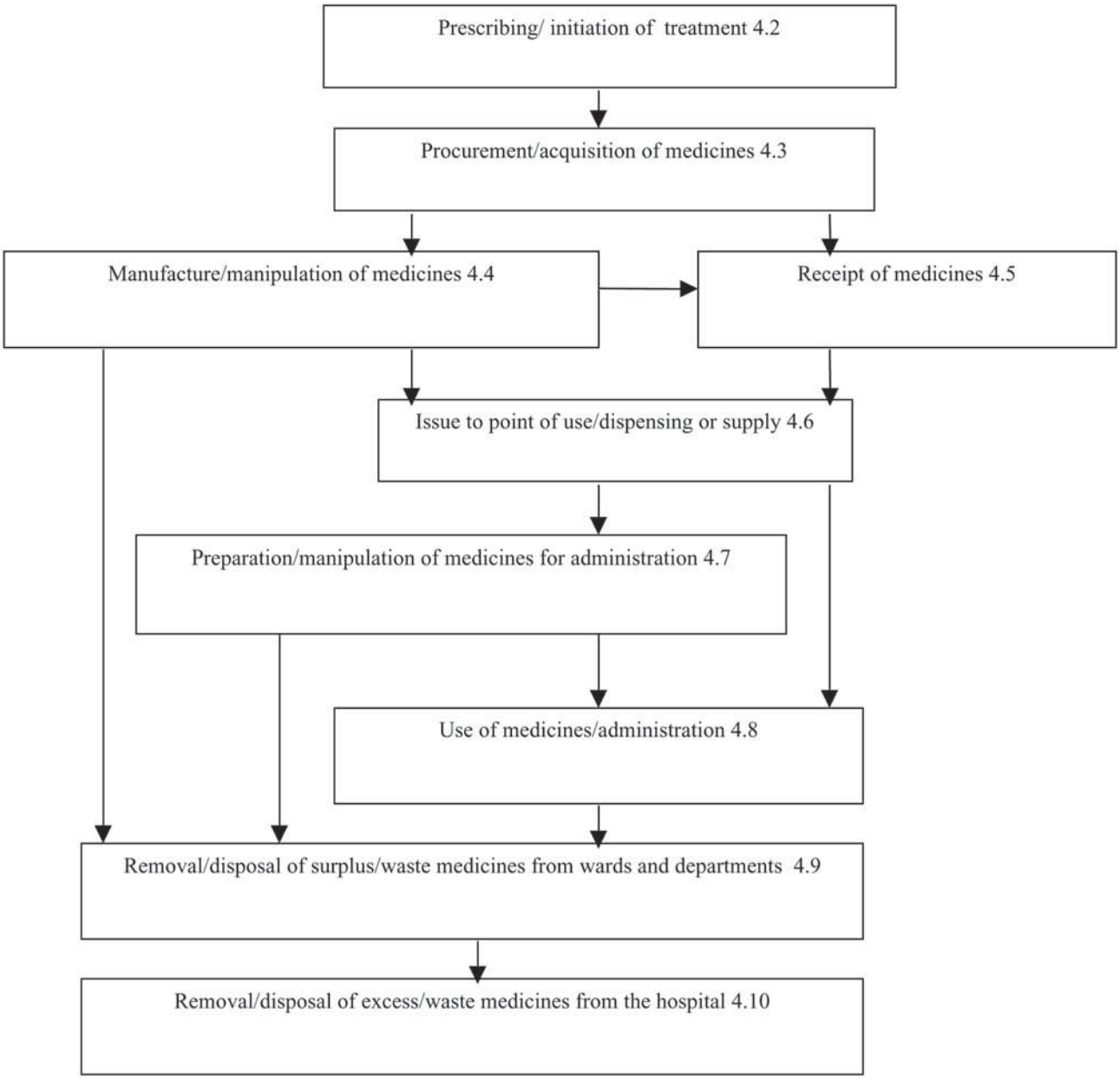
- Patient specific details necessary for dispensing.
- Information about special medicines or formulations - in hospitals where medicines are prepared, either under a "Specials Manufacturing Licence" or using exemption under Section 10 of the Medicines Act, to ensure that a medicine of the correct specification is ordered. (See Guidance Note 14 and NHS QAC document on Specials.)
- Documentation for specific medicines such as Controlled Drugs (see Appendix 1) or radioisotopes.
- Records of the movements of medicines where appropriate.
- Unlicensed medicines/unlicensed us
- Clinical trial supplies

A common feature of link activity is the physical movement of materials. Careful attention to the maintenance of product integrity is required during such movements. Environmental controls and tight security may be needed to ensure that the medicine is handled appropriately and that personnel are not exposed to hazards. In addition, consideration of other aspects such as the cold storage chain is relevant in such transfers.

There should be full compliance with legal requirements and local policies. Internal transfer links require the same attention to detail as external links in order to retain overall product control. Link stages may be eliminated, for example, where stock items are supplied directly from an external source to a ward or department or where the point of manipulation is also the point of issue/dispensing.

Figure 4.1

The simplified medicines trail



Chapter 5

Principles Applicable to the Activities Undertaken in the Medicines Trail

5.1 For each activity there are a number of elements that should be identified and included in the operational procedure.

These can be summarised as follows:

- Description of all the processes undertaken within the activity.
- Process control including documentation/records.
- Transportation of materials.
- Security of materials.
- Product integrity (to ensure quality at point of use).
- Safety (to protect staff and patients from adverse incidents).
- Risk assessment.
- Responsibility/accountability for the activities in the process.

5.2 The process description

All activities undertaken should be described, preferably in the form of a Standard Operating Procedure (SOP).

As a minimum the SOP should:

- Describe activity elements, so that the SOP is comprehensive and reproducible.
- Ensure that each element is described precisely, comprehensibly and unambiguously and should indicate who is authorised to perform it.
- Specify any equipment, facilities and data associated with the process.

- Specify the appropriate written and/or oral supporting information or instructions required in passing to the next stage.

- Include the acceptable form(s) in which instructions can be given.

5.3 Process control including documentation/records

Appropriate members of senior staff and the senior pharmacist should formally approve SOPs. SOPs and activity descriptions should be subject to routine updating and review. A record of such reviews should be maintained. SOPs should be available to any member of staff at the location at which they are used. All SOPs should be dated and the date of review should be included.

As a minimum, the SOP controlling a process should include the following:

- No process should be initiated if the instructions are not comprehensive, clear (legible and unambiguous) and current.

- All activities should comply with legal regulations and local or relevant national policies.

- The documentation should identify those persons currently authorised to undertake any particular activity. Where the authorisation requires competence checks, supporting documentation should detail the scope of the competence, record that the check has been made and confirm the period for which the authorisation remains active.

- Any supporting documentation should identify the key features including, where appropriate, essential data or design provisions should be available.

- An activity should only be carried out by a person authorised and trained to undertake that activity.

- The data required for the task in hand should be comprehensive and current.

- The systems through which quantities of materials present at the beginning and end of the stage/ transfer should be reconciled.

- Appropriate and contemporaneous records of the activity should be made including identification of those undertaking key stages and the source of any materials received. The period for which such records are to be retained should be included.

- The type of record, reporting system and action required when deviations from the process occur.

- Where electronic systems are used in support of, or as part of, the activity, a system of control should exist through which activities and menus are restricted to those authorised to use them.

- The system should indicate which elements of information are mandatory prior to initiation of the next stage and which, if any, are desirable. The initiation of the next stage should only occur when all activities required in the SOP have been completed.

5.4 Transportation (internal or external)

These principles should apply to the transfer of medicines between sites within the same organisation as well as between the organisation and an outside location.

- Transfers should be initiated through a system in which all orders and dispatches are recorded.

- Receipt of goods should be recorded.

- Procedures and equipment used in the transport of products should be designed to ensure that the integrity and quality of the product is not compromised.

- Transfer of medicines outside the healthcare organisation should always be authorised and receipt acknowledged by the receiving body.

- Staff engaged in transportation of medicines should be identified, authorised and appropriately trained. Local procedures should also cover situations where staff transport medicines in the course of their duties.

- Where intermediate carriers (agents) are used, approved systems and controls should be present, including the recording of collections and deliveries.

- Tamper-evident and, preferably, secured containers should be used when the transportation is under personal control throughout. Secured containers in secured vehicles should be used when the medicines are not under personal control throughout the transportation. Arrangements for transport of CDs must comply with current legal requirements. (see Appendix 1).

  Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration.

5.5 Security

From the time of receipt until use or removal from the organisation, all medicines should be kept secure, with access only by authorised personnel. (This includes medicines brought in by the patient but not required for treatment and held prior to return to the patient or disposal). The legal requirements related to the category of medicine should be applied. At each stage where a medicine changes hands, there should be clear policies explaining where the responsibility lies, what should be recorded and how often reconciliation should take place.

- Procedures and policies should be consistent with the general security arrangements within the organisation and relevant staff such as risk managers, security officers and local crime prevention officers should be involved.

- Arrangements should be in place to protect, from attack, staff working in areas where medicines are stored and used.

- Medicines should be stored at a level of security appropriate to their proposed use and at a level appropriate to the staff present at any time. There is a potential cascade of security levels with the most secure area likely to be the pharmacy, followed by the ward medicine cupboard, medicine trolley, bedside cabinet and emergency trolley. Medicines not in current use or used only in an emergency should be moved to a higher security location. The level may be different in locations that are staffed continuously compared with those which are staffed intermittently even when the use of the medicine is the same in each case.

- Procedures should be in place to ensure that security is maintained in any storage area particularly where it is not continuously staffed.

- Equipment used in storage areas or during transport should comply with the relevant standards where they exist.

- Records of stock holding in any location and of transfers between locations should be made. Records should be consistent, accessible and reliable and also be stored securely. It should be possible to audit the process and account for all movements of stock and to identify any inappropriate losses.

- Procedures should cover the action to be taken and the records to be made when products are misappropriated.

- Documentation should be accessible only to those authorised.

- Documents used for procurement or issue of materials outside the organisation such as order sheets and prescriptions should be held in a secure location and all issues of these documents recorded.

- Where electronic systems are used in support of, or as part of, the activity, a system of control should exist by which activities and computer screen menus are restricted to those authorised to use them.

- When patients assume responsibility for their medicines under self-administration schemes, information and advice about keeping their medicines secure should be given (See Chapter 6)

- Staff in any supervisory position should be aware of the signs that may indicate abuse or diversion of medicines (e.g. changes in an individual's behaviour such as lack of concentration, regular unexplained absences from the work area, a change in character, "odd" behaviour, or other changes such as loss of stock, excessive ordering) and take appropriate action.

5.6 Product integrity (quality at the point of use)

- All medicines acquired for use in the organisation, from whatever source, should be subject to appropriate assessment of their fitness for use.

- Appropriate storage and environmental conditions should be specified for all the different types of medicines.

- A standard operating procedure (SOP) should be in place to ensure that medicines are kept within the specified conditions to the point of use or disposal in all locations where they may be held or during transfers. Equipment or devices associated with storage or transfer should not threaten the integrity of the product. For items that require refrigeration, the equipment used should conform to MHRA guidance. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

- A standard operating procedure (SOP) should specify the required condition of a medicine at the time of use and the checks that should be made to ensure it is used according to these conditions. These will include confirmation that the use is appropriate for the patient at that time as well as the physical state of the product.

- Sufficient data and information about the medicine should be available to the staff and/or patient to enable them to identify the product and use it correctly. As a minimum this would comprise the patient information leaflet.

- Where any of the above conditions are not met, the medicine should not be used for treating the patient.

- When patients assume responsibility for their medicines under self-administration schemes, information and advice about maintaining the integrity of the medicine should be given.

5.7 Safety from medicines (staff and patients)

- The risks associated with the handling or administration of any medicine should be assessed for both staff and patients.

- A procedure should be available and followed to minimise the risks during receipt, storage, preparation, administration or disposal of the medicine.

- The risk assessment and procedure should reflect any legal requirements specific to the individual medicine or class of medicines.

- If a medicine without marketing authorisation is used or if a medicine is to be used knowingly outside its marketing authorisation, then the organisation should have an appropriate policy for this as part of its medicines management/clinical governance arrangements.

- Equipment, devices and protective clothing should be available at the point of handling, as specified in the risk minimisation procedure.

- Training should be given to those handling any medicine and, where appropriate, competency checks should be carried out at suitable intervals.

- A standard operating procedure (SOP) should cover actions to be taken, including reporting and record keeping, in the event of unplanned incidents such as spillages.

- The organisation should have a policy for dealing with products recalls (Drug Alerts issued by the MHRA).

5.8 Responsibility/accountability

- The person accountable for any activity should be specified in the written documentation.

- Persons who may accept responsibility for any activity should be defined in the documentation.

- Persons authorised to undertake tasks must comply with legal regulations and/or local or relevant national policy requirements.

- The person assuming responsibility or accountability for a task should ensure that any registration or training requirements are met.

- Tasks should not be delegated to a member of staff who is not legally entitled, authorised or appropriately trained to carry out these tasks.

Chapter 6

Self-administration of Medicines

6.1 Patients may retain or assume responsibility for some or all of their own medicines during their stay in a hospital. Any transfer of responsibility should occur on the basis of an assessment of the patient's ability to manage the tasks involved and with the patient's agreement. The patient's agreement should be recorded with the date and time.

6.2 Schemes for this transfer of responsibility may incorporate a stage in which the patient undertakes self-administration under direct supervision of an authorised member of staff.

6.3 Safe and secure processes will be needed to ensure that the patient has controlled access to an adequate supply of the correct medicines, appropriately stored so that they are fit for use, and that the medicines cannot be subject to unauthorised removal e.g. by other patients

6.4 The organisation should have a policy for self-administration of medicines (SAM) that covers all of these issues. (See also Guidelines for the Administration of medicines. Nursing and Midwifery Council 2002)

Chapter 7

Training and Personnel

7.1 Training

7.1.1 All staff involved in the handling of medicines should be appropriately trained with regard to safety and security of medicines and with regard to safeguarding themselves and those under their supervision from any risks posed by products (e.g. cytotoxic or radioactive medicines)

7.1.2 Such training should include education about locally agreed procedures, as well as defining lines of responsibility and secure methods of handling both medicines and controlled stationery. It should also include advice on secure delegation of work (e.g. rotation of ward or department staff carrying out physical checks of stock).

7.1.3 All staff should understand their scope of practice, and work within it, and must be clearly instructed as to what documentation they may and may not complete.

7.1.4 Clear instruction should also be given in the procedures for dealing with breaches of security such as intruders, discovery of evidence of tampering with medicines etc., or delivery of medicines outside the pharmacy department, including clinical trials materials or samples.

7.1.5 Personnel whose duties may expose them to risk (e.g. porters, transport drivers, stores employees or those carrying medicines into the community) should be trained to ensure understanding of the need for security and laid-down procedures. This should include instruction on the action to be taken in the event of physical threat.

7.1.6 Personnel involved in handling medicines should be trained to ensure understanding of the need for risk management in relation to drug products and procedures.

Chapter 8

Clinical Trials

Introduction

Medicines are subject to human testing prior to licensing and established products may be investigated for new indications. Such testing is regulated by the EU Clinical Trials Directive (EC Directive 2001/20/EC), published in April 2001, and transposed into UK legislation by Regulations in May 2004. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for its implementation and monitoring and detailed guidance can be found at the MHRA website ((www.mhra.gov.uk). The Medical Research Council and the Department of Health have formed a Joint Project that has provided examples of good practice for clinical trials.

8.1 Each organisation should have a policy for medicines under investigation. Such policies should comply with the United Kingdom Regulations, transposing the provisions of EC Directive 2001/20/EC, and the principles of Good Clinical Practice (GCP) set out therein.

8.1.1 As part of the requirements, all clinical trials that fall under the Regulations, including those on human volunteers or patients, will require a favourable opinion from an ethics committee and an authorisation from the MHRA. All investigational medicinal products will need to be manufactured to Good Manufacturing Practice (GMP) Standards and trial sites will be subject to MHRA GCP inspection.

8.2 There are a variety of types of trial, some of which are comparisons of existing marketed products used within their licensed indications. However, as many products under investigation may be unfamiliar to the staff handling them and/or may be coded to prevent ready identification by either the investigator or the patient, extra precautions need to be taken with these products to ensure safety and security in their use.

8.2.1 The relevant pharmacist should hold a copy of all trial protocols, including codes and all patient information sheets for studies being undertaken in either the hospital or community services.

8.2.2 The general route of purchasing, distribution and storage of clinical trial products should follow that of other medicines, except where there are special arrangements for supplies for commercial company trials of new medicines.

8.2.2.1 Stocks of trial medicines should not be maintained on wards, clinics, university departments or in private offices unless the trial involves a medicine used in an emergency situation, when sufficient stocks should be held in the ward or department for immediate use.

8.2.3 In-hospital or clinic administration of medicines to trial participants should be in accordance with locally agreed procedures.

8.2.3.1 The patient information sheet (part of the informed consent package) should be available when medicines are given as part of a clinical trial.

8.2.4 Records should be kept of receipt, dispensing, issue, administration, and disposal of all medicines to facilitate reconciliation. Pharmacies should create standard operating procedures (SOPs) for the receipt, dispensing, issue, and disposal of clinical trial medicines. (E.g. following the guidelines prepared by the Institute for Clinical Research (www.acrpi.com) booklet, SOPs and Checklists for Pharmacy Personnel.)

8.2.4.1 The identities of all those involved with receipt, dispensing, issue, administration, and disposal of all medicines should also be recorded.

8.2.4.2 Records should be regularly audited by pharmacy staff, with reconciliation. They will also be subject to external audit by e.g. the MHRA, independent clinical trial monitors and the organisation's own R&D staff.

8.3 Risk Management

8.3.1 Risk management measures should follow the local risk management policy

8.3.1.1 Risk assessments should be carried out in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

8.3.1.2 Risk management procedures should be in place to minimise the risks from trial medicines or procedures to patients and staff.

Chapter 9

Wards and Other Bedded Units

Introduction

The guidelines in this section are intended to apply to all wards. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Many aspects may be applied to community hospitals and the private and voluntary health care establishments, continuing care establishments and community developments. (see also The Administration and Control of medicines in Care Homes and Children's Services. RPSGB, 2003)

9.1 The System for Security of Medicines

9.1.1 All wards should have standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them (see Chapter 5). Appropriate pharmaceutical advice must be sought in the development of systems for the safe and secure handling of medicines.

9.1.1.1 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

9.2 Responsibility

9.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit should take responsibility and seek pharmaceutical advice when necessary.

9.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines on the ward is maintained. Where no nurse is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit will take responsibility.

9.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed

Nurse in Charge. Where no nurse is employed by the organisation, the Registered Manager will take responsibility.

9.3 Medicines Brought Into Hospital by Patients

9.3.1 Patients may bring their current and/or old medicines with them on admission. This may be hospital policy so that the health care practitioner/ Registered Manager can see what treatment regimen the patient is following and /or it may be because the organisation has a policy of using patients' own medicines (PODs) in some circumstances (e.g. respite care).

9.3.2 There should be a local policy for managing the medicines that patients bring in with them.

9.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

9.3.3.1 These medicines are the property of the patient, and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

9.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly.

9.3.4 One of the following procedures should be followed and all actions should be recorded:

9.3.4.1 The medicines may be retained on the ward, for the sole use of the patient. Responsibility and arrangements for security are the same as with all ward medicine stocks.

9.3.4.2 The medicines may be securely stored by the organisation until returned to the patient prior to or upon discharge.

9.3.4.3 If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for destruction. The pharmacist should take responsibility for their destruction.

9.3.4.4 If the patient insists, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. The patient and/or patient's agent should be advised if the medicines are not safe and/or appropriate for use.

9.4 Medicines Supplied by Pharmacy Department

9.4.1 A list of stock medicines to be held on the ward should be decided by a pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

9.4.1.1 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of ward orders. This may be done automatically using computer-controlled systems and electronic orders.

9.4.1.2 The list should be subject to a regular review at agreed intervals.

9.5 Ordering and Records

9.5.1 The Appointed Nurse in Charge or a member of the pharmacy staff (e.g a designated pharmacy technician) should be responsible for ordering medicines from the pharmacy for maintaining ward stocks and for individual patients.

9.5.1.1 Orders should be in a permanent record and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

9.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

9.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

9.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e., by confirming signatures or by using computer pass-codes).

9.6 Receipt and Records

9.6.1 Medicines coming on to the ward should be received by a Designated Person who should check them against the requisition and record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

9.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

9.6.3 Medicines intended for patients to take home on discharge and which have been obtained directly from the pharmacy on the authorisation of an authorised prescriber should be securely stored on the ward in a way that allows them to be readily identified and separated from ward stocks. If there is a "one-stop" dispensing procedure in operation then these items will also be used for inpatient treatment. Local procedures should ensure that appropriate records of these medicines are maintained.

9.7 Samples and Clinical Trial Materials

9.7.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted on the ward, but if found there they should be sent to the pharmacy department. Wards may participate in clinical trials with appropriate staff and training etc (see Chapter 8).

9.7.2 Properly-labelled clinical trial medicines brought in by a patient on admission, as part of current medication, can be checked by an authorised prescriber in the ward setting, noted, prescribed and administered as directed.

9.8 Security of Ward Medicine Stocks

9.8.1 The security of hospital ward stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of ward stocks, with reconciliation where necessary.

9.9 Storage of Medicines on the Ward

9.9.1 On the ward the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

9.9.2 There should be separate lockable ward cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

9.9.2.1 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

9.9.2.2 Where computer controlled cabinets are used for medicines they should provide at least the same level of security as traditional, lockable cupboards.

9.9.2.3 Medicine trolleys should be lockable and immobilised when not in use.

9.9.2.4 When schemes for self-administration of medicines and/or 'one-stop dispensing' are in operation on the ward each patient involved in the scheme should have a lockable receptacle for medicines (e.g. drawer, individual cupboard), which is not readily portable.

9.9.2.5 The Appointed Nurse in Charge of a ward should be responsible for controlling access (by keys or other means) to the medicine cupboards and trolley.

9.9.2.6 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

9.9.2.7 A second set of keys should be kept in an appropriate, secure location.

9.9.2.8 For clinical emergencies, e.g. cardiac arrest, all wards should have a source of urgent medicinal products.

9.9.2.9 These should be held in boxes clearly marked "for emergency use".

9.9.2.10 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites. (see also 5.5)

9.9.2.11 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

9.10 Authorisation for Administration of Medicines

9.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authorisation is given in one of three ways:

9.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart, or in the electronic prescribing system;

9.10.1.2 — in accordance with locally-agreed clinical procedures;

9.10.1.3 — in accordance with Patient Group Directions, for patients recently admitted to the ward but not examined by a doctor since admission.

9.11 Administration of Medicines to Patients

9.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, section 5.6)

9.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, section 5.7)

9.11.3 Administration to the patient should be in accordance with locally-agreed procedures, and will be accomplished in one of four ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Self-administration by an in-patient. (See Chapter 6)

— Administration by a suitably-trained person

9.11.4 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures.

9.11.5 A record of administration should be made, and the administering nurse identified.

9.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

9.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

9.11.8 For continuous administration (e.g. via intravenous infusions, or syringe drivers) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

9.12 Disposal of Medicines (also see Chapter 19)

9.12.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy with appropriate security precautions.

9.12.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

9.12.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

9.12.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

9.13 Risk Management

9.13.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

9.13.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 10

Operating Departments

Introduction

The guidelines in this section are intended to apply to all areas of Operating Departments. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas which have a limited staff presence may need special precautions.

10.1 The System for Security of Medicines

10.1.1 The Operating Department should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them (see Chapter 5).

10.1.1.1 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

10.2 Responsibility

10.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of the Senior Pharmacist in consultation with the Operating Department manager, appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

10.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines in the Department is maintained.

10.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

10.2.4 Responsibility of individuals within the Operating Department may be summarised as follows:

10.2.4.1 The Appointed Nurse in Charge is responsible for:

— receiving, checking and recording stock from Pharmacy

— the secure storage of stock

10.2.4.2 If a pharmacy-led top-up system is in operation then authority for receiving, checking and recording stock from Pharmacy may be delegated to a suitable member of the pharmacy staff but the Appointed Nurse in Charge will retain overall responsibility. If a computer-controlled drug cabinet is in use it should be designed to ensure secure storage.

10.3 Medicines Supplied by Pharmacy Department

10.3.1 A list of the medicines to be held in the Department should be decided by the Senior Pharmacist in consultation with the Operating Department manager, appropriate medical staff and the Appointed Nurse in Charge.

10.3.1.1 The list should be subject to a regular review at agreed intervals.

10.3.1.2 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This should be stated on the record of department orders. This may be done automatically using computer-controlled systems and electronic orders.

10.4 Ordering and records

10.4.1 A Designated Person should be responsible for ordering medicines from the pharmacy to maintain department stocks.

10.4.1.1 This will normally be the Appointed Nurse in Charge of the Operating Department or where a "satellite" dispensary exists, the pharmacist in charge. If a pharmacy-led top-up system is in operation then the designated member of pharmacy staff should be responsible. If a computer-controlled drug cabinet is in use, ordering may be manual or automatic.

10.4.1.2 All orders should be in a permanent record. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

10.4.1.3 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. A Controlled Drugs order book should be kept separately and locked away. Access to electronic ordering systems should be similarly secure e.g. via password.

10.4.1.4 Where ordering is done using computer technology access to passcodes/terminals should be restricted to Designated Persons.

10.4.1.5 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an appropriate person (i.e. by confirming signatures or by using computer pass-codes).

10.5 Receipt and Records

10.5.1 Medicines coming into the department should be received by a Designated Person who should check them against the requisition and record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

10.5.1.1 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

10.6 Samples and Clinical Trial Materials

10.6.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Operating Department, but if found there they should be sent to the pharmacy department. Clinical trials of surgery involving medicines may fall within the ambit of the Clinical Trials Directive when additional considerations are necessary (see Chapter 8).

10.7 Security of Theatre Medicine Stocks

10.7.1 The security of Operating Department stocks should be checked by pharmacy staff periodically, in accordance with designated procedures. They should carry out inspections of department stocks, with reconciliation where necessary.

10.8 Storage in Department

10.8.1 In the Operating Department, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

10.8.2 There should be separate lockable cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

10.8.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

10.8.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

10.8.5 The Appointed Nurse in Charge should be responsible for controlling access (by key or other means) to the medicine cupboards.

10.8.6 To ensure that medicines are readily available, the Appointed Nurse in Charge may delegate control of access to a qualified deputy or medical practitioner (e.g. anaesthetist) or, exceptionally, to an Operating Department Practitioner (ODP) or an Operating Department Assistant (ODA).

10.8.7 The responsibility for all medicines remains with the Appointed Nurse in Charge, even if he/she decides to delegate the duty of controlling access.

10.8.7.1 A second set of keys should be kept in an appropriate, secure location.

10.8.8 When the theatre is not in use, or between operating sessions, all medicines should be returned to lockable medicine cupboards.

10.8.9 There should be a local policy for secure storage of emergency and resuscitation medicines held in the Operating Department.

10.9 Authorisation for Administration of Medicines

10.9.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of two ways:

10.9.1.1 — an instruction written by a medical practitioner/ authorised prescriber on an official chart or in the electronic prescribing system;

10.9.1.2 — in accordance with locally agreed clinical procedures;

10.10 Administration of Medicines to Patients

10.10.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

10.10.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

10.10.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably-trained person

10.10.4 A record of all administrations should be made. For Controlled Drugs, Theatre Controlled Drugs Registers should show issue, receipt, form of administration (including administration via intravenous infusion or driven syringes), names of patients receiving the Controlled Drugs and ampoules/vials returned/disposed of.

10.10.4.1 For continuous administration (e.g. via intravenous infusion or driven syringes) there should be a record of those involved in setting-up the medication, including the witness.

10.10.5 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures.

10.10.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

10.10.7 For Controlled Drugs, the prescriber concerned in each transaction should sign for the medicines received on the Controlled Drugs Register and record the amount of drug administered on the anaesthetic record in the patient's notes.

10.11 Disposal of Medicines (also see Chapter 19)

10.11.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

10.11.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

10.11.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

10.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

10.12 Risk Management

10.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

10.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 11

Emergency Departments and Outpatient Departments

Introduction

The guidelines in this section are intended to apply to all areas of Accident and Emergency departments and outpatient departments. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas that provide open access to the public, or have a limited staff presence may need special precautions.

11.1 The System for Security of Medicines

11.1.1 Each department should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

11.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

11.2 Responsibility

11.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and the senior nursing staff.

11.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines in the Department is maintained.

11.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

11.3 Medicines Coming into the Department with the Patient

11.3.1 Patients seen in the Department may bring old or current medication with them. Such medicines should stay with the patient for the admission process. Proper evaluation will only be possible after admission.

11.3.2 There should be a local policy for managing the medicines that patients bring in with them.

11.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

11.3.3.1 These medicines are the property of the patient, and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

11.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly.

11.3.4 Should the patient be admitted as an in-patient, then the medicines should be handled according to the procedures set out in section 9.3

11.4 Medicines Supplied by Pharmacy Department

11.4.1 A list of medicines to be held in the Department should be determined by pharmacy staff with appropriate consultation.

11.4.1.1 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This amount should be stated on the records of department orders. This may be done automatically using computer-controlled systems and electronic orders.

11.4.1.2 The list should be subject to a regular review at agreed intervals.

11.5 Ordering and Records

11.5.1 The Appointed Nurse in Charge or a member of the pharmacy staff should be responsible for ordering medicines from the pharmacy to maintain department stocks and for individual patients.

11.5.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

11.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

11.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

11.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass codes).

11.6 Receipt and Records

11.6.1 Medicines coming into the Department should be checked against the requisition by a Designated Person who should record that a check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

11.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal frame-work. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

11.7 Samples and Clinical Trial Materials

11.7.1 Samples and clinical trial materials should be received, from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Department, but if found there they should be sent to the pharmacy department. If patients attending the Emergency Department are found to be participants in a clinical trial, the relevant trial sponsor or investigator should be informed at once.

11.8 Security of Department Medicine Stocks

11.8.1 The security of department stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of department stocks, with reconciliation where necessary.

11.9 Storage of Medicines in the Department

11.9.1 In the Department, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

11.9.2 There should be separate lockable medicines cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

11.9.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

11.9.3.1 Where there is perceived to be an extra risk, the advice of security specialists or Crime Prevention Officers, in consultation with the Senior Pharmacist, should be sought.

11.9.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

11.9.5 Medicine trolleys should be lockable and immobilised when not in use.

11.9.6 The Appointed Nurse in Charge should be responsible for controlling access (by keys or other means) to the medicines cupboards and trolley.

11.9.6.1 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

11.9.7 A second set of keys should be kept in an appropriate, secure location.

11.9.8 Where emergency bags or kits are held (e.g. for emergency teams working outside hospitals, or for major incidents), and it is impractical for these to be locked away they should be placed in an area that is most likely to have a constant staff presence.

11.9.8.1 These kits should be tamper-evident, and once a kit has been opened a replacement should be provided by the pharmacy and the opened kit returned to the pharmacy.

11.9.8.2 Neither the emergency kits themselves nor their contents should be obvious to the general public.

11.9.9 For clinical emergencies (e.g. cardiac arrest), emergency sources of urgent supplementary medicines may be held.

11.9.9.1 These should be held in boxes clearly marked "for emergency use".

11.9.9.2 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

11.9.9.3 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

11.10 Authorisation for Administration of Medicines to Patients

11.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

11.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart or in the electronic prescribing system;

11.10.1.2 — in accordance with locally agreed clinical procedures;

11.10.1.3 — in accordance with Patient Group Directions, in the Emergency Department where the patient is not known, or a Patient Specific Direction in the Outpatient Department where the patients will be know (e.g. by referral letter from GP).

11.11 Administration of Medicines to Patients

11.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

11.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

11.11.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

11.11.4 Where a system of one-nurse administration is used in hospitals the nurse should follow full, locally-agreed checking procedures.

11.11.5 A record of administration should be made, and the administering nurse identified.

11.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

11.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded. However, the ultimate responsibility remains with the administering nurse.

11.11.8 For continuous administration (e.g. via intravenous infusions, or driven syringes) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

11.12 Issue of Medicines to Patients

11.12.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

11.12.2 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

11.12.2.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

11.13 Disposal of Medicines (also see Chapter 19)

11.13.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

11.13.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

11.13.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

11.13.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

11.14 Risk Management

11.14.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

11.14.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the ward.

Chapter 12

Intensive Therapy Units, Cardiac Care Units, and Transplant Units

Introduction

The guidelines in this section are intended to apply to all Intensive Therapy Units, Cardiac Care Units, and Transplant Units, however, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas where visitors have access may need special precautions.

12.1 The System for Security of Medicines

12.1.1 Each unit should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

12.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

12.2 Responsibility

12.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

12.2.2 The Appointed Nurse in Charge should have the responsibility for ensuring that the system is followed and that the security of medicines on the unit is maintained.

12.2.3 The Appointed Nurse in Charge may decide to delegate some of the duties but the responsibility always remains with the Appointed Nurse in Charge.

12.3 Medicines Coming Into the Unit with the Patient

12.3.1 Patients admitted to one of these units may bring their current medication with them.

12.3.2 There should be a local policy for managing the medicines that patients bring in with them.

12.3.3 Local policies should be drawn up in consultation with an appropriate pharmacist and should take into account the current guidance on consent (www.dh.gov.uk) and that:

12.3.3.1 These medicines are the property of the patient and should not, therefore, be destroyed or otherwise disposed of without the agreement of the patient or the patient's agent.

12.3.3.2 Medicines brought in by the patient should only be used in the hospital when they can be positively identified, meet defined quality criteria and are appropriately labelled. They should be approved for use by appropriately-trained staff. Where this is not the case, the patient should be advised accordingly

12.3.4 One of the following procedures should be followed and all actions should be recorded:

12.3.4.1 The medicines may be retained on the Unit, for the sole use of the patient. Responsibility and arrangements for security are the same as for other medicines on the ward or unit.

12.3.4.2 The medicines may be stored by the organisation until returned to the patient prior to or upon discharge.

12.3.4.3 If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for destruction. The pharmacist should take responsibility for their destruction.

12.3.4.4 If the patient insists, the medicines may be returned home via an identified adult. Responsibility for security is given to that adult. The patient and/or patient's agent should be advised if the medicines are not safe and/or appropriate for use.

12.4 Medicines Supplied by Pharmacy Department

12.4.1 A list of stock medicines to be held in the Unit should be decided by the Senior Pharmacist in consultation with appropriate medical staff and the Appointed Nurse in Charge.

12.4.1.1 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. These should be stated on the records of unit orders. This may be done automatically using computer-controlled systems and electronic orders.

12.4.1.2 The list should be subject to a regular review at agreed intervals.

12.5 Ordering and Records

12.5.1 The Appointed Nurse in Charge, or designated member of the pharmacy staff should be responsible for ordering medicines from the pharmacy to maintain unit stocks and/or for individual patients.

12.5.1.1 Orders should be in a permanent record and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

12.5.1.2 Where order books are used they should be considered as controlled stationery, and stocked only in the pharmacy. Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

12.5.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

12.5.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass codes).

12.6 Receipt and Records

12.6.1 Medicines coming on to the Unit should be checked against the requisition by a Designated Person who should also record that the check has been made. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

12.6.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

12.7 Samples and Clinical Trial Materials

12.7.1 Samples and clinical trial materials should be received from the manufacturer or his representatives only by a pharmacist. They should not be accepted in the Unit, but if found there they should be sent to the pharmacy department.

12.8 Security of Unit Stocks

12.8.1 The security of Unit stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of unit stocks with reconciliation where necessary.

12.9 Storage of Medicines in the Unit

12.9.1 In the Unit, the responsibility for the safekeeping of the medicines rests with the Appointed Nurse in Charge.

12.9.2 There should be separate lockable medicines cupboards as follows:

a. Controlled Drugs Cabinet (that complies with the Misuse of Drugs (Safe Custody) Regulations 1973)
b. Internal Medicines Cupboard
c. External Medicines Cupboard
d. Refrigerator/freezer for medicines

and separate storage should be provided as follows:

e. Cupboard for diagnostic reagents, including urine testing
f. Area for intravenous fluids and sterile topical fluids
g. Areas (separate) for flammable fluids and gases.

12.9.3 Drug cupboards to be used for internal and external medicines should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

12.9.4 Where computer controlled cabinets are used for medicines, they should provide the same level of security as traditional, lockable cupboards.

12.9.5 Medicine trolleys should be lockable and immobilised when not in use.

12.9.6 The Appointed Nurse in Charge of the Unit should be responsible for controlling access (by keys or other means) to the medicines cupboards and trolley.

12.9.6.1 The responsibility remains with the Appointed Nurse in Charge even if he/she decides to delegate the duty.

12.9.7 A second set of keys should be kept in an appropriate, secure location.

12.9.8 For clinical emergencies (e.g. cardiac arrest) units should have sources of urgent supplementary medicinal products.

12.9.8.1 These should be held in boxes clearly marked "for emergency use".

12.9.8.2 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

12.9.8.3 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

12.10 Authorisation for Administration of Medicines

12.10.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authorisation is given in one of three ways:

12.10.1.1 — an instruction written by a medical practitioner/authorised prescriber on an official chart, or in the electronic prescribing system;

12.10.1.2 — in accordance with locally-agreed clinical procedures;

12.10.1.3 — in accordance with Patient Group Directions. (PGDs only apply to areas where a patient has been admitted but has not been assessed by a doctor e.g. CCU. It is unlikely that such a situation would arise in ITU or a Transplant Unit)

12.11 Administration of Medicines to Patients

12.11.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

12.11.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

12.11.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of three ways:

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines;

— Administration by a suitably qualified practitioner;

— Administration by a suitably trained person

12.11.4 Where a system of one-nurse administration is used, the nurse should follow full, locally-agreed checking procedures

12.11.5 A record of administration should be made, and the administering nurse identified.

12.11.6 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

12.11.7 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse.

12.11.8 For continuous administration (e.g. via intravenous infusions, or driven syringes) there should be a record of those involved in setting-up the medication and of those involved in monitoring the administration.

12.12 Disposal of Medicines (also see Chapter 19)

12.12.1 Out-of-date medicines and any stock no longer required should be returned to the pharmacy with appropriate security precautions.

12.12.2 The Assigned Nurse in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

12.12.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures.

Other Medicines Liable to Diversion

12.12.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

12.13 Risk Management

12.13.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

12.13.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the unit.

Chapter 13

Midwives

13.1 General

13.1.1 Midwives should comply with all the good practice guidance. In addition, midwives should pay special attention to the provisions relating to Controlled Drugs, and must also refer to the appropriate, up-to-date guidance in the National Prescribing Centre guidelines, Nursing and Midwifery Council Midwives' Rules and Code of Practice and follow any local policy and/or procedures specified by the Local Supervising Authority or the Supervisor of Midwives.

13.2 Supply and Administration of Controlled Drugs

13.2.1 The Misuse of Drugs Regulations 2001 in conjunction with the provisions of the Medicines Act 1968 provide for the supply of pethidine, pentazocine, morphine and diamorphine to midwives using a supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer.

13.2.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate etc).

13.2.2 Supplies of pethidine, pentazocine, morphine and diamorphine should be obtained from a hospital pharmacy, a dispensing general practitioner within the territory in which the midwife works, or a pharmacist in the community to whom he/she has been officially introduced.

13.2.2.1 It should be the duty of the pharmacist or the dispensing GP to ensure that medicines are only supplied on the instruction of an authorised person.

13.2.3 Once medicines are received by midwives working in the community or independent midwives, they become the responsibility of the midwife, and should be stored safely and securely.

13.2.3.1 Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked fixture. If necessary, this should be provided by the employing body.

13.2.4 Midwives should record full details of supply and administration of pethidine or other Schedule 2 drugs in their Controlled Drugs Register, which should be made available for inspection as required by the Supervisor of Midwives.

13.2.4.1 Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures.

13.2.4.2 A record of administration of the Controlled Drugs should also be kept in the patient's records.

13.3 Supply and Administration of other Medicines

13.3.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

13.3.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

13.3.3 A list of medicines (prescription-only and others) which may be supplied to, and used by midwives in accordance with Part III of the Medicines Act 1968 and listed in Schedule 5 Parts I and III of the Prescription Only Medicines (Human Use) Order 1997 should be decided by the Supervisor of Midwives in accordance with local policy. Any medicines to be supplied or administered by a midwife under a PGD should be taken into account in compiling the list.

13.3.3.1 Medicines are usually obtained from the hospital pharmacy. Where the local arrangement is that medicines are obtained from the hospital Maternity Unit stock, the midwife should complete the Unit records.

13.3.3.2 Where local arrangement (e.g. for a rural area) is that a Community Pharmacist supplies these medicines, the pharmacist should keep a record of supply.

13.3.3.3 Midwives should keep a record of supply, administration and disposal of all prescription-only medicines issued to them.

13.3.4 When in the custody of the midwife, the midwife is responsible for the safe and secure transport and storage of medicines.

13.4 Return/Disposal of Controlled Drugs

13.4.1 When a midwife is in possession of reusable stock that is no longer required this should be returned to the pharmacist from whom it was obtained, or to an Appropriate Medical Officer.

13.4.1.1 A record of the return should be made.

13.4.2 When a Schedule 2 Controlled Drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current regulations. (see Appendix 1).

13.4.2.1 A record of the destruction should be made in the midwife's Controlled Drugs Register.

13.4.3 Controlled Drugs obtained by a woman by prescription from her doctor, for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction.

13.5 Return/Disposal of other Medicines

13.5.1 Where a midwife is in possession of other medicines, which are no longer required, but are still usable, they should be returned to the supplying pharmacy.

13.5.1.1 A record of the return of prescription-only medicines should be made in the midwife's record.

13.5.2 When a midwife returns a prescription-only medicine to the supplying pharmacist a receipt should be obtained, and an entry made in the midwife's records.

13.6 Audit of Records

13.6.1 Supervisors of midwives should, as part of their duties, periodically audit and reconcile the records of Controlled Drugs and prescription-only medicines kept by each midwife. Any discrepancies should be investigated.

13.7 Midwives Working in Hospitals and Birth Centres

13.7.1 Administration of Controlled Drugs and other medicines to patients by midwives working in hospitals should be in accordance with locally agreed procedures.

13.7.1.1 It may be locally decided that midwives within the hospital may follow the same practice as midwives working in the community, regarding administration of medicines. This is seen to pose no additional safety or security problems provided that full record-keeping procedures are strictly followed, noting that each patient should have only one medicine record.

13.8 Risk Management

13.8.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

13.8.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced.

Chapter 14

Community Health Services (including Sexual Health Clinics)

Introduction

The guidelines in this section are intended to apply to all Community Health Clinics. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas that have a high degree of public access may need special precautions.

14.1 The System for Security of Medicines

14.1.1 Each clinic site should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in it. (see Chapter 5) Appropriate pharmaceutical advice must be taken in the development of systems for the safe and secure handling of medicines.

14.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

14.2 Responsibility

14.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with medical staff and appropriate nurse manager. Where no pharmacist is employed by the organisation, the Registered Manager or manager with designated responsibility for the unit should take responsibility and seek pharmaceutical advice when necessary.

14.2.2 A Designated Person should control access to the medicines for each speciality or department on the site. That Designated Person should have responsibility for ensuring that the system is followed and that the security of medicines in the clinic site is maintained.

14.2.3 The Designated Person may decide to delegate some of the duties but the responsibility always remains with that Designated Person

14.3 Supply of Medicines

14.3.1 It is the responsibility of the senior pharmacist to ensure there is a secure method of supply and storage of medicines for Community Clinic sites.

14.3.1.1 A list of medicines to be held in the Clinic should be determined by pharmacy staff with appropriate medical staff and the clinic's nursing staff.

14.3.1.2 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

14.3.1.3 The list should be subject to a regular review at agreed intervals.

14.4 Ordering and Records

14.4.1 One Designated Person should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

14.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

14.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person in the clinic. Access to electronic ordering systems should be similarly secure e.g. via password.

14.4.1.3 Prescription pads should only be held by qualified practitioners who have been issued with them and who should be responsible for their security.

14.4.1.4 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

14.4.1.5 It should be the duty of the community health services pharmacist to ensure that systems are in place to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

14.5 Receipt and Records

14.5.1 Medicines coming into the Clinic should be checked against the requisition by a Designated Person who should record that he/she has so checked.

14.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

14.6 Security of Clinic Medicine Stocks

14.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the clinic's stock, with reconciliation where necessary.

14.7 Storage of Medicines in the Clinic

14.7.1 On the clinic site the responsibility for the safekeeping of the medicines lies with the Designated Person who controls access to the medicines.

14.7.2 Lockable cupboards that comply with the relevant regulations should be used for the storage of medicines in the clinic.

14.7.2.1 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

14.7.2.2 Where premises are shared by a number of clinics, each clinic should be responsible for its own stock of medicines, which should be stored separately.

14.7.2.3 Medicine cupboards should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

14.7.3 Medicines for clinical emergencies should be held in packs clearly marked "for emergency use".

14.7.3.1 These packs should be tamper-evident and should be accessible to all practitioners during clinic sessions. They should be secured when the clinic or section is not running sessions.

14.7.3.2 Once a box has been opened, it should be replaced.

14.8 Authorisation for Administration of Medicines

14.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

14.8.1.1 — an instruction written by a medical, or dental practitioner or authorised prescriber on an official chart or in the electronic prescribing system; (this might be evidenced by the label on a dispensed medicine);

14.8.1.2 — in accordance with locally agreed clinical procedures;

14.8.1.3 — in accordance with Patient Group Directions, for new patients attending clinic or a Patient Specific Direction for patients who are returning to the clinic for a further supply.

14.9 Administration of Medicines to Patients

14.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

14.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

14.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following out-patient dispensing.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

14.9.4 A record of administration should be made, and the administering nurse/doctor/practitioner identified (e.g. an entry in the medicines record book or electronic health record (EHR).

14.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

14.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

14.10 Issue of Medicines to Patients

14.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

14.10.2 Contraceptive pills are prescription only medicines and should be issued accordingly.

14.10.3 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

14.10.3.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

14.11 Disposal of medicines (see Chapter 19)

14.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

14.11.2 Designated staff should be responsible for their return

Controlled Drugs

14.11.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures

Other Medicines Liable to Diversion

14.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner. Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered, should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures.

14.11.5 Sealed unit doses need not be destroyed and may be returned to clinic stock. This action should be recorded.

14.12 Risk Management

14.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

14.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the clinic.

Chapter 15

Walk-in Centres and Minor Injuries Units

Introduction

The guidelines in this section are intended to apply to NHS Walk-in Centres and Minor Injuries Units. However, the system for maintaining the security of medicines will need to be tailored to meet particular needs and to reflect specific risks. Areas which have a high degree of public access may need special precautions.

15.1 The System for Security of Medicines

15.1.1 Each Walk-in Centre/ Minor Injuries Unit site should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in it. (see Chapter 5)

15.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

15.2 Responsibility

15.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with medical staff and appropriate nurse manager. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

15.2.2 A Designated Person (who should be a professional) should control access to the medicines. That Designated Person should have responsibility for ensuring that the system is followed and that the security of medicines in the Walk-in Centre/ Minor Injuries Unit site is maintained.

15.2.3 The Designated Person may decide to delegate some of the duties but the responsibility always remains with that Designated Person.

15.3 Supply of Medicines

15.3.1 It is the responsibility of a senior pharmacist to ensure there is a secure method of supply and storage of medicines for NHS Walk-in Centre/ Minor Injuries Unit sites. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility for this.

15.3.1.1 A list of all stock medicines should be decided by the WIC nursing staff, who should seek pharmaceutical advice when necessary.

15.3.1.2 The amount of each stock medicine to be held at any time should be reviewed periodically and pharmaceutical advice sought, if necessary. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

15.3.1.3 The list should be subject to a regular review at agreed intervals.

15.4 Ordering and Records

15.4.1 One Designated Person (but not a lay-worker) should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

15.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

15.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person in the Walk-in Centre/ Minor Injuries Unit. Access to electronic ordering systems should be similarly secure e.g. via password.

15.4.1.3 Prescription pads should only be held by qualified practitioners who have been issued with them and who should be responsible for their security.

15.4.1.4 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

15.4.1.5 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

15.5 Receipt and Records

15.5.1 Medicines coming into the Walk-in Centre/ Minor Injuries Unit should be checked against the requisition by a Designated Person who should record that he/she has so checked.

15.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures. Where no pharmacist is employed by the organisation, the Registered Manager will take responsibility for this. (see Appendix 1).

15.6 Security of Clinic Medicine Stocks

15.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the Walk-in Centre's/ Minor Injuries Unit's stock, with reconciliation where necessary. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

15.7 Storage of Medicines

15.7.1 On the Walk-in Centre/ Minor Injuries Unit site the responsibility for the safekeeping of the medicines lies with the Designated Person who controls access to the medicines.

15.7.2 Lockable cupboards should be used for the storage of medicines in the Walk-in Centre/ Minor Injuries Unit.

15.7.2.1 If Controlled Drugs are kept then a cupboard that complies with the Misuse of Drugs (Safe Custody) Regulations 1973 will be required.

15.7.2.2 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. There should be monitoring of the temperature of the refrigerator on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device, which is recorded and signed by the person monitoring the temperature and a written procedure should be in place indicating the action to be taken if the temperature is outside the normal range.

15.7.2.3 Where premises are shared by a number of clinics, each should be responsible for its own stock of medicines.

15.7.2.4 Medicine cupboards should comply with the current British Standard(s) (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

15.7.3 Medicines for clinical emergencies should be held in boxes clearly marked "for emergency use".

15.7.3.1 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

15.7.3.2 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

15.8 Authorisation for Administration of Medicines

15.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

15.8.1.1 — an instruction written by a medical, dental practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

15.8.1.2 — in accordance with locally agreed clinical procedures;

15.8.1.3 — in accordance with Patient Group Directions.

15.9 Administration of Medicines to Patients

15.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

15.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

15.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following out-patient dispensing.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person

15.9.4 A record of administration should be made, and the administering nurse/doctor/practitioner identified (e.g. an entry in the medicines record book or electronic health record (EHR).

15.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

15.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

15.10 Issue of Medicines to Patients

15.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

15.10.2 Contraceptive pills are prescription only medicines and should be issued accordingly.

15.10.3 For systems in which "take-home" pre-packed medication is issued from the department, pharmaceutical advice should be sought to ensure that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

15.10.3.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

15.11 Disposal of medicines (see Chapter 19)

15.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

15.11.2 Designated staff should be responsible for their return.

Controlled Drugs

15.11.3 Disposal of Controlled Drugs should follow the agreed local procedure and national guidance and must comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures. Where no pharmacist is employed by the organisation, the Registered Manager will take responsibility.

Other Medicines Liable to Diversion

15.11.4 Any medicine liable to diversion should be disposed of in a safe and secure manner.

15.12 Risk Management

15.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

15.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the Walk-in Centre or Minor Injuries Unit.

Chapter 16

Drug Addiction Treatment Units

Introduction

The security system devised for each Drug Addiction Treatment Unit should be suitable for the degree of risk perceived to be involved. In view of the large amounts of Controlled Drugs in use in the Units staff should receive additional training to ensure that they have a good understanding of the legal framework, the need for security and laid-down procedures. Training should include appropriate action to be taken in the event of physical threat. (Also see Chapter 7 -Training and Personnel)

16.1 The System for Security of Medicines

16.1.1 Each unit should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used in them. (see Chapter 5)

16.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

16.2 Responsibility

16.2.1 The responsibility for establishing and maintaining a system for the security of the Unit's medicines should be that of the Senior Pharmacist in consultation with appropriate medical staff and senior nursing staff. Where no pharmacist is employed by the organisation, the Registered Manager should take responsibility and seek pharmaceutical advice when necessary.

16.2.2 One doctor or the Appointed Nurse in Charge should be designated responsible for control of access to the Unit's medicines and should therefore have responsibility for ensuring that the system is followed and that the security of medicines in the Unit is maintained.

16.2.3 The Designated Person who controls the access to the Unit's medicines may decide to delegate some of the duties but the responsibility always remains with that Designated Person.

16.2.4 Where patients have medicines prescribed for their own use, which are kept in their homes and only brought to the Unit for self-administration, these should, where possible, remain the responsibility of the patients themselves and a lockable receptacle should be provided for their storage.

16.3 Supply of Medicines

16.3.1 It is the responsibility of a Senior Pharmacist to ensure that there is a secure method of supply and storage of medicines for Drug Treatment Units.

16.3.2 A list of all stock medicines to be held should be decided by a pharmacist in consultation with appropriate medical staff and the Unit's nursing staff.

16.3.3 Pharmacy staff should determine the amount of each stock medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

16.3.4 The list should be subject to a regular review at agreed intervals.

16.3.5 The method and frequency of delivery should be decided by pharmacy staff in consultation with appropriate medical staff and senior nursing staff. The advantages of irregular delivery patterns, to increase security, should be considered.

16.4 Ordering and Records

16.4.1 One Designated Person (but not a lay-worker) should be responsible for ordering medicines from the pharmacy, to maintain agreed stocks.

16.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

16.4.1.2 Where order books or pads of requisitions are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person Their issue should be limited to Designated Persons. Access to electronic ordering systems should be similarly secure e.g. via password.

16.4.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

16.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer pass-codes).

16.4.2 Where prescription pads are held in a unit their security should be the responsibility of qualified practitioners, who should keep them locked away.

16.5 Receipt and Records

16.5.1 Medicines coming into the Unit should be checked against the requisition and a Designated Person should record that he/she has so checked. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

16.5.2 Receipt and record-keeping for Controlled Drugs should follow the agreed local procedures that comply with the current legal framework. The senior pharmacist should be responsible for devising such local procedures (see Appendix 1).

16.6 Security of Unit Medicine Stocks

16.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, normally every three months, in accordance with locally agreed procedures. They should carry out inspections of the Unit stocks, with reconciliation where necessary.

16.7 Storage of Medicines

16.7.1 In the Unit, the responsibility for the security of medicines lies with the Designated Person who controls access to the medicines.

16.7.2 Lockable cupboards and alarm systems should at least conform to current British Standards, where available.

16.7.3 If heat-sensitive products are kept (e.g. vaccines), a suitable dedicated fridge and/or deep freeze should also be available. (see paragraph 5.6)

16.7.4 Medicines for clinical emergencies should be held in boxes clearly marked "for emergency use".

16.7.4.1 These boxes should be tamper-evident and should not be held in a locked cupboard, but at strategic and accessible sites.

16.7.4.2 Once a box has been opened, a replacement should be provided by the pharmacy and the opened box returned to the pharmacy.

16.8 Authorisation for Administration of Medicines

16.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

16.8.1.1 — an instruction written by a medical, practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

16.8.1.2 — in accordance with locally agreed clinical procedures;

16.8.1.3 — in accordance with Patient Group Directions for new patients attending clinic or a Patient Specific Direction for patients who are returning to the clinic for a further supply.

Controlled Drugs

16.8.1.4 The prescribing of Controlled Drugs to addicted persons must comply with the Misuse of Drugs Act 1971 and the most up-to-date Misuse of Drugs Regulations (see Appendix 1) issued by the Home Office.

16.9 Administration of Medicines to Patients

16.9.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

16.9.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

16.9.3 Administration to the patient should be in accordance with locally agreed procedures, and will be accomplished in one of four ways:

— Self-administration by patient following dispensing on prescription.

— Administration by Authorised Nurses in accordance with authorisation by an appropriate practitioner or on their own responsibility within local guidelines.

— Administration by a suitably qualified practitioner.

— Administration by a suitably trained person.

16.9.4 A record of administration should be made, and the administering nurse/doctor identified (e.g. an entry in the medicines record or electronic health record (EHR).

16.9.4.1 In the case of self-administration by the patient, the person witnessing the administration should sign that they have so witnessed.

16.9.5 Medication that is not given due to refusal, wastage or lack of availability should be recorded.

16.9.6 Where a second nurse checks the administration of a medicine, the identity of the checking nurse should also be recorded; however, the ultimate responsibility remains with the administering nurse/doctor.

16.9.7 For systems in which "take-home" pre-packed medication is prescribed by a doctor/authorised prescriber and issued by a nurse, the senior pharmacist is responsible for ensuring that there is a system to ensure that all medicines handed out to patients are recorded, and properly labelled.

16.9.7.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

16.10 Issue of Medicines to Patients

16.10.1 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

16.10.2 For systems in which "take-home" pre-packed medication is issued from the department, the senior pharmacist is responsible for ensuring that there is a legal system to ensure that all medicines handed out to patients are recorded and properly labelled.

16.10.2.1 These records should be regularly checked by the pharmacy with prescription reconciliation, where necessary.

16.11 Disposal of Medicines (see Chapter 19)

16.11.1 Out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

16.11.2 A Designated Nurse or member of pharmacy staff should be responsible for their return.

Controlled Drugs

16.11.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework. The senior pharmacist should be responsible for devising such local procedures.

16.11.4 Unwanted Controlled Drugs brought into the Unit by a patient are the property of the patient. Local procedures for handling these products should be in place.

Other Medicines Liable to Diversion

16.11.5 Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures.

16.12 Risk Management

16.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

16.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the unit.

Chapter 17

Community Psychiatric Services

17.1 The System for Security of Medicines

17.1.1 Each clinical base for Community Psychiatric Nurses (CPNs), community mental health centre or sector base, where medicines are stored and used, should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure their safety and security. (see Chapter 5)

17.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

17.2 Responsibility

17.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of a Senior Pharmacist in consultation with senior nurse managers and appropriate medical staff.

17.2.2 The nurse team leader should be responsible for control of access to the medicines and should therefore have responsibility for ensuring that the system is followed and that the security of medicines in the clinical base is maintained.

17.2.2.1 In the absence of a nurse team leader, the CPNs should bear the responsibility individually

17.3 Supply of Medicines

17.3.1 There should be a stock of medicines (excluding Controlled Drugs) held at the CPN's clinical base.

17.3.2 It is the responsibility of the supplying pharmacist to ensure that there is a secure method of supply and storage of those medicines for CPN clinical bases.

17.3.2.1 A list of medicines to be held in stock should be decided by a pharmacist in consultation with appropriate medical staff and senior nursing staff.

17.3.2.2 Pharmacy staff should determine the amount of each medicine to be held at any time from usage patterns. This amount should be stated on the record of medicine orders. This may be done automatically using computer-controlled systems and electronic orders.

17.3.2.3 The list should be subject to a regular review at agreed intervals.

17.4 Ordering and Records

17.4.1 A Designated Nurse should be responsible for ordering medicines from the pharmacy to maintain agreed stocks.

17.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

17.4.1.2 Where order books, pads of requisitions or prescriptions pads are used these should be treated as controlled stationery, and kept under lock and key by a Designated Person. Their issue should be limited to Designated Persons Access to electronic ordering systems should be similarly secure e.g. via password.

17.4.1.3 Where ordering is done using computer technology, access to passcodes/terminals should be restricted to Designated Persons.

17.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or by using computer pass-codes).

17.5 Receipt and Records

17.5.1 Medicines coming into the clinical base should be checked against the requisition by a Designated Person who should record that he/she has so checked. If a pharmacy-led top-up system is in operation then a corresponding record should be kept. If a computer-controlled system is in use then it should include provision for either a manual or electronic check.

17.6 Security of Base Medicine Stocks

17.6.1 The security of medicine stocks should be checked by pharmacy staff periodically, in accordance with locally agreed procedures. They should carry out inspections of the base's stocks, with reconciliation where necessary.

17.7 Storage of Medicines at the Base

17.7.1 In the clinical base the responsibility for the safekeeping of medicines rests with those holding means of access to the stock.

17.7.1.1 It is recognised that for clinical bases having no continuous nursing presence it is impractical to have only one person with access to medicines. It is therefore important that records be maintained of all those having such access, by whatever means (e.g. keys, keycards, magnetic swipe cards etc).

17.7.2 Lockable cupboards should be used for storage of all medicines, which should at least comply with current British Standards or otherwise authorised as suitable. (The current British Standard is BS2881 (1989) – NHS Estates Building Note No 29).

17.8 Authorisation for Administration of Medicines

17.8.1 The authorisation of a suitably qualified practitioner should be obtained before medicines can be administered to patients. This authority is given in one of three ways:

17.8.1.1 — an instruction written by a medical practitioner or authorised prescriber on an official chart or in the electronic prescribing system;

17.8.1.2 — in accordance with locally agreed clinical procedures;

17.8.1.3 — in accordance with Patient Group Directions for new patients attending clinic or a Patient Specific Direction for patients who are returning for a further supply.

17.9 Domiciliary Visits

17.9.1 When medicines are issued to nursing staff for use in the community, these medicines become the responsibility of the person to whom they are issued.

17.9.1.1 All medicines carried by the CPN should have been either prescribed as a specific dose for a named patient by a qualified medical practitioner/authorised prescriber or covered by the terms of a PGD under which the CPN may supply or administer the medicine.

17.9.1.2 Each medicine carried should be accompanied by the written prescription on the relevant medicines card and the dosage given should be recorded.

17.9.2 The issue of all medicines from base stocks should be recorded in a record held at the base.

17.9.2.1 The CPN should record administration, along with a note of all medicines refused, wasted or returned to stock.

17.9.2.2 Other medicines no longer required by the CPN should be returned to the pharmacy of origin, and a receipt obtained.

17.9.3 Where it is deemed to be in the patient's best interest for medication to be kept at the base for administration over a series of visits, this should be kept in a lockable cupboard, and used for that patient only.

17.9.3.1 Such medicines should be clearly labelled and kept separately from base stocks (or in a separate part of the same cupboard).

17.9.3.2 Where it is necessary for a CPN to keep medicines under his/her control at home overnight, they should be placed in a secure lockable fixture. If necessary, this should be provided by employing body.

17.10 Clinics Held by CPNs

17.10.1 Sufficient information about medicines should be available to the CPNs and/or patient to enable identification and correct use of the products. (See Chapter 5, paragraph 5.6)

17.10.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. CPNs should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

17.10.3 Patients should be encouraged, wherever possible, to store their medications in their own homes, subject to appropriate risk assessments, and bring them to the clinic for administration.

17.10.3.1 Where it is deemed to be in the patient's best interest to keep these medicines at the base they should be locked away, in a separate cupboard/or an area of the cupboard separated from base stocks.

17.10.4 In the event of patients not bringing medication with them, the issue of all medicines from stock should be recorded.

17.10.4.1 The patient's treatment card or electronic health record (EHR) should be annotated to show the amount that has been administered from base stocks.

17.10.4.2 The base's record book should also be completed to show details of administration, along with the signature of the nurse administering the medicine.

17.10.5 Where clinics are held away from the base where medicines are stored, medicines may be issued from an agreed list, in accordance with local policy, to an individual CPN.

17.10.5.1 These medicines should be the responsibility of that CPN.

17.10.5.2 Full record-keeping procedures should be followed.

17.11 Disposal of Medicines (see Chapter 19)

17.11.1 All out-of-date medicines and any stock no longer required should be returned to the supplying pharmacy, with appropriate security precautions.

17.11.1.1 When there is a nurse team leader he/she should be responsible for their return.

17.11.1.2 In the absence of a nurse team leader, CPNs should individually bear this responsibility.

17.11.1.3 All actions should be recorded in the base records.

17.11.1.4 Medicines obtained by patients for home use, by prescription from authorised prescribers are the patients' own property. When no longer required, the patient should be advised to return them to a local pharmacy for destruction.

17.12 Risk Management

17.12.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and CPNs.

17.12.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced to the clinic.

Chapter 18

NHS Ambulances

Introduction

Medicines are carried on ambulances in both paramedic bags and locked medicines boxes, which themselves contain specialist kits of equipment as well as medicines (e.g. cardiac arrest, respiratory failure etc). The security of medicines within the ambulance service is subject to the same general principles as in any other ward, unit or department.

18.1 System for Security of Medicines

18.1.1 Each ambulance service should have a system of standard operating procedures (SOPs) covering each of the activities concerned with medicines use to ensure the safety and security of medicines stored and used by it. (see Chapter 5)

18.1.2 The procedures for handling Controlled Drugs should take account of the additional legal and good practice requirements for this category of medicines (see Appendix 1).

18.2 Responsibility

18.2.1 The responsibility for establishing and maintaining a system for the security of medicines should be that of the Medical Director in consultation with the Senior Pharmaceutical Advisor, the Paramedic Steering Group and the Chief Executive.

18.2.2 The Chief Executive should have the responsibility for ensuring that the system is followed and that the security of medicines handled by the ambulance service is maintained.

18.2.3 The Chief Executive may decide to delegate some of the duties but the responsibility always remains with the Chief Executive.

18.2.4 Where medicines are carried on an ambulance the Chief Executive should ensure that there is a written protocol for their procurement, storage, administration and handling.

18.2.5 Staff who have undergone the paramedic training programme, and who have been registered as paramedics with the Health Professions Council (HPC), should be personally responsible for the security of all medicines while they are in their possession.

18.2.5.1 These medicines should be stored in a locked receptacle specifically for that purpose, when not in use.

18.3 Supply of Medicines

18.3.1 A list of medicines to be carried in each ambulance should be decided by the Paramedic Steering Group (which includes a Senior Pharmacist) in consultation with appropriate medical staff and the Chief Executive. A recommended list of medicines to be carried by the ambulance service staff has been agreed by the Joint Royal Colleges and Ambulance Liaison Committee (JRCALC) Trusts may wish to refer to this list when drawing up local policies.

18.3.1.1 The amount of each medicine to be carried in each vehicle should be determined by pharmacy staff from usage patterns. This may be done automatically using computer-controlled systems and electronic orders.

18.3.1.2 This list should be subject to a regular review at agreed intervals.

18.3.2 The pharmacy supplying medicines should usually be the pharmacy approved by the Senior Pharmaceutical Advisor.

18.3.2.1 The Senior Pharmacist, in consultation with the Chief Executive should agree a fully documented method of supply from the pharmacy to the authorised ambulance staff.

18.3.3 Ambulance Paramedics are permitted to carry and administer the Controlled Drug, morphine sulphate. JRCALC recommends that an approved process for the safe collection, delivery and use of morphine sulphate be in place. This must include correct order books, hard-backed record books with space for recording all transfers of drugs and doubly-secured containers. Individual vehicle logbooks must be maintained, with use and restocking of drugs recorded against a double signature. Trusts may wish to refer to this when designing local policies and procedures, however, all legal and regulatory requirements must still be complied with.

18.4 Ordering and Records

18.4.1 The Chief Executive should be responsible for ordering specialist kits from the pharmacy for use in his/her ambulance service.

18.4.1.1 Orders should be in a permanent record, and any requisition book locked away. Electronic ordering systems should be designed in such a way that a permanent record of orders is kept.

18.4.1.2 Kits should be tamper-evident and once opened should be replaced. The opened kit should be returned to the original source of supply.

18.4.1.3 Where there is a local arrangement for kits to be supplied via the Accident and Emergency Department, there should be a record of issue held in that department, which should include the signature of the person to whom each kit is ultimately issued.

18.4.1.4 It should be the duty of the pharmacist to ensure that medicines are only supplied on the instruction of an authorised person (i.e. by confirming signatures or using computer passcodes).

18.5 Storage of Medicines

18.5.1 While in the possession of the ambulance service the responsibility for the safekeeping of the medicines rests with the Chief Executive.

18.5.2 The security of medicines in specialist kits should be checked by pharmacy staff periodically, normally every 3 months, in accordance with locally agreed procedures. They should carry out inspections of medicines in specialist kits with reconciliation, where necessary.

18.5.3 Prescription only medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

18.6 Administration of Medicines to Patients

18.6.1 Sufficient information about the medicine should be available to the staff and/or patient to enable identification and correct use of the product. (See Chapter 5, paragraph 5.6)

18.6.2 If there are any risks associated with handling or administration of a medicine, then there should be a procedure to minimise the risks and suitable equipment. Staff should also have undertaken the necessary training. (See Chapter 5, paragraph 5.7)

18.6.3 Each ambulance crew member should keep a record of the administration of all medicines.

18.6.3.1 Administration to the patient should be in accordance with locally agreed procedures.

18.6.3.2 A record of administration should be made, and the administering person identified (e.g. an entry on the medicines record, with the crew member's signature).

18.6.4 Medicines refused, wasted or disposed of should be recorded.

18.7 Risk Management

18.7.1 Risk assessments should be carried out (in accordance with the local risk management policy) in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to patients and staff.

18.7.2 A risk assessment should be carried out on each occasion when a new product or procedure is introduced.

Chapter 19

Return of Medicines for Destruction

19.1 General Principles

19.1.1 Medicines that are no longer to be administered to a patient, for whatever reason, should normally be returned to the relevant pharmacy or dispensing doctor for disposal. Professional disposal arrangements must comply with the paragraph 16 of the Code of Ethics and Standards (set out in the current issue of Medicines, Ethics and Practice: A guide for pharmacists. (RPSGB).

19.1.1.1 In the case of product recalls, the product should be quarantined until a decision has been made about what to do with it.

19.1.2 Destruction of Controlled Drugs must comply with current legislation and good practice guidance (see Appendix 1).

19.1.3 Local SOPs for the disposal of medicines should take account of the current environmental protection regulations.

19.2 Medicines returned within hospitals and other similar institutions

19.2.1 All out-of-date medicines and any stock no longer required should be returned to the pharmacy, with appropriate security precautions.

19.2.1.1 Medicines brought in by the patient remain the property of the patient and may only be sent to the pharmacy for destruction with the prior agreement of the patient or his/her agent. Details of patients own medicines sent to the pharmacy for destruction should be recorded.

19.2.2 The Assigned Nurse/Person in Charge or pharmacy staff should be responsible for their return.

Controlled Drugs

19.2.3 Disposal of Controlled Drugs should follow the agreed local procedure that complies with the current legal framework.
The senior pharmacist should be responsible for devising such local procedures.

Other Medicines Liable to Diversion

19.2.4 Disposal of individual doses of other medicines, which are liable to diversion and which have not been administered should follow an agreed local procedure. The senior pharmacist should be responsible for devising such local procedures. A record should be maintained of medicines liable to diversion that are returned to the pharmacy for destruction.

19.3 Cytotoxics

19.3.1 Containers of part-used cytotoxics should be carefully disposed of in accordance with hospital procedures, which should take account of current environmental protection regulations.

19.3.2 Unused solutions/powders/vials or unopened ampoules/vials should be returned to the pharmacy.

19.3.2.1 The pharmacist should then dispose of these in accordance with guidance laid down by the Health and Safety Executive (or regulations which apply in Northern Ireland).

19.3.3 All actions, and the identities of those involved, should be recorded

19.4 Midwives

19.4.1 The particular arrangements to be followed by Midwives in the community are detailed in Chapter 13.

19.5 Community Psychiatric Nurses

19.5.1 The particular arrangements to be followed by Community Psychiatric Nurses are detailed in Chapter 17.

19.6 Risk Management

19.6.1 Risk management measures should follow the local risk management policy

19.6.1.1. Risk assessments should be carried out in connection with the drug products and procedures (including the use of delivery devices) to determine potential risks to staff.

19.6.1.2 Over and above what is normally required for the safe and effective destruction of CDs, there is a professional need to take into account the management of the additional risks associated with the disposal of devices and equipment that could be classified as clinical waste.

APPENDIX 1

Controlled Drugs

A-1 General

All medicines should be handled safely, with due care and attention given to the current legal framework and good practice requirements.

Controlled Drugs are "dangerous or otherwise harmful drugs". This category of medicines is subject to additional requirements over and above those that apply to other categories of medicines (such as Pharmacy (P) medicines or Prescription Only Medicines (POMs)

Controlled Drugs are covered by both the Medicines Act (1968) and the Misuse of Drugs Act (1971) with associated Regulations. Whenever Controlled Drugs are handled careful attention must be paid to the additional regulatory requirements.

Medicines currently classified as Controlled Drugs are listed in the current Misuse of Drugs Regulations
(see www.homeoffice.gov.uk or current issue of the British National Formulary.)

Much of the legislation concerning Controlled Drugs has been written to avoid diversion and abuse. It needs to be implemented in a practical and sensible way in a healthcare setting, taking account of both the legal framework and accepted good practice, in order to ensure that patients receive the treatment that they need.

In order to support the NHS (in England) in the safe and secure handling of Controlled Drugs, the National Prescribing Centre has prepared, A Guide to Good Practice in the Management of Controlled Drugs in Primary Care. This document attempts to set out, as far as possible, the current legal framework and what is deemed to be good practice within that framework. In addition to primary care issues it also covers primary/secondary care interface issues. This document is available on the National Prescribing Centre website (www.npc.co.uk).

The legal framework affecting Controlled Drugs has been brought in to sharp focus by issues arising from the Shipman case and it is likely to be affected significantly by the recommendations of the Shipman Inquiry. The National Prescribing Centre guidance will be updated in the light of the inquiry recommendations.

We recommend that anyone using these guidelines (Duthie) should refer to the Misuse of Drugs Act 1971 and associated Regulations, the Medicines Act 1968, the latest version of NPC document, A Guide to Good Practice in the Management of Controlled Drugs in Primary Care and any other relevant national guidance, for up-to-date information on the handling of Controlled Drugs.

A-2 Controlled Drugs in hospitals

It will normally be the responsibility of the Senior Pharmacist to devise local procedures for the handling of Controlled Drugs in hospitals. Such procedures should comply with up-to-date legislation and good practice guidance. Reference may be made to the current issue of the RPSGB document, Professional standards factsheet no. 2: Controlled Drugs and Hospital Pharmacy (www.rpsgb.org.uk). The NPC guidance document, although largely concerned with primary care, may also contain information that is of value in the hospital situation. It is advised to consult this guidance to keep abreast of changes to storage, record and disposal requirements. These requirements will obviously change as a result of the Shipman Enquiry. In addition, the following points may be taken into consideration when drafting local procedures.

Receipt

Controlled Drugs coming on to the ward, theatre or other department should be received by a Designated Person who should check them against the requisition and record that a check has been made.

Storage and Security

Storage arrangements for Controlled Drugs must comply with the Misuse of Drugs (Safe Custody) Regulations.

This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case the advice of security specialists or Crime Prevention officers should be sought.

The security of Controlled Drugs should be checked, by pharmacy staff, with audit and reconciliation, at least every three months and when overall responsibility for drugs changes (e.g. change of appointments).

Registers

Details of Controlled Drugs should be entered in the ward or department Controlled Drugs Register, along with the details of the person who has received them.

Each area should have its own Controlled Drugs Register.

Controlled Drugs Registers should be kept in a secure place.

The stock balance of Controlled Drugs should be reconciled regularly, however the frequency of this check should be decided on the basis of local operational considerations by the Appointed Nurse in Charge in consultation with the nurse manager. It is intended that maintenance of a running balance will eventually become a legal requirement.

Disposal

Individual doses of Controlled Drugs, which are prepared, but not administered, should be destroyed on the ward in the presence of a second person who may be a pharmacist, nurse or doctor.

All other drugs should be sent to the pharmacy for destruction.

Controlled drugs whose shelf life has expired may be returned, via a pharmacist, for destruction according to the Special Waste Policy (see paragraph 19.2.4)

In all cases an entry should be made in the ward Controlled Drugs Register, including the names of those involved.

A-3 Supervision of Destruction of Controlled Drugs

Any person required by the regulations to keep records of Controlled Drugs may only destroy them in the presence of a person authorised by the Secretary of State. Since devolution, each of the home countries has become responsible for making its own arrangements for witnessing destruction of Controlled Drugs. Up-to-date guidance should be sought from the Office of the Chief Pharmacist in each of the Devolved Administrations For England guidance can be found in EL(97)22 and at http://www.dh.gov.uk

APPENDIX 2

Members of working party

MEMBERSHIP OF THE ORIGINAL DUTHIE REVIEW GROUP SELECTED BY THE HOSPITAL PHARMACISTS GROUP 1997

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Clinical trials/ethics committees
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Authorisation of persons to supervise the destruction of controlled drugs
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Mrs Gul Root, Office of the Chief Pharmacist, DH, England

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National Prescribing Centre
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Ambulance services
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Mental Health services
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Midwifery services

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Other Organisations that responded to the consultation process

The Ambulance Service Association
The British Medical Association
Dispensing Doctors Association
Guild of Healthcare Pharmacists
Home Office – Drug Legislation & Enforcement Unit
National Patient Safety Agency
Nursing Midwifery Council
Primary and Community Care Pharmacy Network
Royal College of Midwives
Royal College of Nursing
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of Ophthalmologists
Royal College of Surgeons

Welsh Nursing and Midwifery Committee

Association of Scottish Trust Chief Pharmacists
Lothian Primary Care NHS Trust
NHS Education for Scotland (Nursing)
Royal College of Nursing Scotland

The above does not represent a complete list of individuals or organisations that responded to the consultation process. The committee was originally convened in 1997 and the report was completed in 2005. Sincere apologies for any omissions to the list of contributors. The full list of individuals organisations and that were consulted and contributed to the preparation of the revised report can be found on the website of the Royal Pharmaceutical Society of Great Britain (www.rpsgb.org)

GLOSSARY

Appointed Nurse-in-Charge	The senior nursing appointment for the ward or department (e.g. Ward Sister, Charge Nurse, Clinical Ward Manager etc.)
Appropriate Medical officer	A doctor who is for the time being authorised in writing by the local supervising authority for the purposes of Regulation 11 of the Misuse of Drugs Regulations 1985 or (for signing Midwives' Supply orders only) a Supervisor of Midwives who is so authorised for the purposes of Regulation 11(2) of those Regulations.
Assigned Nurse in Charge	The senior nurse on duty for the ward or department who has been identified as the Nurse-in-Charge for that shift.
Audit trail	A system whereby all transactions regarding a specific medicine can be traced from the act of purchase to the point of use.
Authorised Nurse	Any registered nurse who satisfies the criteria to enable him/her to administer medicines without supervision — i.e. First Level Registered Nurse or Second Level Nurse under the conditions outlined in Rule 18(2) of Statutory Instrument 1983 No 873. (No nurse should be expected to accept the responsibility for administering such medicines against his/her will and those who do accept the responsibility must remember the requirements of the NMC Code of Conduct.)
Authorised prescriber	A person who is authorised to undertake independent or supplementary prescribing according to current legislation. (see Department of Health website)

Care Commission	The Commission for Healthcare Audit and Inspection (CHAI), known as Healthcare Commission (regulates Private and Voluntary Healthcare in England) www.healthcarecommission.org.uk The Commission for Social Care Inspection (CSCI) (regulates Care Homes, Children's services and agencies in England). www.csci.org.uk The Care Standards Inspectorate for Wales (CSIW) www.wales.gov.uk/subisocialpolicycare-standards; The Scottish Commission for the Regulation of Care (SCRC) www.carecommission.com
Controlled Drugs	Controlled Drugs (CDs) are classified in various schedules depending on their therapeutic usefulness and potential for harm. Each schedule has different requirements in relation to storage, handling, record-keeping. The classifications are set out in the current Misuse of Drugs Regulations.
Controlled Stationery	All stationery, which in the wrong hands, could be used to obtain medicines fraudulently.
Community Pharmacy	A retail pharmacy i.e. not attached to an NHS hospital.
Computer-controlled cabinet	A secure cabinet for the storage of medicines, access to which is controlled by computer passcode. Such a cabinet may also be linked electronically to the pharmacy department.
Designated Nurse	Any registered nurse who has been identified by the Appointed Nurse in charge as competent and appropriate to perform a specific function and his/her designation as such has been communicated to and recognised by any other relevant professional.
Designated Person	A person who has been identified as being suitable for, and therefore given responsibility for a specific duty, by the person having overall responsibility for the security system.

Diversion (of medicines)	The prevention of part or all of a medicine from reaching its intended destination (i.e. patient, storage place, or point of destruction).
External Medicines	Those medicines applied to body surfaces (e.g. lotions, creams etc).
First Level Registered nurse	A nurse whose name is on the First Level part of the Register, i.e. MHN, RN, RNMH, HV, RSCN or RM.
Form of Access	May be key, key-card, magnetic strip-card, or computer pass-code (depending on the system in use).
"High-Risk" medicines	Those medicines whose potential for diversion is high. Note: this may include Family Planning requisites and steroids as well as the recognised drugs of abuse.
Immobilised (in reference to medicine trolleys)	Secured to a floor or wall, or inside a locked room.
Internal Medicines	Those medicines given by mouth or injection to include eye drops, eardrops, suppositories, pessaries and inhalers.
Locally Restricted Medicines	Medicines or groups of medicines over which individual districts wish to exert tighter control. This may involve anything from specified signatures to full stock balance and record-keeping.
Local Supervising Authority	Local Supervising Authority as defined in the Nurse, Midwives and Health Visitors Act 1997 (In England and Wales, Health Authorities; in Scotland, Health Boards; and in Northern Ireland, Health and Social Services Boards.)
Medicine	Medicinal products as defined in Section 130 of the Medicines Act i.e., a substance administered by mouth, applied to the body, or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function.

Medicines and Healthcare products	Regulatory Agency (MHRA) The Medicines and Healthcare products Regulatory Agency (MHRA) was established on 1st April 2003 as a result of the merger of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA).
Operating Department	Aggregate of all the theatre suites — which may be in more than one physical location.
Organisation	NHS Trust, PCT or equivalent in Wales, Scotland, Northern Ireland or relevant corporate body.
Paramedic, State Registered	A person who is registered in the register of paramedics maintained by the Health Professions Council pursuant to paragraph 11 of Schedule 2 to the Health Professions Order 2001.
Patients	Service users, clients, consumers or customers of the health services
Patient Group Direction (PGD)	A written instruction to enable a healthcare professional to supply and/or administer a medicine to groups of patients who may not be individually identified before presentation for treatment. The majority of clinical care should be provided on an individual, patient-specific basis.
Patient Specific Direction (PSD)	A patient-specific direction is a written instruction from a doctor or dentist for a medicine or appliance to be supplied or administered to a named patient. In primary care, this might be a simple instruction in the patient's notes. Examples in secondary care include instructions on a patient's ward drug chart. Where a patient-specific direction exists, there is no need for a Patient Group Direction.
Private and voluntary health care establishments	Private hospitals, Hospices, Mental Health Hospitals, clinics and other establishments which in England are registered to provide health care with the Healthcare Commission
Reconciliation	The process of using any audit trail to ensure the integrity of individual transactions.

Registered Manager	Registered Person – A person carries on the home and registered to do so with a Care Commission or who manages the home and is registered with a Care Commission to do so.
Second Level Nurse	A nurse whose name is on the Second Level part of the Register, i.e. EN(G), EN(M), EN(MH).
Senior Pharmacist	The pharmacist appointed by the health authority/board (to assume responsibility for medicines control) who would normally have managerial responsibility for the provision of a major proportion of pharmaceutical services in a health authority/board.
Specialist Kits	Items (equipment as well as medicines) put together for specialist use (e.g. cardiac arrest or ambulance use).
Suitably qualified practitioner	For the purposes of these guidelines - usually a doctor or dentist, but additionally a midwife within professional and statutory restrictions.
Suitably trained person	For the purposes of these guidelines – someone trained in the administration of medicines to a locally-agreed level of competence
Theatre Suite	One operating theatre and its anaesthetic room.

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MEDICINES MANAGEMENT STANDARD
(SAFE AND SECURE HANDLING OF MEDICINES

Standard

The organisation handles medicines safely and securely, in accordance with legislative requirements and best practice.

Overview

The Audit Commission (2001) defined medicines management as encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care. Medicines governance more specifically focuses upon the safety and risk management issues concerned with medicines and importantly, systems risks that can lead to error and resultant adverse incidents.

This standard, while addressing many of the components identified above is not designed to cover the more specific clinical aspects of medicines management, although there are obviously intrinsic linkages. This is not to minimise the importance of the clinical and cost effective use of medicines and organisations are expected to work to these goals in the provision of optimal patient care.

The safe and secure handling of medicines in both the hospital and primary care settings requires appropriate policies, procedures and quality assurance systems to be in place. It covers processes throughout the organisation, not just in pharmacy.

This standard outlines the legislative framework and best practice relating to the safe handling of medicines, including controlled drugs. The main legislation addressed within this standard includes:

- The Medicines Act 1968, (partially repealed by the Human Medicines Regulations 2012);
- The Human Medicines Regulations 2012 which set out a regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance;
- The Misuse of Drugs Act 1971, whose main purpose is to prevent the misuse of controlled drugs and achieves this by imposing a complete ban on the possession, supply, manufacture, import and export of controlled drugs except as allowed by regulations or by licence from the Secretary of State;
- The Misuse of Drugs Regulations (Northern Ireland) 2002, which provide for the legitimate medical use of some of the substances controlled under the Misuse of Drugs Act 1971;
- Health Act 2006;

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

Guidance

Each HSC body (Board, Trust, and Agency as it relates to them) needs to ensure the safe and secure handling and storage of medicines. This will require a review of the different locations in which medicines are stored, dispensed and transported and consideration of the various staff groups responsible for these functions.

Within the HSC body, attention should focus on a review of the risks associated with, and control systems covering: procurement, ordering, delivery, storage, distribution, prescribing, dispensing, issue, supply, administration, record-keeping and disposal within and between the various locations (acute / community facilities, staff working in the community, in GP practices etc). Any such review should also consider continuing professional development as related to pharmacy and medicines management, along with other associated human resource issues (such as COSHH training, skill mix, training in the management of controlled drugs, handling and disposal of drugs in the community, adverse event reporting etc). The HSC body also needs to ensure that the organisation has effective systems in place for the reporting of adverse events involving medicinal products and can demonstrate a pro-active approach to investigating any incidents locally (as well as responding to DHSSPS or MHRA alerts).

In addition to reviewing its own internal systems in relation to medicines management, the HSC body should also request evidence from organisations with which the HSC body holds service level agreements etc. as to the effectiveness of their risk management concerning the handling and storage of medicines (eg Ambulance Trust and Out-Of-Hours Service Providers) since risks need to be considered across organisational boundaries.

If an organisation undertakes a robust risk assessment against this standard and deems a particular criterion to be non-applicable, it is essential that the rationale for any such decision is documented and evidence is available to support this assessment.

It is also important to consider the linkages between this and other standards (e.g. risk management, governance, management of purchasing, medical equipment and devices), which seek to ensure that there are controls in place to minimise all risks across the organisation.

Controlled Drugs

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 requires each Designated Body to appoint an Accountable Officer (AO). The AO is responsible for ensuring their Designated Body, and any body or person providing services on behalf of, or providing services under arrangements made with their Designated Body, establishes and operates safe and effective systems relating to the management and use of controlled drugs.

This legislation also places a duty of collaboration on Responsible Bodies to share (within certain constraints) information regarding concerns about the use of controlled drugs.

Assessment Guidance

HSC organisations vary significantly in size and in the nature of the services they deliver. It follows that not all controls assurance standards will apply to each organisation. This is implicit in the current Departmental guidance, e.g. *The Reference Table on Applicability and Expected Levels of Compliance* which should be referred to before commencing the self-assessment exercise.

Even where a standard is generally applicable to the work of an organisation it is quite possible that not all of the criteria will be materially applicable. Before self-assessing against a standard, therefore, an organisation should consider the relevance of each criterion to its own business and conduct its assessment accordingly. Thus, where a criterion is clearly relevant to an organisation, the score should be based on the **totality of the action taken to address the requirement**. Where there is little or no relevance, the criterion should be considered "not applicable" and ignored for scoring purposes as explained in the guidance on *Reporting Compliance* issued by the Department.

This approach will ensure that the assessment has no unfairly detrimental effect on the organisation's overall score but reflects a proper evaluation of the key areas of risks identified and the actual levels of controls put in place to manage those risks.

Likewise, the *Examples of Verification* set out in the standard are just that – examples, for guidance only. Once again, it is the nature of each organisation's business that determines the type of evidence needed to prove that appropriate controls are in place. In effect, this may mean that only some of the examples listed are relevant to a particular HSC organisation or, indeed, that there are other more relevant examples which can be adduced as evidence of compliance. It is also the case that some evidence can be deployed to demonstrate compliance with more than one criterion or standard.

KEY REFERENCES

In addition to any DHSSPS and HSC alerts, circulars and correspondence received on the safe and effective use of medicines the key references below are noted.

Best Practice Guidance for Supplementary Prescribing by Nurses within the HPSS in Northern Ireland, July 2006

British National Formulary BNF

British National Formulary for Children BNF

Chief Pharmaceutical Officer Letter Updated Guidance on Reporting Defective Medicines issued 18/02/2011

Chief Pharmaceutical Officer Letter 31 May 2012 Improving practice and reducing risk in the provision of parenteral nutrition for neonates and children: Report of the Paediatric Chief Pharmacists Group November 2011

Chief Pharmaceutical Officer Letter 8 April 2013 – Use and Control of Medicines Policy – DHSSPS intention **not** to publish a further edition of the guidance

Circular HSS Issued 7 September 2000 - Patient Group Directions (and as amended by legislative changes)

Circular HSS (PPM) 8/2004 – Governance in the HPSS: Controls assurance standards – update

Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services

Circular HSS (PPM) 13/02 Governance in the HPSS: Risk Management

Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance

Circular HSC(SQSD) 61/2008

1) National Patient Safety Agency: Rapid Response Report 4: Using Vinca Alkaloid Minibags (Adult/Adolescent Units)
(2) HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy

Circular DH1/10/19728 Non-Medical Prescribing: Changes in legislation regarding mixing of medicines and prescribing unlicensed medicines February 2010

Circular DH1/11/96040 The Responsibilities of Non-Medical Prescribers intending to prescribe on a private basis, letter, 16 June 2011

Circular DH1/12/112169 30 April 2012 The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012 - Controlled Drug prescribing by nurse and pharmacist independent prescribers

Patient Safety Alerts NPSA/2011/PSA001 and NPSA/2009/PSA004B Safer spinal (intrathecal), epidural and regional devices – Part A and Part B Jan 2011 Version 2

Circular HSS (PPM) 4/05 AS/NZS 4360:2004 – Risk Management

Circular HSC (SQSD) 2/13 11 December 2013 NICE Technology Appraisals - Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland

Circular HSC (SQSD) 3/13 NICE Clinical Guidelines - Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland

Clinical Pharmacy Review (2001), DHSSPS

DHSSPS -An Assurance Framework: a Practical Guide for Boards of DHSSPS Arm's Length Bodies, March 2009

The Data Protection Act 1998

DHSSPS Good Management Good Records (GMGR)

Domiciliary Care Agencies Minimum Standards - RQIA August 2011

European Commission Council Directive Title V of 2001/83/EC Labelling and Leaflet Directive

Expected Levels of Compliance with Controls Assurance Standard

Guidance on the Management of Enteral Feeding in Domiciliary Care Agencies RQIA August 2011

Guidelines for the Control and Administration of Medicines Domiciliary Care Agencies - RQIA January 2009

RQIA Letter to Providers 09 March 2012 - Monthly Quality Monitoring by Registered Persons

Template for Monthly Quality Monitoring Visits by a Registered Provider or Designated Person to a Domiciliary Care Agency

Health Act 2006

Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 - Guidance for employers and employees

Health Building Note 14-01: Pharmacy and radiopharmacy facilities

Health Services Management. The Way Forward for Hospital Pharmaceutical Services, DHSS 1989 (HSS(GHS)2-89)

HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services

HSCB correspondence relating to Medicines Management Policy

Improving Patients' Access to Medicines: A Guide to Implementing Nurse and Pharmacist Independent Prescribing within the HPSS in Northern Ireland, Dec 2006

Improving the use of medicines for better outcomes and reduced waste An Action Plan Report and Action Plan of the Steering Group on Improving the Use of Medicines (for better outcomes and reduced waste) October 2012

Independent Review of the Management of Controlled Drug Use in Trust Hospitals - Regulation and Quality Improvement Authority June 2013.

Managing patients' medicines after discharge from hospital Care Quality Commission October 2009

Medicines Act 1968 c 67 The Stationery Office, London

MHRA Guidance note 14; The supply of Unlicensed relevant Medicinal Products for Individual Patients 01/2008 – amendment pending

MHRA Best practice guidance on the labelling and packaging of medicines May 2012

MHRA Rules and guidance for Pharmaceutical Manufacturers and Distributors 2014 "Orange Guide". The Stationery Office, London

Misuse of Drugs Act 1971 (c.38) The Stationery Office, London

NHS Estates (1994) HTM 02-01 Medical gas pipeline systems. The Stationery Office, London

NHS Executive (1999) Continuing Professional Development. Quality in the new NHS HSC 1999/154

Device Bulletin Reporting adverse incidents and disseminating alerts Northern Ireland version of DB2010(NI)-01 (v.2.0) March 2013

Northern Ireland Chemotherapy Service Standards 2006

Northern Ireland Clinical Pharmacy Standards October 2013

Northern Ireland Medicines Management Formulary (including a compendium of prescribing guidance developed through the Pharmaceutical Clinical Effectiveness Programme) as published by HSCB

NPC A single competency framework for all prescribers May 2012

Nursing and Midwifery Council: Medicines Management Standards (2008)

Patient Group Directions - NICE good practice guidance August 2013

Pharmaceutical Society of Northern Ireland Code of Ethics and Professional Standards and Guidance Documents

PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments October 2008

Poisons (NI) Order 1976 No. 1214 (N.I. 23)

Professional Guidance on Pharmacy Services for Clinical Trials - National Pharmacy Clinical Trials Advisory Group October 2013

Research Governance Framework for Health and Social Care second edition (2005), Department of Health, London

Research Governance Framework for Health and Social Care, (2006) DHSSPS

Research Governance Implementation Plan (2001), Department of Health, London

Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005

Regional Unlicensed Medicines Policy

Safe Management of Healthcare Waste HTM 07-01 (Northern Ireland)

Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) DHSSPS

Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland) DHSSPS

Safer Management of Controlled Drugs Guidance on Standard Operating Procedures for (Northern Ireland) DHSSPS

Standards Australia Risk Management AS/NZS 4360:2004

Supplementary Prescribing by Nurses and Pharmacists within the HPSS in Northern Ireland April 2004

The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003. SR 2003 No 34 (as amended) The Stationery Office, London

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR 2009 No 225 The Stationery Office, London

The Health and Safety at Work (Northern Ireland) Order 1978. SI 1978 No 1039 (NI 9). The Stationery Office, London

The Human Medicines Regulations 2012 SI 2012 No. 1916 (as amended) The Stationery Office, London

The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London

The Management of Health and Safety at Work Regulations 1999. SI 1999 No. 3242. The Stationery Office, London

The Medicines (Administration of Radioactive Substances) Regulations 1978 SI 1978 No 1006 The Stationery Office, London

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 SI 2008 No. 2789 The Stationery Office, London

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 SR 1973 No 179 (as amended) The Stationery Office, London

The Misuse of Drugs Regulations (Northern Ireland) 2002 SR 2002 No 1 (as amended) The Stationery Office, London

The Prescription Only Medicines (Human Use) Order 1997 SI 1997 No 1830 (as amended) The Stationery Office, London (NB The whole of the Order except articles 1(1) to (5), 5 and 10 and Schedules 1 and 2, was revoked and consolidated by the Human Medicine Regulations 2012)

The Radioactive Substances Act 1993 (c. 12) The Stationery Office, London

ADDITIONAL READING

Department of Health - 'Building a Safer NHS. Improving Medication Safety' (2004)

Department of Health (2000) The NHS Cancer Plan: a plan for investment, a plan for reform Department of Health, London

Department of Health (2001) External inquiry into the adverse incidents that occurred at Queen's Medical Centre, Nottingham Department of Health, London

Department of Health - Patients First and Foremost: the Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Francis Report – Francis Report February 2013

Department of Health (2001) The Prevention of Intrathecal Medication Errors Department of Health, London

Ensuring Best Practice in Pharmaceutical Procurement. Pharmaceutical Contracting Executive Group September 2004

Good practice in prescribing and managing medicines and devices 2013 General Medical Council

Handbook of Extemporaneous Preparation A Guide to Pharmaceutical Compounding Jackson, Mark; Lowey, Andrew May 2010

Healthcare Commission - 'The Best Medicine, The management of medicines in acute and specialist Trusts' (2007)

Healthcare Commission - Acute Hospitals Portfolio-Medicines management 2005/2006.

Healthcare Commission - Talking about medicines: The management of medicines in trusts providing mental health services (2007).

Hospital Pharmacist (2002) One-stop dispensing, use of patients' own drugs and self-administration scheme (article March 2002 Vol 9).

Hospital Pharmacy Practice in the UK and the Responsible Pharmacist Requirements, Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland

Institute of Physics and Engineering in Medicine. Medical and Dental Guidance Notes.
A Good Practice Guide on all Aspects of Ionising Radiation Protection in the Clinical Environment

National Advisory Group on the Safety of Patients in England - A promise to learn – a commitment to act: improving the safety of patients in England - Berwick Report – August 2013

Manual of Cancer Services (as updated) Department of Health, London

National Service Frameworks (NSF) as published by Department of Health

NHS Executive (1999) Clinical Governance in the New NHS. HSC 1999/065. 1999

NHS Executive (2000) The Employment of Operating Department Practitioners (ODPs) in the NHS Letter dated 20 March 2000.

NHS Pharmaceutical Quality Control Committee (2004) Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for Prescribers and Pharmacists 3rd edition June 2004.

NICE guidance endorsed by DHSSPS for implementation in the HSC

NICE guidance Developing and updating local formularies August 2013

NICE Evidence summaries: unlicensed/off-label medicines

Prescribing Specials Five guiding principles for prescribers NPC 2011

NHS Commissioning Board Special Health Authority / NPSA alerts cascaded by DHSSPS

Pharmacy in the Future - Implementing the NHS Plan Department of Health (2000)

Review into the Quality of Care and Treatment Provided by 14 Hospital Trusts in England - Keogh Report July 2013

The Handling of Medicines in Social Care RPSGB (2007)

The International Committee on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice E6(R1) 2006. www.emea.europa.eu

INDEX OF MEDICINES MANAGEMENT

Criterion 1 (*Accountability*)

1. Board level responsibility for the safe, secure and cost effective handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Criterion 2 - 13 (*Processes*)

2. Procurement of medicines is cost effective in compliance with current legislation, professional standards and best practice and having regard for patient safety.

3. Storage, distribution and handling of medicines is safe and secure and conducted by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

4. Manufacturing / production of medicines (sterile and non sterile) is carried out under MHRA "Specials" Licence by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

5. Prescribing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance, utilising resources cost effectively and in a manner which promotes patient safety.

6. Dispensing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

7. Supply and administration of medicines is safely, securely and cost effectively carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance and in a manner which safeguards patients and the public.

8. Destruction or otherwise disposal of medicines no longer required is carried out by appropriately authorised, qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

9. Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE (OCE) 1/97

10. Supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines.

11. Arrangements for the management and use of controlled drugs comply with all legislative requirements, professional standards and good practice guidance and safeguard patients and the public.

12. The organisation has an effective system for the management of defective medicinal products / devices and reports adverse incidents involving medicinal products and devices to the relevant agency and appropriately manages any subsequent required action.

13. The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Criterion 14 & 15 (*Capability*)

14. The organisation, through the Head of Pharmacy and Medicines Management, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

15. Adequate resources support the processes outlined in criterion 2 – 12 to ensure the safe, secure, cost effective and appropriate use of medicines.

Criterion 16 & 17 (*Monitor, review, learn, improve*)

16. Key indicators capable of showing improvements in the safe, secure, cost effective handling and procurement of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

17. The system in place for the safe, secure cost effective handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Criterion 18 (*Independent assurance & Outcomes*)

18. The board seeks independent assurance that an appropriate and effective system for the safe, secure and cost effective handling of medicines is in place and that the necessary level of controls and monitoring is being implemented.

CRITERION 1

Board level responsibility for the safe, secure and cost effective handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Source

- Standards Australia Risk Management AS/NZS 4360:2004
- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HSC.
- Audit Commission (2001) A Spoonful of Sugar. Medicines management in NHS hospitals. Audit Commission, London.
- Audit Commission (2002) Procurement and Supply. Review of National Findings, Acute Hospital Portfolio, No.5, p.20.
- Patients First and Foremost: the Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry – Francis Report Feb 2013
- Review into the Quality of Care and Treatment Provided by 14 Hospital Trusts in England - Keogh Report July 2013
- A promise to learn – a commitment to act: improving the safety of patients in England - Berwick Report – August 2013

Guidance

The Chief Executive of the organisation has the overall statutory responsibility for the safe, secure, cost effective handling of medicines. The Head of Pharmacy and Medicines Management has responsibility for ensuring that systems are in place to appropriately address all aspects of the safe, secure and cost effective handling of medicines.The organisation's commitment to the safe and secure handling of medicines should be clearly signalled.

Clear lines of accountability for the safe, secure and cost-effective handling of medicines throughout the organisation should be established; these should define the relationships between the board, board sub-committee(s) responsible for overseeing all aspects of risk management and governance, Pharmacy Services and other relevant groups. There must be a Drug and Therapeutics Committee or equivalent medicines management committee whose responsibility it is to review, analyse and monitor and advise medicines management processes.

Examples of Verification

- Accountability arrangements chart
- Minutes of the board sub-committee(s) responsible for overseeing risk management
- Board minutes
- A strategy for medicines use, within the organisation, has been approved by the board, reviewed and reported annually
- Terms of reference for any medicines management committee required.
- Job description of Head of Pharmacy and Medicines Management.

Links with other Standards

All Standards

CRITERION 2

Procurement of medicines is cost effective, in compliance with current legislation, professional standards and best practice and having regard for patient safety

Source

- The Public Contracts Regulations 2006 SI 2006 No 5
- The Public Contracts and Utilities Contracts (Amendment) Regulations 2007 SI 2007 No 3542
- Public contracts (Amendment) Regulations 2009 No 2992
- Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for prescribers and pharmacists. NHS Pharmaceutical Quality Control Committee 3rd Edition, 2004
- N.I. Public Procurement Policy Version 8 October 2012 and Guidance Notes (issued through the Department of Health, Social Services & Public Safety) http://www.dfpni.gov.uk/index/procurement-2/cpd/cpd-policy-and-legislation.htm
- Circular HSS (PPM) 7/2004. Procurement strategy for Health, Social Services and Public Safety. DHSSPS
- DHSSPS best practice guidance on joint working between the HSC and Pharmaceutical Industry and other relevant commercial organisations 2010
- Quality Assurance Policy for contract procurement of licensed pharmaceuticals. NHS Pharmaceutical Quality Assurance Committee 2nd Edition April 2011
- Managing Medicines Shortages Policy and Procedure for HSC Trusts RPCEG December 2013
- Regional Unlicensed Medicines Policy January 2013
- College of Emergency Medicine and National Poisons Information Service- Guideline on Antidote Availability for Emergency Departments (December 2013) Appendix 1. Stock levels & storage recommendations

Guidance

Under the management of Heads of Pharmacy and Medicines Management, wherever possible, corporate action should be taken to ensure the efficient and effective procurement of all medicines, particularly in the context of the Regional Pharmaceutical Contracting Executive Group, established by Trust Chief Executives and aligned to public procurement policy and strategy. Any deviation from this principle of regional action should be the exception rather than the rule.

Examples of Verification

- There is a local procurement of medicines policy in place, which complies with relevant aspects of legislation
- Relevant staff are aware of, and have access to the organisation's procurement policy including its unlicensed medicines policy
- Implementation of a 'purchasing for safety' policy for procurement of pharmaceuticals
- Quantity and value of pharmaceuticals procured by quotation or tender according to the DHSSPS Procurement Controls Limits – Procurement Guidance, as a percentage of the whole, subject to regional procurement
- Procedures for ordering and stock control of medical gases are in place
- Compliance with Good Procurement Practice as defined by Audit Commission (2002)
- Procedures in place to manage supply chain failures
- SLA with Regional Pharmacy Procurement
- SLA with BSO PaLS
- Antidote levels comply with Antidote Availability for Emergency Departments (December 2013) Appendix 1. Stock levels & storage recommendations
- Evidence of management and recording of approval of Single Tender Actions
- Implementation of a managing medicines shortages policy
- Trust Unlicensed Medicines Policy
- Standard Operating Procedures for all procurement procedures
- RPCEG Annual Report and Minutes

Links with other Standards

Health and Safety
Management of Purchasing

CRITERION 3

Storage, distribution and handling of medicines is safe and secure and conducted by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003. SR 2003 No 120 The Stationery Office, London
- The Radioactive Material (Road Transport) Regulations 2002 SI 2002 No. 1093 (as amended) The Stationery Office, London
- The Radioactive Material (Road Transport) (Northern Ireland) Order 1992 SI 1992 No 234 (NI 2). The Stationery Office, London
- Pressure Systems Safety Regulations 2000 SI 2000 No 128 The Stationery Office, London
- NHS Estates (1994) HTM 02-01 Medical gas pipeline system. The Stationery Office, London
- Health Building Note 14-01: Pharmacy and radiopharmacy facilities
- The Medicines (Administration of Radioactive Substances) Regulations 1978 as amended
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London
- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- DHSS Good Management Good Records (GMGR)

Other Reading

Guidance

The revised Duthie report sets out standards for the handling, administration, storage and custody of medicinal products, in Trusts (including Trust community facilities), community clinics, residential and nursing homes, domiciliary care, supported living, community nursing or midwife units and the ambulance service. At each step where a medicine changes hands there should be clear procedures which document:

- Where responsibility lies, whether it may be delegated and how far it extends
- What should be recorded where, by whom and how long records should be kept
- How often stock reconciliation should take place and who should undertake the task
- Appropriate procedures must be in place for the ordering, stock control, storage, movement and safe handling of all medicines having particular regard to those with specialised requirements such as medical gases and those of a hazardous nature. A mechanism to alert in event of supply failure or discrepancy should be in place.

Particular attention should be paid to all medicine security issues including:

- *Storage of medicines, whether in bulk in the pharmacy or in smaller quantities elsewhere including robots*
- *Methods of ordering medicines (electronic and paper-based)*
- *Means of delivery*
- *Receipts procedures, including full records*
- *Adequate and robust audit trails*
- *Methods of distribution both within and between hospitals*
- *Dispensing of medicines including patients own medicines, dispensing for discharge and self administration*
- *Administration of medicines*
- *Disposal of medicines*
- *Where self-administration schemes are in operation*

Physical security measures include:

- *Control of access to cabinets and cupboards*
- *Lockable cupboards, freezers and fridges for the storage of medicines, with temperature monitoring as appropriate conforming to British Standards where applicable*
- *Cupboards which meet the requirements as set out in the revised Duthie report for all medicines*
- *Lockable medicine trolleys which are immobilised when not in use*
- *Lockable, bedside medicine storage cupboards, which are not easily portable (where appropriate)*
- *Lockable / tamper evident security sealed containers for transporting / moving medicines*
- *Entrances to pharmacies and other controlled areas have solid doors, fitted with security locks and intruder alarms, with appropriate access control.*
- *Reception areas interfacing with dispensary are adequately separated protecting medicines and staff.*
- *Stationery including requisition books, order books and blank prescription forms should be kept in a locked cupboard or access controlled secure area.*

Where medicines are stored, even temporarily, other than in locked cupboards / receptacles robust systems are in place to ensure that unauthorised access is prevented and audit systems are in place to ensure that any misappropriation of medicines is promptly identified, reported and investigated.

COSHH regulations require organisations to ensure that precautions are taken by staff handling medicinal products, which are hazardous to health by any route (inhalation, ingestion, and absorption through the skin or contact with the skin). Contact should either be prevented or, where this is not reasonably practicable, adequately controlled.

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Examples of Verification

- Access controls pertaining to automated / electronic systems are safely and securely managed, monitored and reviewed.
- There is a local policy / Medicines Code in place, which complies with relevant aspects of legislation
- Local procedures comply with the organisations' security policy and the principles of the revised Duthie report "Safe and Secure Handling of Medicines - A Team Approach". RPSGB March 2005.
- There is a policy in place, of which staff are aware, which states the required action to be taken when there is a breach of security
- Policy on the security of medicines which are stored, even temporarily, other than in locked cupboards / receptacles
- Systems in place to identify, report and investigate the misappropriation of medicines
- Audit of adherence to local medicines policies
- COSHH assessments
- Procedures for storage, movement and safe handling of medical gases are in place and approved by the Medical Gas Committee
- The organisation audits itself against these principles, and can demonstrate, if necessary, those mechanisms have been put in place to change practice.
- Training and development plans for all staff aligned to their individual CPD, training and competency needs
- Documentation of training / CPD and competency checks
- Evidence of audit and monitoring to assess and assure compliance with organisational policies and procedures
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)

Links with other Standards

Health and Safety
Management of Purchasing
Medical Devices and Equipment
Information Management
Security Management
Waste Management

CRITERION 4

Manufacturing / production of medicines (sterile and non sterile) is carried out under MHRA "Specials" Licence by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- The Human Medicines Regulations 2012 (SI 2012/1916)
- MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 – Pharmaceutical Press
- MHRA Guidance Note 14 (revised January 2008 – amendment pending), "The supply of unlicensed relevant medicinal products for individual patients".

Other Reading

- British Pharmacopoeia monograph for unlicensed medicines
- MHRA Questions and Answers for Specials Manufacturer's http://www.mhra.gov.uk/home/groups/commsic/documents/websiteresources/con326474.pdf

Guidance

The manufacturing / production of medicines by an organisation should be restricted to situations where a licensed product is unavailable. All manufacturing / production must be carried out under the appropriate MHRA licence. The holder of a manufacturer 'Specials' licence (MS) will be authorised to perform a defined range of manufacturing, quality control and / or importation activities. Licensed activities are subject to regular inspection by the MHRA Inspectors.

The over-labelling or re-packing of medicinal products is an assembly activity and is therefore licensable

Wholesaling of medicines can only take place under a full wholesale dealer licence (WDA(H)) which allows the holder to wholesale deal pharmacy (P), prescription only (POM), traditional herbal medicinal products (THMP), General Sale List (GSL) and can include dealing in unlicensed medicines. This includes procurement, holding, or wholesale distribution of medicinal products for human use (including "specials") sourced in the UK or another EEA Member State, unless exempt. Those holding a manufacturing licence may undertake wholesaling of the products manufactured under that licence.

There should be a programme of capacity planning for equipment and staff.

Examples of Verification

- Manufacturer's licence
- Wholesale Dealer licence
- Maintenance and retention of relevant manufacturing/wholesaling records
- Policy
- Regular internal and external audit reports with a GMP focus and progress on follow-up
- Record of rejects and delays in service provision
- Staff skill mix and competence assessed
- Records of appropriate training
- SOPs are present, suitable, comply with all relevant legislation and are reviewed in accordance with GMP guidance (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Capacity plan
- Error/near miss reporting in place

Links with other Standards

Human Resources
Health and Safety
Medical Devices and Equipment

CRITERION 5

Prescribing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance. utilising resources cost effectively and in a manner which promotes patient safety.

Source

- The Human Medicines Regulations 2012 SI 2012 No. 1916 (as amended) The Stationery Office, London
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012 SR 2012 No 168
- Crest Guidance 2006: Protocol for the Inter Hospital Transfer of Patients and their Records
- GAIN Guidance June 2011 – Guidelines on Regional Immediate Discharge Documentation for Patients being Discharged from Secondary into Primary Care
- NICE Good practice guidance Patient Group Directions August 2013
- Medicines and Healthcare Products Regulatory Agency. MHRA guidelines on the Yellow Card Scheme. (www.mhra.gov.uk)
- NI Clinical Pharmacy Standard
- Priorities for Action, DHSSPS
- HSCB correspondence and guidance relating to prescribing including, regional prescribing guidelines and the NI formulary
- DHSSPS approved NICE guidance
- DHSSPS correspondence and guidance for nurse and pharmacist non medical prescribers

Other Reading

-
- NMC Standards of proficiency for nurse and midwife prescribers
- GMC Good practice in prescribing and managing medicines and devices (2013)
- PSNI Standards and Guidance for Pharmacist Prescribers 2013
- NPC A single competency framework for all prescribers May 2012
- National Confidential Enquiry into Patient Outcome and Death report 2008, ‘Systemic Anti-Cancer Therapy: for better, for worse?

Guidance

Medical and non-medical prescribers (NMP) may prescribe, administer or supply Prescription Only Medicines directly to a patient in areas where they are competent and should ensure separation of prescribing and administering or supply activities whenever possible. A register of NMPs is maintained and arrangements are in place for approving each NMP’s scope of practice within the organisation. Supplementary prescribers may only prescribe under and in accordance with the terms of an agreed patient specific clinical management plan and the patient’s agreement.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis. Where the direction of a prescriber is not patient

specific, the responsible organisation would need to ensure that the appropriate patient group direction complies with current legislation and good practice guidance.

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Patients should be appropriately monitored and prescribing decisions adjusted in response to the outcomes of such monitoring.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products and all such decisions are supported by a robust risk assessment.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the Northern Ireland cancer network (NICaN). In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSC(SQSD)61/2008.

The BNF and BNF for children contains guidance on how to write prescriptions to ensure clarity and safety. These principles should be adopted, and adapted for local use as appropriate. Ward/Clinical pharmacy services should be in place to ensure that prescriptions are safe, clear, legible etc, and comply with local and national guidance.

Prescribing choices should take into account the regional prescribing policies, NI Prescribing Formulary and NICE guidance and the organisation should ensure that these are observed within in-patient, out-patient and other settings.

Examples of Verification

- Staff groups are subject to regular qualification and registration checks:
- All patient group directions have been identified, located, reviewed and are in date
- Compliance with Northern Ireland Chemotherapy Service Standards 2006
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- A register maintained of all non-medical prescribers recording the scope of practice approved within the organisation.
- Robust procedures in place for the procurement and use of unlicensed medicines
- Audit of prescriptions and treatment cards (e.g. using ward / clinical pharmacist intervention records).
- Training and development plans for all staff and training records
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Protocol(s) for communication and transfer of patient information relating to medicines, prescribing and medication history

- Audit of adherence to the NI Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors
- HSCB performance management and service improvement directorate (PMSID) data on clinical pharmacy services
- NI Safety Forum Medicines Collaborative data and action plans
- Policy for use of unlicensed medicines

Links with other Standards
Human Resources
Information Management
Risk Management

CRITERION 6

Dispensing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- The Human Medicines Regulations 2012 SI 2012 No. 1916 (as amended) The Stationery Office, London
- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 SI 2008 No. 2789 The Stationery Office, London
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01
- MHRA Guidance Note 14 – The supply of Unlicensed Relevant Medicinal Products for Individual Patients (Revised January 2008 – amendment pending)
- PSNI sale and supply of medicines
- PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments October 2008
- Handbook of Extemporaneous Preparation A Guide to Pharmaceutical Compounding Jackson, Mark; Lowey, Andrew May 2010

Other Reading

Guidance

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products.

In accordance with legislation patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Pharmacists have a legal and professional duty to ensure the safe, accurate and clinically appropriate dispensing of medicines, including those that are extemporaneously prepared. All staff undertaking any role in the dispensing of medicines must be appropriately trained and competent.

The pharmacist who has responsibility for the dispensing activities must ensure that the staff involved in carrying out the delegated tasks is suitably trained and competent to undertake the tasks required

Similarly, good practice dictates that such controls should be in place for the dispensing of medicines for patients to take home, for one stop dispensing for discharge and for inpatient use. Appropriate clinical pharmacy input should also be provided.

The pharmacist who has responsibility for the dispensing activities must at all times be satisfied that suitable systems are in place to discharge their legal and professional duties of supervision. These systems must be fully documented in suitable standard operating procedures (SOPs), which adequately cover all the processes by which dispensing, and its associated activities are undertaken. The SOPs should be reviewed at least every 2 years or earlier if triggered by a near miss, an adverse incident, new guidance or legislation.

The SOPs should include a suitable system for reporting, recording and prompt review of known dispensing errors.

Extemporaneous preparation should be carried out in accordance with good practice and the professional guidance issued by the PSNI within the Code of Ethics & Professional Standards.

Examples of Verification

- Responsible pharmacist records for registered pharmacies
- Staffing schedules are in place to ensure adequate cover
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Maintenance records
- COSHH records
- Relevant post-basic training schemes (e.g. accredited technician checking) are suitable and are appropriately accredited
- CPD policy
- Training and development plans for all staff
- Documentation of training / CPD and competency checks
- Log of errors / near misses and procedures for dealing with errors present
- Dispensing complete with patient information leaflet
- Audit of adherence to local medicines policies and can demonstrate, if necessary, that mechanisms have been put in place to change practice.

Links with other Standards

Health and Safety
Human Resources
Medical Devices and Equipment
Information Management
Risk Management

CRITERION 7

Supply and administration of medicines is safely, securely and cost effectively carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance and in a manner which safeguards patients and the public.

Source

- The Human Medicines Regulations 2012 (SI 2012/1916)
- Crest Guidance 2006: Protocol for the Inter Hospital Transfer of Patients and their Records
- GAIN Guidance June 2011 – Guidelines on Regional Immediate Discharge Documentation for Patients being Discharged from Secondary into Primary Care
- Patient Safety Alerts NPSA/2011/PSA001 and NPSA/2009/PSA004B and Safer spinal (intrathecal), epidural and regional devices – Part A and Part B
- NICE Evidence summaries: unlicensed/off-label medicines
- NMC, PSNI, GMC standards

Other Reading

- RQIA Minimum Standards

Guidance

Prescription Only Medicines (POM) may only be supplied to a patient against the prescription or written direction of an 'appropriate practitioner', as stated in regulation 214 of the Human Medicines Regulations 2012. The sale, supply and administration of GSL, P and POM medicines are governed by legislation and best practice requirements. Practitioners must operate strictly within the legislative boundaries.

The principal supply route is through the pharmacist and pharmacy staff should be involved in replenishing, monitoring, and adjusting medicines stock control.

Medical and non-medical prescribers may prescribe, administer or supply Prescription Only Medicines directly to a patient in areas where they are competent and should ensure separation of prescribing and administering or supply activities whenever possible.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis.

As with other circumstances when medicines are prescribed, supplied and administered, there must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products. Evidence of consent should be obtained, where appropriate.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the Northern Ireland cancer network. In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSC(SQSD)61/2008

In accordance with legislation patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Examples of Verification

- Staff groups are subject to regular qualification and registration checks.
- Training and development plans for all staff and training records
- Pharmacy technician/assistant "top-up" service
- There is a policy in place that includes an assessment checklist to support the use of patient's own drugs (POD) if applicable
- Protocol(s) for communication and transfer of patient information relating to medicines, prescribing and medication history
- There is an agreed protocol to assess patients' suitability for self-administration of medicines, which documents informed consent to participate if applicable.
- Robust procedures in place for the procurement and use of unlicensed medicines
- Compliance with Northern Ireland Chemotherapy Service Standards 2006
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- Training records for all staff involved in the administration and management of medicines which confirm that staff are appropriately trained
- Audit of prescriptions and treatment cards (e.g. using ward / clinical pharmacist intervention records).
- Responsible pharmacist records for registered pharmacies
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- There is a suitable policy / procedure in place for dealing with discrepancies in reconciliation of stock:

  The policy should include when to involve
  - external organisations
  - pharmacy destruction records where appropriate

Links with other Standards
Health and Safety
Human Resources
Medical Devices and Equipment
Information Management
Risk Management

CRITERION 8

Destruction or otherwise disposal of medicines no longer required is carried out by appropriately authorised, qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- Environmental Protection Act 1990 (c. 43) The Stationery Office, London
- HTM 07-01 (Northern Ireland) The 'Safe Management of Healthcare Waste'
- The Hazardous Waste Regulations (Northern Ireland) 2005 (SR 2005/300)

Other Reading

- Guidelines for Medicine Donations (WHO) 3rd edition (2010 Pub Oct 2011)

Guidance

A number of principles should be adopted when disposing of medicines:

- Witnessed accountability
- Secure transit
- Protection of personnel
- Protection of the environment
- Adequate documentation
- Legally authorised persons to carry out and, where necessary, witness the destruction
- Adherence to legislation
- Denaturating methods which adhere to professional guidance

Producers of healthcare waste including medicinal waste must undertake an assessment to determine the classification of waste to ensure that they comply with the necessary regulatory requirements including the Hazardous Waste Regulations. This assessment will allow the segregation of waste to allow appropriate transport and disposal. Further guidance on the management of healthcare waste is provided in HTM 07-01 The safe management of healthcare waste available on the publications area of the DHSSPS website at www.dhsspsni.gov.uk.

Examples of Verification

- There is a written policy relating to the safe disposal of medicines
- Staff are aware of, and have access to the organisation's policy
- Methods of destruction follow locally agreed procedures but they must take into account national guidance when appropriate
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)

Links with other Standards

Environmental Management
Health and Safety
Information Management
Waste Management

CRITERION 9

Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE(OCE)1/97.

Source

- Ionising Radiations Regulations 1999. Approved Code of Practice and Guidance. The Stationery Office, London. ISBN 071761-7467 HSE Books
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI 1978 No 1006 The Stationery Office, London as amended
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London and relevant amendments
- The Radioactive Substances Act 1993 (c. 12) The Stationery Office, London
- Radioactive Substances Act 1993 (Amendment) Regulations (Northern Ireland) 2011
- MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2014 – Pharmaceutical Press
- Circular HSSE (OCE) 1/97 Aseptic Dispensing in HPSS Hospitals
- Pharmaceutical Isolators: A guide to their application, design and control. Pharmaceutical Press, 2004 ISBN 0 85369 5733
- Quality Assurance of Aseptic Preparation Services A.M. Beaney (4th Edition) Pharmaceutical Press, October 2005 ISBN 0 85369 6152
- HC (76) 9 Report of the working party on the addition of drugs to intravenous fluids Department of Health and Social Security, 1976.
- Chief Pharmaceutical Officer Letter (CPh3/03) Aseptic dispensing in HPSS hospitals. DHSSPS.
- Chief Pharmaceutical Officer Letter (CPh (1/95) Aseptic Dispensing for NHS Patients Farwell J. [Farwell report]. London: Department of Health; 1995.
- Chief Pharmaceutical Officer Letter 31 May 2012 Improving practice and reducing risk in the provision of parenteral nutrition for neonates and children: Report of the Paediatric Chief Pharmacists Group November 2011

Other Reading

- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources (March 2006) as revised. Administration of Radioactive Substances Advisory Committee (ARSAC)
- Medical and Dental Guidance Notes A Good Practice Guide on all Aspects of Ionising Radiation Protection in the Clinical Environment prepared by the Institute of Physics and Engineering in Medicine. ISBN 1903613 09 4
- Quality assurance of radiopharmaceuticals. Joint working party of the UK Radiopharmacy Group and the NHS Pharmaceutical Quality Assurance Committee April 2012
- Responsibilities of Chief Pharmacists for the purchase and supply of radiopharmaceuticals UK Radiopharmacy Group and NHS Pharmacy QA Committee 2009

- Guidelines for the provision of radiopharmacy services in the UK Report of a working group of the BNMS Radiopharmaceutical Sciences Group and the UK Radiopharmacy Group March 2012
- Northern Ireland Chemotherapy Service Standards 2006
- Pharmaceutical Resource for Oncology in Northern Ireland, Report of the RMSC working group (2003)
- National Occupation Standards for Chemotherapy Skills for Health 2011
- NCEPOD report. Systemic Anti-Cancer Therapy: For better, For worse (2008).
- NCEPOD report: Parenteral Nutrition: A Mixed Bag (2010).
- NCAG report: Chemotherapy Services in England. Ensuring quality and safety. Aug 2009.
- Guidelines for the safe prescribing, handling and administration of hazardous drugs NICaN September 2009.

Guidance

The Medicines Act 1968 allows HSC hospital pharmacies to carry out aseptic preparation without a manufacturer's licence, if the activity is under the supervision of a pharmacist and in accordance with a prescription given by a practitioner.

Unlicensed aseptic dispensing facilities in hospital pharmacies should undergo regular inspections every 12-18 months in accordance with National Guidelines. The inspections are carried out by the Regional Pharmaceutical Quality Assurance Service. The results of the inspections should be made known to the trust Chief Executive and those commissioning health services so that standards are maintained. There should also be a programme of regular internal audit.

There should be a programme of capacity planning for equipment and staff.

Aseptic dispensing is an increasing and demanding activity. Extant guidance indicates that it should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors sometimes associated with the preparation of parenteral medication at ward level.

Radiopharmaceutical dispensing activities, in addition, must take into account the registration of open sources by the Environment Agency, additional training requirements for staff, the radiological implications for staff and a prospective programme for quality assurance of products.

Verification that users of radiopharmaceuticals are authorised to do so must be sought prior to use. Where products are transported to other sites, proper packaging and the services of a safety adviser must be employed. Radiopharmacies should be licensed unless operated under the direct supervision of a pharmacist.

Examples of Verification

- Policy
- Regular internal and external audit reports to Professional leads and Organisations together with progress on follow-up
- Staff skill mix and competence assessed
- Capacity plan
- Error/near miss reporting in place
- Robust systems in place for high risk procedures e.g. vinca alkaloids and intrathecal injections
- Range of products prepared linked to risk assessment of hospital usage of intravenous products
- Records of appropriate training
- SOPs are present, suitable, comply with all relevant legislation and are reviewed in accordance with GMP guidance (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Copies of the Radioactive Substances Act regulations authorisation from the Environment Agency for storage and disposal of radioactive materials
- COSHH assessments
- Radiation exposure monitoring of staff
- Certification of clinicians under the Medicines (Administration of Radioactive Substances) Regulations 1978 (Commonly referred to as "ARSAC" certificates)

Links with other Standards

Infection Control
Human Resources
Health and Safety
Medical Devices and Equipment

CRITERION 10

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

Source

- Statutory Instrument 2004/1031 The Medicines for Human Use (Clinical Trials) Regulations 2004
- Statutory Instrument 2006/1928 The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- Statutory Instrument 2008/2984 The Medicines for Human Use (Clinical Trials) Amendment (No. 2)Regulations 2006
- Statutory Instrument 2008/941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008
- The Medicines for Human Use (Miscellaneous Amendments) Regulations SI 2009 1164
- EU Directive 2001/20/EC. Good Clinical Practice in Clinical Trials
- EU Directive 2005/28/EC. Good Clinical Practice
- Clinical Trials Research Governance Framework for Health and Social Care R&D Office DHSSPS Dec 2006
- Eudralex - The Rules Governing Medicinal Products in the European Union, Vol 4, EU Guidelines to Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use, Annex 13 Investigational Medicinal Products
- Guidance on Good Clinical Practice and Clinical Trials (2006), Department of Health, London
- Professional Guidance on Pharmacy Services for Clinical Trials - National Pharmacy Clinical Trials Advisory Group October 2013

Other Reading

- The International Committee on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice 2006. www.emea.europa.eu
- Clinical Trials Toolkit - a comprehensive resource for practical help in meeting requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and the EU Clinical Trial Directive. www.ct-toolkit.ac.uk
- Good Clinical Practice for Trials on Medical Products in the European Community, 111/3976/88-EN Final, Office for Official Publications of the European Community.

Guidance

All clinical trials involving medicines must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 SI 2004/1031 as amended. The regulations can be found at http://www.mhra.gov.uk. The key points relating to medicines are included in Parts 5, 6, and 7 of these regulations.

Key points include:

- A suitably trained and competent pharmacist designated as responsible for clinical trials supplies
- Responsibility of the pharmacist to ensure that the authorisation certificate is in place before the trial starts
- Active participation in the Trust research governance processes
- Pharmaceutical review of the clinical trial protocol
- Ordering, storage and dispensing in accordance with the requirements of 'Good Clinical Practice for Trials on Medical Products in the European Community' and the guidelines provided in the revised Duthie Report.
- The manufacture, assembly or importation of Investigational Medicinal Products (IMPs) is carried out in accordance with a manufacturing authorisation (MIA (IMP)), granted by the licensing authority.
- Each production batch of IMP is checked and certified by a Qualified Person (QP) prior to release for use in a clinical trial.
- Stock accountability
- Access to trial protocols
- Reimbursement of pharmacy costs

Examples of Verification

- Training records for designated, competent staff trained in GCP
- Drug trial policy
- Approvals obtained from Ethics Committee, MHRA and Trust R&D committee including relevant approvals for any subsequent amendments..
- Records of receipt, dispensing and study administration and waste disposal to GCP standard
- Job description for the designated pharmacist
- Appropriate records of receipt, dispensing and stock reconciliation
- Evidence of Pharmacist involvement in:
    - Protocol development
    - Risk assessment
    - Documentation and designing of Standard operating procedures
    - Patient information
    - Secure Database of all the studies managed by the pharmacy department.

Links with other Standards

Health and Safety
Human Resources
Information Management
Research Governance
Risk Management
Waste Management

CRITERION 11

Arrangements for the management and use of controlled drugs comply with all legislative requirements, professional standards and good practice guidance and safeguard patients and the public.

Source

- The Misuse of Drugs Act 1971
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR 225
- The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 SR 1973 No 179 (as amended)
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR 2002 No 1 (as amended)
- Circular DH1/12/112169 30 April 2012 The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2012 - Controlled Drug prescribing by nurse and pharmacist independent prescribers
- Independent Review of the Management of Controlled Drug Use in Trust Hospitals - Regulation and Quality Improvement Authority June 2013
- The Data Protection Act 1998

Other Reading

- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) DHSSPS
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland) DHSSPS
- Safer Management of Controlled Drugs Guidance on Standard Operating Procedures for (Northern Ireland) DHSSPS
- DHSSPS *Good Management Good Records* (GMGR)
- Managing and Sharing Concerns

Guidance

The Chief Executive must ensure that, where applicable, an Accountable Officer (AO) is appointed within the organisation to secure the safe management and use of controlled drugs and that they are provided with sufficient resources to carry out their role. The AO has responsibility for ensuring, both throughout his organisation and for those services provided under arrangements with his organisation, that safe systems are established, covering all aspects of the management and use of controlled drugs (Schedule 1–Schedule 5).

Possession, storage, supply and record keeping of controlled drugs must meet the requirements of both the Human Medicines Regulations 2012 and the Misuse of Drugs Act and regulations made under the Act. Guidance is available in the BNF and BNF for children, professional standards, Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) and Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland).

There should be documented systems and procedures in place for all activities relating to controlled drugs, including patients' own drugs, which provide a clear audit trail.

The Accountable Officer should be made aware of each non-medical prescriber who is authorised to prescribe controlled drugs for services for which the Accountable Officer has responsibility.

Controlled drugs subject to safe custody requirements must be stored in lockable cabinets which meet or exceed the requirements of the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973. Electronic / automated storage facilities and access arrangements must be securely managed, regularly monitored and reviewed to ensure that unauthorised access does not occur and that log-on / passwords are user specific and compliant with organisational policy and best practice.

Any person required by the Misuse of Drugs Regulations (Northern Ireland) 2002 to keep records of Controlled Drugs in Schedule 1, 2 may only destroy these controlled drugs within these schedules in the presence of a person authorised for the purpose by DHSSPS Medicines Regulatory Group.

In addition, any person who is required to keep records for controlled drugs in Schedules 3 and 4 may only destroy these controlled drugs in the presence of an authorised witness. This would include any person manufacturing products containing Schedule 3 or 4 controlled drugs.

Under the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, the Accountable Officer must ensure that appropriate systems are in place to ensure the safe and effective management and use of controlled drugs, Schedules 1-5

The AO must have regard to best practice in relation to the management and use of controlled drugs including:

1. Securing the safe management and use of controlled drugs
2. Ensuring adequate destruction and disposal arrangements for controlled drugs
3. Ensuring monitoring and auditing of the management and use of controlled drugs
4. Ensuring relevant individuals receive appropriate training
5. Monitoring and audit the management and use of controlled drug by relevant individuals, and to monitor and assess their performance
6. Maintaining a record of concerns regarding relevant individuals
7. To assess and investigate concerns
8. Taking appropriate action if there are well-founded concerns

9. Co-operating by disclosing information as regards relevant persons
10. Submitting quarterly Occurrence Reports
11. Maintaining appropriate records of their actions in accordance with legislative requirements

Examples of Verification

1. Compliance with the RQIA Independent Review of the Management of Controlled Drug Use in Trust Hospitals June 2013.
2. SOPs covering all aspects of controlled drug activities are in place, suitable, accessible to relevant staff and compliant with all relevant legislation.
3. Schedule and evidence of monitoring by pharmacy and nursing staff to evaluate and document compliance with controlled drug SOPs
4. SOPs are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation).
5. Records of induction and ongoing staff training in the management and use of controlled drugs
6. The arrangements for reporting incidents is clearly described and understood by healthcare staff.
7. The Accountable Officer maintains a record of each non-medical prescriber who is authorised to prescribe controlled drugs.
8. Evidence of monitoring the management and use of controlled drugs by relevant individuals and assessment of their performance.
9. Evidence of actions taken to address system and practice deficiencies identified through controlled drug incidents and the results of monitoring.
10. There is a suitable policy / procedure in place for dealing with discrepancies in reconciliation of stock.
11. Evidence of timely reporting of controlled drug incidents (where appropriate) to relevant authorities including professional body, HSCB, Police and Medicines Regulatory Group (DHSSPS).
12. Quarterly Occurrence Reports are securely submitted by the Accountable Officer to the Chair of the Local Intelligence Network.
13. Evidence of attendance at Local Intelligence Network meetings by the Accountable Officer / Deputy.
14. Incidents relating to controlled drugs which raise concerns about a relevant person are reported by the Accountable Officer in a timely fashion in compliance with legislation and best practice.
15. Concerns relating to a relevant person are reviewed appropriately by the Accountable Officer and in accordance with legislation, best practice and local policy.
16. Declaration and Self–assessment form if requested by RQIA and DHSSPS

Links with other Standards

Information Management
Governance
Security Management
Risk Management
Waste Management

CRITERION 12

The organisation has an effective system for the management of defective medicinal products / devices and reports adverse incidents involving medicinal products and devices to the relevant agency and appropriately manages any subsequent required action.

Source

- Device Bulletin DB2010(NI)-01 (v.2.0) March 2013 revision Reporting adverse incidents and disseminating alerts
- Updated Guidance on Reporting Defective Medicines - Letter from CPO 18 Feb 2011
- HSCB/PHA Protocol for Implementation of Safety and Quality Alerts - August 2013
- Procedure for the Reporting and Follow up of Serious Adverse Incidents HSCB October 2013
- Company-led recalls Letter from CPO 21 November 2012

Other Reading

- Department of Health 2000, An Organisation With A Memory. Report of An Expert Group on Learning From Adverse Events in the NHS. The Stationery Office, London.
- Department of Health 2001, Building a Safer NHS for Patients. Implementing An Organisation With A Memory, Department of Health, London
- A Guide to Defective Medicinal Products – Reporting, Investigating and Recalling Suspected Defective Medicinal Products. MHRA
- Learning from Adverse Incidents and Near Misses reported by HSC organisations and Family Practitioner Services HSC (SQSD) 08/2010
- Early Alert system HSC (SQSD) 10/2010
- National framework for reporting and learning from serious incidents requiring investigation. Ref: 0974. March 2010

Guidance

Organisations must identify and learn from all patient safety incidents and demonstrate improvements in practice, based on local and national experience and from the information derived from analysis of incidents.

1. Adverse Drug Reactions

HSC organisations should encourage the prompt reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) of *any* suspected adverse

reactions due to "black triangle" drugs and any serious or unusual suspected reactions to established products. Staff should be aware of the process for reporting an adverse drug reaction and report suspected adverse reactions via the yellow card system.

2. Defective Products

a) Defective Medicinal Products

Adverse incidents arising from any medicinal product, thought to be defective, as opposed to incidents due to error, should be reported to the MHRA and Pharmacy Advice and Services Branch, DHSSPS in accordance with Updated Guidance on Reporting Defective Medicines - letter from the Chief Pharmaceutical Officer, 18 Feb 2011 DHSSPS.

b) Defective Medical Devices

Procedures should be established and maintained to ensure the prompt reporting of adverse incidents relating to medical devices to the Northern Ireland Adverse Incident Centre (NIAIC) to conform with the NIAIC Medical Device Alert
Device Bulletin Reporting adverse incidents and disseminating alerts DB2010(NI)-01 (v.2.0) March 2013 (revision)

Organisations should ensure that:

Defective medicinal products and devices

- Products are kept and, if necessary quarantined, until the option of investigating the incident has been dismissed.

DHPSS/MHRA Led recalls

- An auditable procedure is in place in primary and secondary care relating to the management of drug recalls.

3. Medication Incidents

The organisation should have a local, multidisciplinary, medication incident (prescribing, dispensing, and administration) reporting and monitoring system as part of the risk management system. Trusts should consider facilitating online reporting of medication incidents. Staff should ensure that both actual incidents and near misses are considered and that all serious incidents are managed in accordance with organisational policy and, where appropriate, subject of a root

cause analysis. These incidents should be analysed and recommendations considered for regional application where appropriate. The analyses should be used to inform the priorities of the Medicines Governance Team.

The best practice policies, safety memos and learning bulletins issued by the Northern Ireland Medicines Governance Team should be evaluated and implemented.

Examples of Verification

There are policies that outline:

1. Required and timely action taken in the event of a suspected defect with a medicinal product or device and staff are aware of the policies;
2. Response to drug alerts, including out of hours, with a named lead professional and annual audit of results from the system;
3. Prompt reporting and analysis of adverse medication incidents.
4. A pharmacist is nominated to co-ordinate the reporting of adverse incidents arising from any medicinal product / any action(s) resulting from a 'drug alert' letter
5. A Liaison Officer is nominated to co-ordinate the reporting of incidents / local dissemination of NIAIC safety warnings.
6. Regular reviews are undertaken to ensure the procedures are effective and are being followed.
7. Medication incidents should be promptly reported on the organisational incident reporting system and investigated appropriately
8. The organisation contributes to the regional analysis of medication incidents undertaken by the Northern Ireland Medicines Governance Team
9. Learning from incidents is utilised to develop and revise SOPs
10. The organisation implements best practice policies/safety memos/learning bulletins/guidance from the Medicines Governance Team and DHSSPS and HSCB
11. Record of those incidents investigated in more detail, including resulting action plans.
12. Minutes from the organisation's multi-professional management committees for medication incidents.
13. Induction/training schedule and content
14. Record of actions taken in response to a drug recall or alert

Links with other Standards
Health and Safety
Human Resources
Information Management
Medical Devices and Equipment
Risk Management

CRITERION 13

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Source

- Standards Australia Risk Management AS/NZS 4360:2004
- Establishment of an Early Alert system HSC (SQSD) 10/2010 28 May 2010
- Procedure for the Reporting and Follow up of Serious Adverse Incidents HSCB October 2013

Guidance

Risks should be systematically identified and recorded on a continuous basis. Risks associated with the safe and secure handling of medicines can be systematically identified using a number of approaches including:

- Control self assessment workshops
- Use of checklists
- Judgements based on experience and records
- Flow charts
- Systems analysis
- Scenario analysis
- And systems engineering techniques

Historic data, including adverse event data, medication incident reports, complaint and claim information, staff sickness/absence details can also be a valuable source of information to identify risk.

The following risk management elements should be in place:

- All identified risks should be documented as part of a 'risk register' and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented (in order of priority and alongside other risk treatments which are necessary to deal with wider risks faced by the organisation, where appropriate) in order to minimise risk.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed on a continuous basis.
- Senior management and the board should be informed of any significant risks and associated risk treatment plans.
- Upon induction all medical, nursing and pharmacy staff including those on fixed term contracts, and other relevant stakeholders should receive information and training on systems in place to minimise risks associated with the safe and secure handling of medicines.

Examples of Verification

- Risk Register
- Risk treatment plans
- Staff training/information log
- Induction schedule and content
- Correspondence with stakeholders
- Reporting mechanisms that inform risk management process
- Evidence of audit and monitoring of the management and use of controlled drugs
- Relationship with Risk Management Standard

Links with other Standards

Human Resources
Information Management
Risk management

CRITERION 14

The organisation, through the Head of Pharmacy and Medicines Management, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Guidance

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the DHSSPS.

As a minimum, the organisation should have access to the key references listed on the front page of this standard.

There should be appropriate mechanisms in place for the dissemination of information.

There are many sources of information on legislation and guidance on the safe and secure handling of medicines, including books and, through subscriptions to specialist information providers, CD-ROMs containing the full text and at http://www.legislation.gov.uk/. Up-to-date DHSSPS guidance can be accessed on the Internet on the DHSSPS website (http//www.dhsspsni.gov.uk). Equivalent NHS documents can be accessed via the Department of Health COIN database (http://www.doh.gov.uk). The Medicines and Healthcare products Regulatory Agency (http://www.mhra.gov.uk) contains some information. Full text copies of all legislation issued from 1 January 1997 can be downloaded from http://www.official-documents.co.uk, which contains information on UK official documents.

Wherever possible, the DHSSPS website www.dhsspsni.gov.uk/index/hss/governance/governance-controls.htm contains the relevant information pertaining to the development of controls assurance standards for Northern Ireland.

Examples of Verification

- Library
- CD-ROMs
- Internet access
- Cascade process chart

Links with other Standards

All standards

CRITERION 15

Adequate resources support the processes outlined in criteria 2 – 13 to ensure the safe, secure, cost effective and appropriate, use of medicines.

Source

- Managing Public Money NI A3.1 : Governance Statement **http://www.dfpni.gov.uk/index/finance/afmd/afmd-key-guidance/afmdmpmni/a.3.1_governance_statement.pdf**
- Circular HSS (PPM) 3/2002 – Corporate Governance: Statement of Internal Control
- Circular HSS (PPM) 8/2002 - Risk Management in the Health and Personal Social Services
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance
- NICE Technology Assessments and Clinical Guidelines endorsed by DHSSPS

Guidance

A fundamental element of the safe and secure handling of medicines is the need for all parts of the system to be adequately resourced with competent personnel and suitable facilities and equipment. In addition it is vitally important that there is strong collaboration across Primary and Secondary Care relative to the use of medicines. A range of NICE guidelines are endorsed by DHSSPS and communicated to HSC for implementation. The Pharmaceutical Clinical Effectiveness (PCE) Programme aims to achieve improvement in the quality and safety in the use of medicines and related pharmaceutical technology while delivering significant patient benefits and savings for the health service in Northern Ireland through influencing prescribing practices by both primary and secondary care medical staff. The programme has produced regional guidelines on procurement, prescribing, dispensing and monitoring, activities across HSC. Both NICE and PCE guidance have informed the contents of the NI Regional Formulary for primary and secondary care.

Examples of Verification

- Baseline data for services against standards
- Benchmarking
- CPD – Training budgets/staffing budget
- Audit – Critical incidents, facilities
- Capacity Planning
- Business Plan
- Review monitoring process to ensure that pharmacy remains adequately resourced
- Minutes of meetings of Drug and Therapeutics Committee or equivalent medicines management committee
- Document joint initiatives, policies etc.

- Audit of adherence to the NI Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors

Links with other Standards
Financial management
Medical Devices and Equipment
Risk Management

CRITERION 16

Key indicators capable of showing improvements in the safe, secure and cost effective handling and procurement of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Quality Standards for Health and Social Care – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

The organisation should develop indicators, which demonstrate that medicines are being safely and securely handled and risks are minimised. One indicator is degree of compliance with this standard. Ideally the indicators should be designed to demonstrate improvement in the performance of pharmacy services and staff prescribing and handling medicines over time. The number of indicators devised should be sufficient to monitor all aspects of the process, including risk management. It is not necessarily the case that the organisation will use all the indicators. The organisation should select those, which are useful for ensuring that the internal controls are working satisfactorily and medicines are being safely and securely handled.

Examples of Verification

1. Indicators
2. Evidence of usage at all levels
3. Audit of adherence to the Northern Ireland Medicines Management Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors

Links with other Standards

All standards

CRITERION 17

The system in place for the safe, secure and cost effective handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)
- Trading Medicines for Human Use: Shortages and Supply Chain Obligations

Guidance

It is the responsibility of management and the board to monitor and review all aspects of the system for the safe and secure handling of medicines, including:

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

The review should be carried out by individuals with the relevant knowledge and expertise of the safe and secure handling of medicines and should include review of any adverse incidents.

The committee with responsibility for risk management will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the board. The Audit Committee should review internal audit findings.

Examples of Verification

- Internal audit report(s)
- Audit Committee minutes
- Minutes of the board sub-committee(s) responsible for overseeing risk management and governance
- Declarations and self assessments

Links with other Standards

All standards

CRITERION 18

The board seeks independent assurance that an appropriate and effective system for the safe, secure and cost effective handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

Source

- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed, bearing in mind its timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the board.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of other bodies for example RQIA.

In addition, the HSC organisation will be subject to independent inspection by the DHSSPS Medicines Regulatory Group on those areas subject to statutory authority.

Examples of Verification

- Schedule of planned reviews
- Copy of report
- Committee minutes

- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff involved in the review

Links with other Standards

All Standards

MEMO

From the Permanent Secretary and HSC Chief Executive

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

From: Richard Pengelly

Date: 30 March 2018

To: ALB Chief Executives

Ref: RP2213

CC ALB Governance Leads
CAS Policy Leads

REVIEW OF CONTROLS ASSURANCE STANDARDS (CAS)

I wrote to you in August 2017 setting out the rationale for ceasing the Controls Assurance Standards (CAS) from 1 April 2018 with a view to providing more comprehensive and proportionate assurance to the Department.

Departmental Policy Leads have been engaging with their counterparts in the ALBs to ensure that suitable and proportionate assurance arrangements are in place for each of the standards from 1 April 2018. Where a slight delay is anticipated, appropriate contingency arrangements have been put in place.

Governance Leads in the ALBs have also been kept informed throughout this process and a further update will be shared with them on foot of this letter.

In future, proportionate assurance will be provided by ALBs to relevant policy leads in the Department. Where applicable, assurance will be provided in mid-year assurance/governance statements. The formal accountability process remains the vehicle for highlighting any exception issues.

This approach does not preclude you, as Accounting Officer, putting in place whatever arrangements you deem necessary in your organisation to provide you with assurance.

RICHARD PENGELLY

MAHI - STM - 089 - 4009

Review of Controls Assurance Standards – Update Report – March 2018

Medicine Management (MM)

Engagement with ALBs

Medicines Policy Group has engaged both face-to-face and by email with relevant ALBs and have developed a shorter, more streamlined version of the current Medicines Management CAS. This document focuses on the extant responsibilities of organisations to oversee delivery of Medicines Codes which support safe, effective practice and compliance with legislation. The review of CAS has been raised and discussed with representatives of the five acute HSC Trusts at the Strategic Leadership Group for Pharmacy (SLGP) and the initiative was welcomed. One to one engagement has also taken place with NIAS and NIBTS, who have indicated that the medicines management standard is no longer applicable to the organisation due to recent changes in use of medicines there. A workshop was held on 30 November 2017 to review the Medicines Management CAS, following which a draft document was prepared for circulation to stakeholders. Following feedback and incorporation of comments, an agreed version of the document will be discussed at an upcoming SLGP meeting on 26 March 2018.

Approach that will replace the CAS from 1 April 2018

Medicines Policy Group have produced a self-assessment checklist based on the MM standards criteria. Every year this checklist will be issued to HSC organisations by the Medicines Policy Group asking them to confirm that they are compliant with the standard. Failure to comply will necessitate an explanation outlining the relevant circumstances and detailing what remedial action is being taken to resolve the issue(s), including timeframes. The checklist will be signed by the Chief Executive in collaboration with the Director of Pharmacy and Medicines Management or equivalent.

Level of assurance required by the Department and how this will be provided

DoH will seek evidence of compliance annually through a self-assessment checklist (compliance will continue to be expressed as now, i.e. moderate/substantive). HSC organisations will have to maintain a portfolio of evidence and effective systems in order to demonstrate compliance with self-assessment and external audit. BSO will continue to externally audit the standards periodically, not more than once every 3 years.

Timescales

The updated medicines management standards will be issued to the relevant ALBs by 1 April 2018, with first returns of self-assessment paperwork to Medicines Policy Group due in March 2019. The finalised documents will be reviewed in February / March 2021 but may be amended/updated as needed to address changes in policy or legislation.

ICT

Engagement with ALBs

Engagement has taken place with the HSCB and BSO to agree an analysis/ suggested future approach in respect of the ICT CAS. This suggested approach has recently been communicated to all ALBs for consideration by 23 March.

Approach that will replace the CAS from 1 April 2018

It has been proposed that at present the Department still requires assurance on one of the criteria within the CAS – ICT Security and Information Governance. This reflects the current particular focus on cyber-security. This assurance currently comes to the Department through regular reports to TMG by the HSCB's Director of eHealth, Sean Donaghy. BSO are taking forward work to address cyber-security in the medium to long term and to recruit a cyber-security programme manager and SRO to develop a full regional approach. In view of this, and of the anticipated implementation of the *Network and Information Systems Regulations 2018* in May which will lead to the development of additional mechanisms for overseeing the security of Trust information systems, it is considered that the need for continued Departmental assurance on this issue should be reviewed in 2019.

Level of assurance required by the Department and how this will be provided

As above

Timescales

It is anticipated that the new arrangements will be in place by 1 April 2018.

Emergency Planning

Engagement with ALBs

The proposed revision of the Emergency Planning CAS was first raised with Emergency Planning Leads in the relevant ALBs in January 2016 through the quarterly Health Emergency Planning Forum (HEPF). This is a quarterly forum which is co-chaired by the head of Emergency Planning Branch (EPB) and the PHA Emergency Planning Lead. Representation includes all of the sector's Emergency Planning Leads. The forum allows engagement by the sector on a range of emergency planning issues.

The rationale behind the review and initial views from Emergency Planning Leads on the effectiveness of the existing CAS were sought at this meeting. Further discussions have taken place at HEPF meetings in September 2016, June 2017, October 2017 and January 2018 to outline the proposed approach that the Department plans to take in developing alternative arrangements.

A meeting was held with the Emergency Planning Leads of the PHA and the HSCB on 22 February 2018 to specifically discuss the Department's proposed revised CAS framework. The Emergency Planning leads expressed some concerns relating to the proposed new framework and it was agreed that a further meeting, to include representation from NIAS and NIFRS, should be held to discuss and finalise the framework.

Approach that will replace the CAS from 1 April 2018

The proposed revised methodology is based on the NHS England Core Standards Framework adapted to conform to Northern Ireland standards. It consists of a spreadsheet based approach. Each of the core standards will be listed and ALBs will be required to assess and report on their organisation's level of assurance against the specific core standards, based on the Evidence of Assurance examples provided.

In instances where full assurance cannot be confirmed, ALBs will be required to identify the action they propose to take to attain full compliance, together with lead responsibility and target completion dates. It is proposed that this will then assist ALBs to prioritise the remedial work required within their Emergency Preparedness Business Plan for the coming year. Completion of the revised CAS review for the following year will allow assessment of the extent to which the work programme has been achieved.

Level of assurance is required by the Department and how this will be provided

It is proposed that ALBs would provide completed spreadsheets to EPB and these would be used to assess the level of emergency preparedness across the HSC sector. It is anticipated that review of these would allow EPB to identify potential gaps, areas for more effective collaboration, sharing of good practice and better

enable provision of improved levels of support to further develop emergency preparedness and resilience.

Timescales

Due to staffing issues within EPB, work on the replacement for CAS has been delayed and there remains some work to be done before a final version of the new framework will be ready to be issued to ALBs. We will have a clearer idea of when new arrangements will be ready following the meeting with NIAS, NIFRS, HSCB and PHA, which is due to take place in April. It is our intention to have new arrangements in place by the end of June 2018.

During the intervening period, the Department will continue to hold quarterly HEPR meetings which will provide an opportunity for the Department to confirm with ALBs that work on Emergency Planning is being progressed as required.

Infection Prevention and Control (IPC)

Engagement with ALBs

The removal of the Infection Prevention and Control CAS has been discussed with the Assistant Director of Public Health (ADPH) for Health Protection in the Public Health Agency, and the Chair of the Infection Prevention & Control Lead Nurse Forum for Northern Ireland and both agreed that the IPC Controls Assurance Standards are outdated.

The ADPH is content with the proposed approach to replacing CAS, as set out below.

At operational level, PHA leads a Regional Healthcare-Associated Infections (HCAI) and Antimicrobial Resistance (AMR) Improvement Board, on which each Trust is represented.

At strategic level, the removal of CAS and the proposed alternatives will be considered in March by the Strategic Antimicrobial Resistance and Healthcare-Associated Infections Group (SAMRHAI), which is chaired by CMO. The membership of SAMRHAI includes representatives of PHA, of the Trust Medical Directors, of the Trust IPC nurses and of the Trust-based Antimicrobial Pharmacists' Network. SAMRHAI's Terms of Reference deliberately exclude any accountability function, and this enables candid sharing of information about any significant IPC or AMR issues that arise in the Trusts.

Approach that will replace the CAS from 1 April 2018

The key elements of these arrangements will be:

- surveillance of healthcare-associated infections and antimicrobial stewardship (AMS) in the Trusts, including
    - in-patient episodes of Clostridium difficile infection and MRSA, as per the ministerial targets that have been set since 2007;
    - surgical site infections;
    - bloodstream infections, including enhanced surveillance of Gram-negative BSIs (see below);
    - antimicrobial usage, in particular inappropriate prescribing of antibiotics, and
    - uptake of seasonal flu vaccination healthcare workers in each Trust;

- continuation of unannounced inspections of hospitals including hygiene inspections;

- monitoring by Trust Boards of ward-level compliance with NI-wide and local IPC policies, as evidenced by the RAG-rated IPC audit (two-page document) considered at each Trust Board meeting;

- continued engagement by Trusts with the Regional HCAI and AMS Improvement Board;

- monitoring by the Department of Early Alerts relating to outbreaks and suspected outbreaks, and the Trusts' responses to these, and

- use of Department-Trust accountability processes to raise any issues of concern directly with the Trusts. Health Protection Branch can advise on any such issues.

Level of assurance required by the Department and how this will be provided to the Department

Most of the arrangements described above are already in place. The Integrated Indicator is being developed and is expected to be operational during 2018/19.

PHA surveillance of HCAIs, AMR and antimicrobial usage (AMU) is rigorous and reliable. With regards to surveillance of healthcare-associated infections, each Trust has annual ministerial targets for reducing HCAIs, i.e. patient episodes of Clostridium difficile infection and MRSA. The targets are set taking into account the performance of peer groups consisting of comparable trusts in England. The Department receives monthly monitoring reports throughout the year.

In addition we have proposed that the 2018/19 Commissioning Plan Direction should include targets for reducing healthcare-associated Gram-negative bloodstream infections and for reducing inappropriate antibiotic prescribing. I have invited the HSCB leads for primary care, integrated care and commissioning to comment on the proposed targets.

Surveillance by PHA of HCAIs is much broader than the two organisms covered by the ministerial targets, and includes surgical site infections; bloodstream infections; Pseudomonas aeruginosa; ventilator-associated pneumonias; cannula-associated infections; catheter-associated infections; drug-resistance organisms; and antimicrobial usage (AMU) in Trusts.

As of 1 April 2018 there will be mandatory enhanced surveillance of the three most prevalent hospital-acquired Gram-negative bloodstream infections: *E. coli*, *Klebsiella species* and *Pseudomonas aeruginosa*. Trusts will be required to submit information about all cases of these infections and data about Trust antimicrobial use to the Public Health Agency. The enhanced surveillance will collect risk factor data, which will inform the Trusts' and PHA's future measures to reduce these infections.

The Early Alert system enables the Department to monitor serious and potentially serious incidents including outbreaks.

Regular reports from the General Register Office are provided to the Department giving, by Trust, numbers of deaths for which C. difficile or MRSA is mentioned as the main cause or a contributing cause.

RQIA inspections of hospitals including the rolling programme of unannounced hygiene inspections, will continue to assess the extent to which Trusts comply with NICE guidance and quality standards, in particular PH36 of November 2011 (http://www.nice.org.uk/guidance/ph36) and with environmental hygiene standards set by the Department.

Each Trust has a duty to provide their Non-Executive Directors (NEDs) with information about HCAIs in the Trust that is accurate, unambiguous, timely, relevant and presented clearly. For the purposes of Board-to-ward assurance within Trusts regarding HCAIs and AMR, the Department's 'Ten Elements' aide-mémoire specifies the following areas for a continuous monitoring: hand hygiene; clinical practice, in particular care bundles; dress, uniform and the use of personal protective equipment; antimicrobial prescribing; environmental cleanliness; water management; policies on visiting; IPC training for staff; diarrhoea risk assessment and isolation; MRSA screening and isolation; the use of escalation procedures for a potential or identified outbreak, including cohort nursing and the isolation of patients; and effective communications with patients and carers.

PHA has recently begun work on a survey to assess the strength of board-to-ward assurance in the Trusts in relation to PIC and antimicrobial stewardship.

Timescale

In respect of IPC and AMS, the arrangements described above provide more comprehensive and more reliable forms of assurance to the Accounting Officer than the IPC CAS and these arrangements are either already in place or will be operational from 1 April 2018.

Work is in hand to further strengthen surveillance of HCAIs and antimicrobial resistance, usage and stewardship and therefore strengthen the assurance that can be provided.

Food Hygiene and Environmental Cleanliness

Engagement with ALBs

Officials met with HSC patient environment policy leads in early November 2017 to agree an approach to the development of an alternative governance and assurance framework to the CAS. It was agreed that the Trusts would take this forward with support from the Department by setting up a working group at operational (Assistant Director) level to refocus the current standards and incorporate the full breadth of existing governance and control arrangements. Working groups were set up for each standard and have met several times since November to consider new arrangements and agree suitable evidence to support assurance statements.

Approach that will replace the CAS from 1 April 2018

The basic approach agreed for each standard has been to refocus the essential criteria and reduce these from 11 & 12 criteria to 5 or 6 key elements that support a central assurance statement. The process entails an annual Chief Executive Assurance statement commissioned by Investment Directorate. For food hygiene this will be:

Arrangements to provide appropriate assurance to senior management that appropriate governance structures, operational systems and procedures are in place for Food Hygiene and Safety.

For environmental cleanliness the assurance statement will be:

Arrangements to provide appropriate assurance to senior management that appropriate governance structures, operational systems and procedures are in place for environmental cleanliness

Level of assurance is required by the Department and how this will be provided

Underlying these statements will be ongoing evidence collection during the year to support routine statutory requirements as well as an annual Board paper and assurance statement. For Food Hygiene, evidence will be collated from existing systems and procedures required to support statutory food hygiene requirements leading to a small reduction in the level of overall administration required. It is expected that this process will form part of the routine HSC audit cycle and the frequency of audit will be dependent on risk rather than a set annual basis.

Timescales

The new arrangements will be communicated to the ALBs by the Department through new guidance which will be issued during April 2018.

Information Management (IM)

Engagement with ALBs

Information Management Branch (IMB) have been liaising with Information Governance leads in the Trusts and ALBs via Information Governance Advisory Group (IGAG) and have kept them appraised of the review of the IM CAS. At the IGAG meeting on 11th January 2018, IMB updated the group and the Head of Internal Audit (IA) in BSO on progress of the review of the IM CAS. The revised Information Management assurance documents comprise a guidance document and annual checklist which were shared with IGAG members and the Head of BSO IA following the meeting with comments requested by 20 February 2018. Further minor amendments have been made to the documents on receipt of comments. It is anticipated that finalised versions of the documents will be issued to IGAG colleagues for sharing within their organisations this week.

Approach that will replace the CAS from 1 April 2018

IMB has reviewed the IM CAS with a view to streamlining the process with assurance being sought at a higher level.

The current IM CAS has been revised to produce a shorter more focussed guidance document (Information Management Assurance Guidance) covering 6 broad categories of IM for HSC and BSO Internal Audit. HSC organisations will be required to maintain the best practice standards set out in this guidance document in order to be able to both provide assurance to the Department and for BSO Internal Audit purposes. The guidance document will be revised where necessary and issued every 2 years.

Although the ALBs will be asked to give assurance in the same areas as now they will not be asked to score for moderate or substantive compliance or provide written narrative or evidence to the Department. BSO Internal Audit will continue to audit HSC organisations' IM compliance on a periodic basis, as is currently the case.

The Department will also issue a checklist (Information Management Assurance Checklist – IMAC) every year to HSC organisations asking them to confirm that they are maintaining the best practice standards set out in the guidance document. The checklist is based on the broad categories in the guidance document. The checklist will be signed by the CEX in collaboration with the SIRO and the PDG for each organisation.

Following feedback from the HSC, IMB staff have merged the checklist with the annual SIRO assurance statement to avoid duplication, which further streamlines the annual assurance processes around Information Management governance in the HSC. The separate SIRO assurance will not be required from 18/19 onwards. From 18/19 IG assurance will be sought via the IMAC.

Level of assurance required by the Department and how this will be provided

The Department requires a high level annual assurance from ALBs that they carrying out their obligations in relation to Information Governance which ensures the organisation can maintain information in a manner which effectively services its needs and those of its stakeholders in line with appropriate legislation.

It is for each organisation, as legal Data Controller, to satisfy itself that it has all the necessary processes and procedures in place to manage any risk to the information. If not managed and if data breaches occur under the General Data Protection Regulation, (GDPR) which comes into force on 25 May 2018 and the new Data Protection Act 2018 (which is currently in Bill form and being progressed), the organisation could incur significant fines; it could also contribute to failure to deliver safe care to service users which could result in legal action.

Timescales

IMB anticipates issuing the finalised documents to IG colleagues in the HSC for further dissemination within their organisation later this week, therefore, the new arrangements will be in place for 1 April 2018. The documents will then be reviewed in February/March 2020.

Procurement

Engagement with ALBs

A finance circular has been drafted and was discussed at Regional Procurement Board in October 2017 which would illustrate some basic criteria for good control over the commissioning cycle for the benefit of Accounting Officers. DoH would leave it to HSC organisations and Accounting Officers to decide when and how they assure themselves of sufficient controls in this area. However, the circular would make having continuous improvement plans, and an internal forum to monitor those, key minimum structures within the control environment in larger purchasing organisations. This is not significantly different from the key structures in place at present, instead it provides smaller bodies with more discretion with respect to structures and makes it clear that AOs must judge the efficacy of their own systems.

In November a letter was issued by Neelia Lloyd, Finance Director, to the ALB Chief Executives to consult on the draft finance circular, comments have been taken on board and changes made, further consultation was engaged in with a narrower range of bodies to check the final drafting.

Approach that will replace the CAS from 1 April 2018

To replace the Purchasing Controls Assurance Standard the intention is to provide very brief guidance and examples on control over the commissioning cycle via a finance circular, which does not try to reproduce existing rules or guidance applicable to the whole public sector. The assurances provided at mid-year and end year will become slightly more detailed.

It is the view of DoH that, at this time, the achievement of best practice in the commissioning cycle needs to be given continual consideration, given the size of procurement spend in its sponsored organisations. Therefore particular structures to support control should be consistently in place as a minimum where the sponsored organisation concerned has significant purchasing spend. The circular suggests that all HSC Trusts, NIFRS, NIAS, PHA and HSCB should:

a) Constitute a Procurement Board which reports to their Audit and Risk or equivalent Committee. The role of that Board will be to assist the Finance Director, as the official with responsibility for good financial management under MPMNI, to, inter alia, provide assurance to the Accounting Officer, Board and Audit Committee on control, on law, policy and best practice compliance and on continuous improvement in relation to non-payroll expenditure. Its standing members should include staff drawn from areas where responsibility is delegated from either of the CoPEs and PaLS. Other relevant officials including CPD HP representatives should attend as required.
b) Constitute an organisational Procurement Action Plan for each year accommodating regional initiatives and adding on local considerations. This should consider relevant issues including compliance with law and policy, regional policy changes, efficiency and savings initiatives as well as

identifying and addressing local areas for improvement. Such plans should address all non-payroll related elements of the commissioning cycle.

c) Maintain a statement of their strategy on procurement.

While the high level criteria will remain, these are currently examples, as is the ToR for Procurement Boards.

Level of assurance required by the Department and how this will be provided

The assurances required by DoH from individual ALBs will be provided through the in-year and annual signoffs on assurance statements. We propose that the Department seeks a replacement generalised assurance terms of each ALB having proper controls to enable it to comply with standards, policies, law and guidance. This would deal with procurement compliance and NIPPP and other CAS standard topics. The four year MSFM signoff will also support ongoing assurance. Any big issue with procurement would be a big control issue which would lead to it being described in the end and mid-year statements.

Timescales

We are currently working on final review points from Finance Director to enable issue of the circular. Therefore we will ensure the necessary guidance is in place for 1 April 2018. Some organisations will have a new governance structure. They have been on notice about that since last November, but we will particularly draw this to their attention when the circular issues. We have provided Corporate Management Directorate with changes to the Mid Year Assurance Statement and year end statement and are advised that changes to the Mid Year Assurance Statement and year end signoffs will be processed into changes to manuals nearer to the time these need to be signed in the autumn.

Financial Management

Engagement with ALBs

Finance Directorate has engaged with Assistant Finance Directors in the HSC and BSO Internal Audit in a series of meetings on the future of the Financial Management CAS.

Approach that will replace the CAS from 1 April 2018

All ALBs are required to comply with legal and policy drivers including Managing Public Money and NIGEAE. Specific arrangements for each ALB are set in the organisation's Management Statement/Financial Memorandum. The current Financial Management framework encompasses structured monitoring and reporting systems and professional teams with multi-level input from the Department, BSO internal Audit, Audit committees and the NIAO. In light of this the Department considers that the Finance CAS is duplicative and there is sufficient existing mechanisms that provide the Department with appropriate assurance on financial management.

Level of assurance required by the Department and how this will be provided

Assurance to the Department will be provided through the existing mechanisms described above, including the mid-year assurance statement and Governance Statement. The formal accountability process remains the vehicle for escalation of any exception issues.

Timescale

This proposed approach has been discussed with Assistant Finance Directors and BSO IA but will shortly be formally communicated to Chief Executives. ALBs will have the opportunity to provide feedback with a view to having the proposed approach agreed by June 2018. Given the existing assurance mechanisms in place we do not foresee any risks associated with this short delay.

Human Resources

Engagement with ALBs

Engagement with HR Directors has already taken place at HRD Forum to secure commitment to the proposed approach.

Approach that will replace the CAS from 1 April 2018

It is proposed that ALBs would continue to use the existing HR CAS for the purposes of providing the Director of Workforce Policy with an end year assurance statement for 2018/19, as a transitional arrangement.

The transitional arrangement would provide an opportunity for HSC HR Directors to work with the Department to revise the standard, bringing it in line with the Workforce Strategy.

Level of assurance required by the Department and how this will be provided

An annual assurance statement to be provided by the ALBs to the Director of Workforce Policy.

Timescales

Transitional arrangements as described for 2018/19. From 2019/20, the updated standard would be the basis of annual assurance statements to be provided by ALBs.

Health & Safety

Engagement with ALBs

Workforce Policy Directorate coordinated a piece of work to revise and update the Health and Safety CAS in 2016/17 through the Regional Health & Safety Group.

Approach that will replace the CAS from 1 April 2018

It is proposed that ALBs would continue to use the revised standard and self-assessment for the purposes of providing the Director of Workforce Policy with an end year assurance statement for 2018/19, as a transitional arrangement.
The transitional arrangement would provide an opportunity for the Regional Health and Safety Group to assess ISO standard 45001 (Occupational health and safety management systems), due to be published by April 2018, as a potential standard for assessment from 2019/20. If accepted, it would be for each Trust to decide whether to proceed with an attempt to gain accreditation to the standard but those who did not would still be able to measure against it.

Level of assurance required by the Department and how this will be provided

The Director of Workforce Policy would continue to receive assurance statements from ALBs on the basis of how they measured against the standard.

Timescales

Transitional arrangements for 2018/19 as described above with new arrangements in place for 2019/20.

Security Management

Engagement with ALBs

Workforce Policy Directorate has been co-ordinating a piece of work with Regional Security Management representatives across the HSC to refine the existing CAS criteria. An updated draft has been shared with these representatives as well as smaller ALBs for consideration and any input.

Approach that will replace the CAS from 1 April 2018

It is proposed that the refined standard would form the basis of annual assurance statements to be provided by ALBs to the Director of Workforce Policy from 2018/19.

Level of assurance required by the Department and how this will be provided

An annual assurance statements to be provided by ALBs to the Director of Workforce Policy from 2018/19.

Timescales

Transitional arrangements for 2018/19 as described above with new arrangements in place for 2019/20.

Buildings, Land and Plant; Decontamination of Medical Devices; Environmental Management; Fire Safety; Fleet and Transport Management; Medical Devices and Equipment; and Waste Management

Engagement with ALBs

Active engagement has taken place with ALBs covering the initial exploration of potential options to replace the controls assurance standards. The proposed governance frameworks and assurance process will only apply to HSC Trusts and we are therefore content that we have engaged as appropriate.

Approach that will replace the CAS from 1 April 2018

We proposed that the current governance and accountability process should continue to be supported by an appropriate assurance reporting mechanism to the Department covering aspects of these specialist areas through submission of an annual assurance report comprising an explanatory narrative covering identified gaps in assurance.

The narrative was intended to provide sufficient information on the major operational risks that are impacting on compliance levels and actions being taken to manage those risks. This is to enable an informed review of HSC risk management in these operational areas to be undertaken and allow for appropriate escalation, if necessary, through the established accountability arrangements.

It was proposed that the governance frameworks would be developed under the following three main themes:

- **Environmental Governance Framework** – Amalgamation of the Waste and Fleet Transport Standards together with the Environmental Standard to form a composite governance framework covering the key environmental management aspects of each. This fits with our responsibility for sustainable development matters.

- **Medical Device Management Framework** – Amalgamation of the Decontamination and Medical Device Standards to form a medical device management governance framework covering the key medical device and decontamination management aspects of each.

- **Estates Infrastructure Safety Framework** – Amalgamation of Fire Safety standard together with the life-critical engineering infrastructure management aspects of the Buildings, Land and Plant standard to form a composite governance framework covering the key safety aspects of each. The content in relation to Fire Safety will be commensurate with the focus on fire safety following the Grenfell Tower fire.

However, following further engagement with Trust Governance Managers, it has become clear that managers in HSC Trusts responsible for specific operational areas value the Controls Assurance Standards as their checklist for compliance and wish for the proposed new frameworks to replicate the standards in terms of criteria.

Feedback however suggests that the existing process offers limited oversight or challenge to actual risk assessment at an operational level. This would support our view of the CA process as not now being fit for purpose with the process being used as a tick box/checklist rather than a meaningful governance and assurance tool.

This has required a reassessment of our proposed approach as it was not intended to replicate the controls assurance standard criteria in the new frameworks. Should the Trusts consider that they require this level of detail then we have made it clear that they remain free to utilise the standards as their assurance framework however the Department will have no role in maintaining the standards.

The framework will now be restricted to a number of key prompt questions for consideration by HSC Trusts to determine what level of detail they need to consider to obtain an appropriate level of assurance that risks are being assessed, managed and that planning is in place across the framework areas.

Level of assurance required by the Department and how this will be provided

From April 2018 the requirement for reporting compliance levels with the individual Controls Assurance Standards for which we are responsible either as policy lead or DoH lead will cease however we will be seeking a statement of assurance in the mid-year assurance and Governance statements from HSC Trusts covering the three frameworks as outlined. In line with the established governance and accountability processes, we would seek HSC Trusts to outline any significant control divergences in their assurance statements and the assurance statement templates will require to be amended to reflect this position.

A draft assurance statement covering these points is provided as follows:

Environmental, Medical Device Management and Estates Infrastructure Safety Governance

In respect to Environmental, Medical Device Management and Estates Infrastructure Safety Governance, I confirm that my organisation has controls in place to enable it to meet the requirements of all extant statutory obligations upon it, that it complies with all standards, policies and strategies set by the Department and all applicable guidance set by other parts of government. Any significant control divergences are reported below together with an outline of action plans in place to address these divergences.

Timescale

The arrangements as outlined can be put in place by 1 April 2018 however we are arranging a further engagement session in April 2018 with HSC Trust Governance Managers together with a number of Trust operational managers to fully clarify the Department's position and seek agreement on the key prompt questions.

HSC Trust Governance Managers have acknowledged that new arrangements do not need to be in place by 1 April 2018 given that their assurance process was undertaken throughout the assurance assessment and reporting cycle. However,

clarity on the level of assurance to the Department and what form this should take would be welcomed as soon as possible after 1 April 2018.

Governance and Risk Management

Engagement with ALBs

Corporate Management Directorate has been engaging with ALB Governance Leads. On 11 September 2017 a letter was sent to ALB Governance Leads setting out the proposed way forward and the approach received support from ALB governance leads at a meeting in October 2017.

Approach that will replace the CAS from 1 April 2018

Existing governance and accountability tools provide the Department with appropriate assurance on governance and risk management namely –

- Accountability process and sponsorship function;
- Board Governance Self-Assessment Tool;
- Assurance Framework;
- Mid-Year Assurance and Governance Statement;
- Independent assurance – BSO Internal Audit/RQIA; and
- Management Statement/Financial Memorandum.

Level of assurance required by the Department and how this will be provided

As above.

Timescales

These arrangements are already in place.

Research Governance

Engagement with ALBs

This work has been led by Professor Young and Dr Janice Bailie from the HSC R&D Division in the PHA. R&D Directors in the ALBs have been involved in discussions on the proposed way forward.

Approach that will replace the CAS from 1 April 2018

The existing CAS will be replaced by a new reporting tool. This tool will be a more appropriate reporting mechanism and will facilitate benchmarking with the UK. R&D Directors are currently gathering metrics for the new tool.

Level of assurance required by the Department and how this will be provided

The level of assurance required by the Department will be determined when the new tool has been developed.

Timing

Due to staffing issues in the R&D office, the development of a new tool has been delayed to September 2018. HSC organisations are familiar with and compliant with best practice in this area so it is unlikely that there will be any governance issues for the Department associated with a delay. Dr Bailie has undertaken to alert the Department to any exception issues that arise as the new tool is developed.

From the Chief Pharmaceutical Officer
Dr Mark Timoney

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

BY EMAIL

Castle Buildings
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BELFAST
BT4 3SQ
Tel: [redacted]
Email: [redacted]
Ref: HE1/18/72344
Date: 5 April 2018

Heads of Pharmacy and Medicines Management, HSC Trusts

Dr Nigel Ruddell, Interim Medical Director, NIAS

Dear Colleague,

DISCONTINUATION OF MEDICINES MANAGEMENT AND OPTIMISATION CONTROLS ASSURANCE STANDARD – NEW ARRANGEMENTS

As you will be aware Controls Assurance Standards were discontinued on 1 April 2018. Over recent weeks and months the Department has worked with colleagues across the relevant ALBs to ensure that suitable alternative, proportionate assurance arrangements are in place for the area of Medicines Management and Optimisation.

A shorter, more streamlined standard has been developed which focuses on the extant responsibilities of organisations to oversee delivery of Medicines Codes / Policies which support safe, effective practice and compliance with legislation. As before, HSC organisations will be required to maintain a portfolio of evidence and effective systems in order to demonstrate compliance with self-assessment and for external audit.

Medicines Policy Group at the Department will seek assurance of compliance with the revised standards from ALBs on an annual basis in the form of completion and return of a self-assessment checklist, with first returns for 2018/19 due to the Department in March 2019. The self-assessment checklist should be completed and signed by the relevant individual with responsibility for Medicines Management and Optimisation

within the organisation. Completed and signed self-assessment checklists should be returned by email to [redacted]

Achieving full compliance with the agreed standards is critical in ensuring that suitable and proportionate assurance is in place for medicines management, and so it will be important that in areas where standards are not being met that full explanation and details of remedial actions and timeframes are identified and actioned.

The revised standards will be reviewed in February / March 2021 but may be amended as needed to address any changes in policy or legislation.

Yours sincerely

DR MARK TIMONEY

Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

www.dhsspsni.gov.uk

The Quality Standards for Health and Social Care

SUPPORTING GOOD GOVERNANCE AND BEST PRACTICE IN THE HPSS

March 2006

FOREWORD BY THE MINISTER

The people of Northern Ireland are entitled to the highest standards of health and social care. Having standards in place to ensure that people have the right care wherever they live in Northern Ireland is a fundamental principle of reform and modernisation of the health and social care system.

I am committed to putting patients, clients and carers first. The *Quality Standards for Health and Social Care* set out the standards that people can expect from Health and Personal Social Services (HPSS). In developing these standards, my aim is to raise the quality of services and to improve the health and social wellbeing of the people of Northern Ireland. At the heart of these standards are key service user and carer values including dignity, respect, independence, rights, choice and safety.

The standards have five key quality themes:

- Corporate leadership and accountability of organisations;
- Safe and effective care;
- Accessible, flexible and responsive services;
- Promoting, protecting and improving health and social well-being; and
- Effective communication and information.

The publication of the quality standards is an important milestone in the process of putting patients first. They will be used by the new Regulation and Quality Improvement Authority to assess the quality of care provided by the HPSS. The new Authority will be looking to see how the HPSS provide quality services and will be reporting their findings both to the Department and to the public.

Given the rapidly changing environment in which the HPSS now operates including changes arising from the Review of Public Administration, it is important that these standards do not become outdated or serve to stifle innovation. Therefore, the standards will be reviewed by the end of 2008.

SHAUN WOODWARD MP
Minister for Health, Social Services and Public Safety

CONTENTS PAGE

Section 1: Introduction to the Development of Standards

1.1 Introduction

Almost 95% of the population of Northern Ireland makes contact with health and social services on an annual basis. This contact may be through primary care services, community care services or through hospitals. In all of these contacts, people are entitled to the highest standards of health and social care.

This document sets out clearly for the public, service users and carers, and those responsible for the commissioning, planning, delivery, and review of services, the quality standards that the Department considers people should expect from Health and Personal Social Services (HPSS). It represents a significant step in the process of placing the needs of the service user and carer, and the wider public, at the centre of planning, delivery and review of health and social care services.

1.2 Background to the development of standards

Quality improvement is at the forefront of the development of health and social care services in Northern Ireland. These improvements are centred around five main areas, which are an integral part of modernisation and reform:

- setting of standards – to improve services and practice;
- improving governance in the HPSS - in other words, the way in which the HPSS manages its business;
- improving the regulation of the workforce, and promoting staff development through life-long learning and continuous professional development;
- changing the way HPSS organisations are held to account for the services they provide; and
- establishing a new, independent body to assess the quality of health and social care.

The consultation document “Best Practice – Best Care”, published in April 2001, sets out the detail of this framework to improve the quality of care. This included links to national standard setting bodies such as the National Institute for Health and Clinical Excellence (NICE) and the Social Care Institute for Excellence (SCIE).

1.3 Improving governance in health and social care

The outcome of the Review of Public Administration, announced in November 2005, signalled major changes to the structure and functions of HPSS organisations. Regardless of these changes there remains a statutory duty of quality on HSS Boards and Trusts. This means that each organisation has a legal responsibility for satisfying itself that the quality of care it commissions and/or provides meets a required standard. This requirement is just as important as the responsibility to demonstrate financial regularity and propriety. Organisations must ensure that there are visible and rigorous structures, processes, roles and responsibilities in place to plan for, deliver, monitor and promote safety and quality improvements in the provision of health and social care. This process is known as *Governance*.

1.4 The setting of standards

In addition to drawing on national and professional standards, a range of local standards is being developed to enhance governance arrangements in the HPSS. These include controls assurance standards, so that by 2006-07, there will be a comprehensive set of specific assurance standards, which the HPSS can use to assess compliance against the required attainment levels. In addition, a number of care standards have been developed to facilitate the inspection and regulation of specific health and social care services provided by the HPSS and the independent sector. These care standards are specified in legislation and will be inspected, regulated and monitored by a new organisation called the Health and Personal Social Services Regulation and Improvement Authority (the Regulation and Quality Improvement Authority - RQIA).

The development of the *Quality Standards for Health and Social Care*, as outlined in this document, is intended to complement standards already issued or currently in development. Consequently, evidence of compliance with existing or new standards, such as professional standards, charter standards, controls assurance and/or care standards will form part of the evidence of practitioner or organisational commitment to these new quality standards.

1.5 What is a standard?

A standard is a level of quality against which performance can be measured. It can be described as ‘essential’- the absolute minimum to ensure safe and effective practice, or ‘developmental’, - designed to encourage and support a move to better practice. The *Quality Standards for Health and Social Care*, which are contained in this document, are classed as essential.

Given the rapidly changing environment in which the HPSS operates, it is important that standards do not become outdated or serve to stifle innovation.

To prevent this, standards need to be regularly reviewed and updated. It will be the Department's responsibility, drawing on the best evidence available, including advice, reports and/or information from the RQIA, to keep the quality standards under consideration, with a formal review being completed by the end of 2008.

1.6 Why are standards important?

Raising and maintaining the quality of services provided by the HPSS is a major objective for all involved in the planning, provision, delivery and review of health and social care services. Currently, there remains unacceptable variation in the quality of services provided, including timeliness of delivery and ease of access.

In order to improve the quality of these services, change is needed, underpinned and informed by a more cohesive approach to standards development.

Standards:

- give HPSS and other organisations a measure against which they can assess themselves and demonstrate improvement, thereby raising the quality of their services and reducing unacceptable variations in the quality of services and service provision;
- enable service users and carers to understand what quality of service they are entitled to and provide the opportunity for them to help define and shape the quality of services provided by the HPSS and others;
- provide a focus for members of the public and their elected representatives, to consider whether their money is being spent on efficient and effective services, and delivered to recognised standards;
- help to ensure implementation of the duty the HPSS has in respect of human rights and equality of opportunity for the people of Northern Ireland; and
- promote compliance, and underpin the regulation and monitoring of services to determine their quality and safety and to gauge their continuous improvement.

By promoting integration, these *Quality Standards for Health and Social Care* will contribute to the implementation of clinical and social care governance in the HPSS and will be used by HPSS and other organisations, service users and carers, the wider public and the RQIA to assess the quality of care provision.

1.7 The five quality themes

There are five quality themes on which the standards have been developed to improve the health and social well-being of the population of Northern Ireland. These themes have been identified through consultation with service users, carers and HPSS staff and through a review of standards developed elsewhere at local, national and international level.

The five quality themes are:

1. Corporate Leadership and Accountability of Organisations;
2. Safe and Effective Care;
3. Accessible, Flexible and Responsive Services;
4. Promoting, Protecting and Improving Health and Social Well-being; and
5. Effective Communication and Information.

1.8 Assessing quality

The RQIA was established by the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 and began work on 1 April 2005. It has two main functions:

- inspection and regulation of specified health and social care services provided by the HPSS and the independent sector; and

- inspection and review of the services provided by the HPSS in Northern Ireland.

The RQIA has a general duty to encourage improvements in the quality of services commissioned and provided by HPSS and other organisations. It will promote a culture of continuous improvement and best practice through inspection and review of clinical and social care governance arrangements.

The RQIA has taken over responsibility for the registration, inspection and regulation of providers of care, for example, residential care, nursing homes and day care facilities. On a phased basis, the RQIA will assume further responsibilities over the coming years, including reporting on the quality of care provided by the HPSS. Where serious and/or persistent clinical and social care governance problems come to light, it will have a key role to play, in collaboration with other regulatory and inspectoral bodies, in the investigation of such incidents. It will report on its findings to the Department and to the public.

1.9 How will the standards be used to measure quality?

The RQIA, in conjunction with the HPSS, service users and carers, will agree how the standards will be interpreted to assess service quality. It is envisaged that specific tools will be designed to allow the RQIA to measure that quality and to assist the HPSS in assessing themselves. Once developed, not only will these tools assess HPSS structures and processes but they will also contribute to the assessment of clinical and social care outcomes.

Whilst it is for the RQIA to provide guidance on what assessment methods it will use, it is recognised that collecting the evidence to demonstrate that relevant standards have been successfully achieved may be a time consuming process for the HPSS. Therefore, information that is currently compiled on existing standards will also be able to be used to contribute to the demonstration of achievement for these standards.

The RQIA will commence reviewing clinical and social care governance within the HPSS in 2006/07, using the five themes contained within this document. RQIA will report on the quality of care provided by the HPSS following its review. This approach will promote quality improvement across organisations.

Section 2: Values and Principles Underpinning the Standards

2.1 Introduction

There are three key premises, which underpin these quality standards and are central to all aspects of planning, provision, delivery, review and improvement of the HPSS. They are that:

- people in receipt of services should be actively involved in all decisions affecting their lives and should fully contribute to any planning for, delivery and evaluation of, services;

- clinical and social care governance in the HPSS must take account of the organisational structures, functions and the manner of delivery of services currently in place. Clinical and social care governance must also apply to all services provided in community, primary, secondary and tertiary care environments;

- service users and carers should be fully valued by HPSS staff who, in turn, should be valued by service users, carers and others.

2.2 The values underpinning the Standards

The quality of a service provided is dependent on managers and HPSS staff basing their practice on the following values and principles; these complement those already outlined in the care standards for independent agencies, establishments and certain other services provided by HPSS organisations.

They are:

DIGNITY AND RESPECT	The uniqueness and intrinsic value of the individual is acknowledged and each person is treated with dignity and respect. This is applicable to service users, carers, staff and others who come in contact with services.
INDEPENDENCE	A balance between the promotion of independence and risk taking is needed. Service users have as much control as possible over their lives. Service users are informed about risk whilst being protected against unreasonable risks.
PROMOTION OF RIGHTS	In the context of services delivered to them, the individual and human rights of service users are promoted and safeguarded. Where necessary, appropriate advocacy arrangements are put in place.
EQUALITY AND DIVERSITY	Equality of opportunity and positive outcomes for service users and staff are promoted; their background and culture are valued and respected.
CHOICE AND CAPACITY	Service users are offered, wherever possible, according to assessed need and available resources, the opportunity to select independently from a range of options based on clear and accurate information, which is presented in a manner that is understood by the service user and carer.
PRIVACY	Service users have the right to be free from unnecessary intrusion into their affairs and there is a balance between the consideration of the individual's safety, the safety of others and HPSS organisational responsibilities.
EMPOWERMENT	Service users are enabled and supported to achieve their potential in health and social well-being. Staff are supported and developed to realise their ability and potential.
CONFIDENTIALITY	Information about service users and staff is managed appropriately and everyone involved in the service respects confidential matters.
SAFETY	Every effort is made to keep service users, staff and others as safe as is possible. In all aspects of treatment and care, service users are free from exploitation, neglect or abuse.

2.3 The principles underpinning the Standards

The following principles are fundamental to the development of a quality service.

PUBLIC AND SERVICE USER INVOLVEMENT	The views and experiences of service users, carers, staff and local communities are taken into account in the planning, delivery, evaluation and review of services. Service users and carers, wherever possible, are involved in, and informed about, decisions made when they seek access to or receive services during their treatment or care.
SAFETY AND EFFECTIVENESS	Systems are in place to ensure that the safety of service users, carers, staff and the wider public, as appropriate, underpin all aspects of health and social care delivery. For example, the imperative to protect children and vulnerable adults may take precedence over the specific wishes of the service user and their carers. In addition, the protection of staff may need to be balanced with the specific wishes of service users, carers, families and friends. Quality systems are in place to enable staff to play a full and active role in providing effective and efficient health and social care services for all who use these services. Staff are fully supported, regularly supervised and appropriately trained and educated, to provide safe and effective health and social care services.
ROBUST ORGANISATIONAL STRUCTURES AND PROCESSES	Robust organisational structures and processes are in place, which are regularly reviewed to promote safe and effective delivery of care. Timely information is shared and used appropriately to optimise health and social care.
QUALITY of SERVICE PROVISION	Policies, procedures and activities are in place to encourage and enable continuous quality improvement. Service developments and provision are based on sound information and knowledge of best practice, as appropriate.

Section 3: Format of the Standards

3.1 The five quality themes

The five quality themes are applicable to the whole of the HPSS, including those services, which are commissioned or provided by HPSS organisations and family practitioner services. They are underpinned by the duty of quality on HSS Boards and Trusts. Where care is commissioned outside Northern Ireland, commissioners must ensure that the quality of care is commensurate with these and other associated standards.

The five quality themes, encompassing the standards, are set out in sections four to eight of this document. These are:-

- Corporate Leadership and Accountability of Organisations (Section 4);
- Safe and Effective Care (Section 5);
- Accessible, Flexible and Responsive Services; (Section 6);
- Promoting, Protecting and Improving Health and Social Well-being (Section 7); and
- Effective Communication and Information (Section 8).

3.2 Format of the standards

Each theme has a **title**, which defines the area upon which the standard is focused. Then, a **standard statement** will explain the level of performance to be achieved. The reason why the standard is seen to be important will be covered by the **rationale**. The standard statement will then be expanded into a series of **criteria**, which will provide further detail of areas for consideration by the HPSS and by RQIA.

Section 4: Corporate Leadership and Accountability of Organisations (Theme 1)

4.1 Standard Statement

The HPSS is responsible and accountable for assuring the quality of services that it commissions and provides to both the public and its staff. Integral to this is effective leadership and clear lines of professional and organisational accountability.

4.2 Rationale

The HPSS must provide effective leadership and a clear direction to make the most of its resources (people, skills, time and money), and to deliver high quality services to the public in as safe an environment as is possible. The aim is to ensure a competent, confident workforce and an organisation that is open to learning and is responsive to the needs of service users and carers. This will facilitate staff in the organisation to take individual, team and professional responsibility in order to promote safe, sustainable and high quality services. The organisation needs to maintain and further enhance public confidence.

4.3 Criteria

The organisation:

a) has a coherent and integrated organisational and governance strategy, appropriate to the needs, size and complexity of the organisation with clear leadership, through lines of professional and corporate accountability;

b) has structures and processes to support, review and action its governance arrangements including, for example, corporate, financial, clinical and social care, information and research governance;

c) has processes in place to develop leadership at all levels including identifying potential leaders of the future;

d) actively involves service users and carers, staff and the wider public in the planning and delivery, evaluation and review of the corporate aims and objectives, and governance arrangements;

e) has processes in place to develop, prioritise, deliver and review the organisation's aims and objectives;

f) ensures financial management achieves economy, effectiveness, efficiency and probity and accountability in the use of resources;

g) has systems in place to ensure compliance with relevant legislative requirements;

h) ensures effective systems are in place to discharge, monitor and report on its responsibilities in relation to delegated statutory functions and in relation to inter-agency working;

i) undertakes systematic risk assessment and risk management of all areas of its work;

j) has sound human resource policies and systems in place to ensure appropriate workforce planning, skill mix, recruitment, induction, training and development opportunities for staff to undertake the roles and responsibilities required by their job, including compliance with:

- Departmental policy and guidance;
- professional and other codes of practice; and
- employment legislation.

k) undertakes robust pre-employment checks including:

- qualifications of staff to ensure they are suitably qualified and are registered with the appropriate professional or occupational body;
- police and Protection of Children and Vulnerable Adults checks , as necessary;
- health assessment, as necessary; and
- references.

l) has in place appraisal and supervision systems for staff which support continuous professional development and lifelong learning, facilitate professional and regulatory requirements, and informs the organisation's training, education and workforce development;

m) has a training plan and training programmes, appropriately funded, to meet identified training and development needs which enable the organisation to comply with its statutory obligations; and

n) has a workforce strategy in place, as appropriate, that ensures clarity about structure, function, roles and responsibilities and ensures workforce development to meet current and future service needs in line with Departmental policy and the availability of resources.

Section 5: Safe and Effective Care (Theme 2)

5.1 Standard Statement

Safe and effective care is provided by the HPSS to those service users who require treatment and care. Treatment or services, which have been shown not to be of benefit, following evaluation, should not be provided or commissioned by the HPSS.

5.2 Rationale

A quality service is one which is safe, effective and sustainable. Diminished standards on safety reflect a poor quality of service. The provision of health and social care is complex and will never be one hundred percent error-free. However, more can always be done to avoid injury and harm to service users, from the treatment and care that is intended to help them. This is an integral part of continuous quality improvement. Services must be delivered in a way that appropriately manages risk for service users, carers, staff, the public and visitors. Where an adverse incident has occurred or has been prevented from happening (a near miss), then systems need to be in place to assist individuals and organisations to learn from mistakes in order to prevent a reoccurrence.

It is acknowledged, however, that in some situations, living with a risk can be outweighed by the benefit of having a lifestyle that the individual really wants and values. In such circumstances, risk taking can be considered to be a positive action. Health and social care staff need to work in partnership with service users and carers to explore choices and agree on how risk can be managed and minimised for the benefit of individual service users, carers, families and communities.

The promotion of safe care must be complemented by the provision of effective care. Care should be based on the best available evidence of interventions that work and should be delivered by appropriately competent and qualified staff in partnership with the service user. Systems and processes within organisations should facilitate participation in, and implementation of, evidence-based practice.

This theme of “Safe and Effective Care” has been subdivided into three areas:

- ensuring safe practice and the appropriate management of risk;
- preventing, detecting, communicating and learning from adverse incidents and near misses; and
- promoting effective care.

5.3 Criteria

5.3.1 Ensuring Safe Practice and the Appropriate Management of Risk

The organisation:

a) has effective person-centred assessment, care planning and review systems in place, which include risk assessment and risk management processes and appropriate interagency approaches;

b) acknowledges and promotes the central place that patients, service users and carers have in the prevention and detection of adverse incidents and near misses;

c) has policies and procedures in place to identify and protect children, young people and vulnerable adults from harm and to promote and safeguard their rights in general;

d) promotes effective interagency working in relation to raising awareness of the risk factors associated with abuse, including domestic violence and in the promotion of effective interagency responses;

e) has a safety policy in place which takes account of the needs of service users, carers and staff, the public and the environment; and

f) has properly maintained systems, policies and procedures in place, which are subject to regular audit and review to ensure:

- efficacy and comparability of outcomes in health and social care;
- compliance with professional and other codes of practice;
- effective and efficient procedures for obtaining informed consent for examination, treatment and/or care;
- accurate, timely and consistent recording of care given or services provided and associated outcomes;
- protection of health, welfare and safety of staff;
- awareness raising and staff knowledge of reporting arrangements for adverse incidents and near misses, and whistleblowing arrangements when poor performance and/or unsafe practice in examination, treatment or care comes to light;
- there is choice where food and/or fluid is provided, which reflects cultural and spiritual preferences and that procedures are in place to promote the safe handling of food and a healthy diet;

- safe practice in the selection, procurement, prescription, supply, dispensing, storage and administration of medicines across the spectrum of care and support provided, which complies with current medicines legislation;

- promotion of safe practice in the use of medicines and products, particularly in areas of high risk, for example:

    - intrathecal chemotherapy;
    - blood and blood products;
    - intravenous fluid management;
    - methotrexate;
    - potassium chloride; and
    - anticoagulant therapy.

- risk assessment and risk management in relation to the acquisition and maintenance of medical devices and equipment, and aids and appliances across the spectrum of care and support provided;

- promotion of general hygiene standards, and prevention, control and reduction in the incidence of healthcare acquired infection and other communicable diseases;

- appropriate decontamination of reusable medical devices;

- safe and effective handling, transport and disposal of waste, recognising the need to promote the safety of service users and carers, staff and the wider public, and to protect the environment;

- interventional procedures and/or any new methods undertaken by staff are supported by evidence of safety and efficacy;

- address recommendations contained in RQIA reports (when available), service and case management reviews; and

- participation in and implementation of recommendations contained in local or national enquiries, where appropriate, e.g. National Confidential Enquiries.

5.3.2 Preventing, Detecting, Communicating and Learning from Adverse Incidents and Near Misses

The organisation:

a) has systems and processes in place to prevent, identify, assess and manage and review adverse incidents and near misses across the spectrum of care and support provided;

b) promotes an open and fair culture, rather than one of blame and shame, to encourage the timely reporting and learning from adverse incidents and near misses;

c) has reporting systems in place to collate, analyse and learn from all adverse incidents, and near misses, share knowledge and prevent reoccurrence of adverse incident or near miss; and

d) has systems in place that promote ongoing communication with service users and carers when treatment or care goes wrong, and puts in place an individual care plan to minimise injury or harm.

5.3.3 Promoting Effective Care

The organisation:

a) provides relevant, accessible, information to support and enhance service user and carer involvement in self-management of their health and social care needs;

b) promotes a person-centred approach and actively involves service users and carers in the development, implementation, audit and review of care plans and care pathways;

c) promotes a culture of learning to enable staff to enhance and maintain their knowledge and skills;

d) ensures that clinical and social care interventions are carried out under appropriate supervision and leadership, and by appropriately qualified and trained staff, who have access to appropriate support systems;

e) uses recognised clinical and social care standards and outcomes as a means of measuring health and social care quality;

f) promotes the implementation of evidence based practice through use of recognised standards and guidelines including guidance from the Department, NICE, SCIE and the National Patient Safety Agency (NPSA);

g) has in place systems to promote active participation of staff in evidence based practice, research, evaluation and audit;

h) has systems in place to prioritise, conduct and act upon the findings of clinical and social care audit and to disseminate learning across the organisation and the HPSS, as appropriate;

i) provides regular reports to the organisation's executive and non-executive board directors on clinical and social care governance arrangements and continuous improvement in the organisation; and

j) promotes the involvement of service users and carers in clinical and social care audit activity.

Section 6: Accessible, Flexible and Responsive Services (Theme 3)

6.1 Standard Statement

Services are sustainable, and are flexibly designed to best meet the needs of the local population. These services are delivered in a responsive way, which is sensitive to individual's assessed needs and preferences, and takes account of the availability of resources.

Each organisation strives to continuously improve on the services it provides and/or commissions.

6.2 Rationale

To meet the needs of local communities and to narrow inequalities in health and social well-being, services should take account of the current and anticipated needs of the local community. Service users, carers, front line staff and the wider public should be meaningfully engaged in all stages of the service planning and decision-making cycle. Assessment of need should be undertaken in partnership with the statutory, voluntary, private and community sectors. This should be informed by the collation and analysis of information about the current health and social well-being status of the local population, unmet need, legislative requirements, and evidence of best practice and review of current service provision. Service planning should also take account of local and regional priorities and the availability of resources.

In order to promote systematic approaches to the development of responsive, flexible and accessible services for the local population and for individuals, this theme has been sub-divided into two main areas:

- service planning processes; and
- service delivery for individuals, carers and relatives.

6.3 Criteria

6.3.1 Service Planning Processes

The organisation:

a) has service planning processes which promote an equitable pattern of service provision or commissioning based on assessed need, having regard to the particular needs of different localities and people, the availability of resources, and local and regional priorities and objectives;

b) integrates views of service users, carers and local communities, and front line staff into all stages of service planning, development, evaluation and review of health and social care services;

c) promotes service design and provision which incorporates and is informed by:

- information about the health and social well-being status of the local population and an assessment of likely future needs;
- evidence of best practice and care, based on research findings, scientific knowledge, and evaluation of experience;
- principles of inclusion, equality and the promotion of good relations;
- risk assessment and an analysis of current service provision and outcomes in relation to meeting assessed needs;
- current and/or pending legislative and regulatory requirements;
- resource availability; and
- opportunities for partnership working across the community, voluntary, private and statutory sectors.

d) has service planning and decision-making processes across all service user groups, which take account of local and/or regional priorities;

e) has standards for the commissioning of services which are readily understood and are available to the public; and

f) ensures that service users have access to its services within locally and/or regionally agreed timescales.

6.3.2 Service Delivery for Individuals, Carers and Relatives

The organisation:

a) ensures that all service users, carers and relatives are treated with dignity and respect and that their privacy is protected and promoted, including, where appropriate, the use of advocates and facilitators;

b) has systems in place to ensure that service users, carers and relatives have the appropriate information to enable them to make informed decisions and choices about their treatment and care, or service provision;

c) ensures that information, where appropriate, is provided in a number of formats, which may include, large print, audio format on tape or compact disc, computer readable format, Braille, etc. and is:

- written in easy to understand, non-technical language;
- laid out simply and clearly;
- reproduced in a clear typeface;
- available on the internet; and
- in the preferred language of the reader, as necessary;

d) incorporates the rights, views and choice of the individual service user into the assessment, planning, delivery and review of his or her treatment and care, and recognises the service user's right to take risks while ensuring that steps are taken to assist them to identify and manage potential risks to themselves and to others;

e) ensures that individual service user information is used for the purpose for which it was collected, and that such information is treated confidentially;

f) promotes multi-disciplinary team work and integrated assessment processes, which minimise the need for service users and carers to repeat basic information to a range of staff; and

g) provides the opportunity for service users and carers to provide comment on service delivery.

Section 7: Promoting, Protecting and Improving Health and Social Well-being (Theme 4)

7.1 Standard Statement

The HPSS works in partnership with service users and carers, the wider public and with local and regional organisations to promote, protect and improve health and social well-being, and to tackle inequalities within and between geographic areas, socio-economic and minority groups, taking account of equality and human rights legislation.

7.2 Rationale

Individuals, families and carers have a major part to play in their own and their dependents' health and social well-being. Although many factors influence the health and social well-being of individuals, many of these factors are societal issues and are outside the control of individuals. Examples include poverty, social exclusion, poor education, unemployment, crime, and poor housing. Resolving these issues requires a broad-based approach and concerted action by a wide range of people and agencies including the statutory, voluntary, community and business sectors. The HPSS, working in partnership with these other agencies and community groups, should actively seek to influence and support better decision-making, and establish systems to promote and improve the health and social well-being of the public and to reduce inequalities. The goal is to improve the health and social well-being of the population of Northern Ireland, by increasing the length of their lives, improving the quality of life through increasing the number of years spent free from disease, illness, or disability, and by providing better opportunities for children and support for families.

7.3 Criteria

The organisation:

a) has structures and processes in place to promote and implement effective partnership arrangements, to contribute to improvements in health and social well-being, and promote social inclusion and a reduction in inequalities;

b) actively involves the services users and carers, the wider public, HPSS staff and the community and voluntary sectors, in the planning and development of local solutions to improve health and social well-being and to reduce inequalities;

c) is committed to human rights, as identified in human rights legislation and United Nations Conventions, and to other Government policies aimed at tackling poverty, social need and the promotion of social inclusion;

d) actively pursues equality screening and, where appropriate, equality impact assessment in compliance with section 75 of the Northern Ireland Act 1998;

e) promotes ownership by service users, carers and communities to enable service users and the public to take responsibility for their own health, care and social well-being, and to participate as concerned citizens in promoting the health and social well-being of others;

f) collects, collates, develops and uses health and social care information to assess current and future needs of local populations, taking account of health and social well-being inequalities;

g) has effective and efficient emergency planning processes and co-ordinated response action plans in place, as appropriate, to deal with major incidents or emergency situations and their aftermath. The planning processes and action plans are compliant with Departmental guidance;

h) has processes to engage with other organisations to reduce local environmental health hazards, as appropriate;

i) has evidence-based chronic disease management programmes and health promotion programmes and, as appropriate, community development programmes, which take account of local and regional priorities and objectives;

j) has systems to promote a healthier, safer, and “family friendly” workforce by providing advice, training, support and, as appropriate, services to support staff;

k) has quality assured screening and immunisation programmes in place, as appropriate, and promotes active uptake among service users, carers and the public;

l) uses annual public health and social care reports in the development of priorities and planning the provision and delivery of services; and

m) provides opportunities for the use of volunteers, as appropriate.

Section 8: Effective Communication and Information (Theme 5)

8.1 Standard Statement

The HPSS communicates and manages information effectively, to meet the needs of the public, service users and carers, the organisation and its staff, partner organisations and other agencies.

8.2 Rationale

Good communication and effective use of information are the basis for decision-making by individuals, the public and organisations. They ensure that all relevant facts are collated and used to inform treatment and care, and the assessment, planning, service delivery and resource allocation processes. For information to be useful, it needs to be in an understandable format, accessible to those who need it and readily available. The communication and information management processes within an organisation must take account of the needs of service users and carers, staff and the public and the media, and any legislative or regulatory requirements. Protecting personal information and confidentiality are important to ensure that information is appropriately communicated to those who need to know and effectively used to inform any decisions made. The HPSS should be sensitive to the range of information needs required to support individuals, communities and the organisation itself.

8.3 Criteria

The organisation has:

a) active participation of service users and carers and the wider public. This includes feedback mechanisms appropriate to the needs of individual service users and the public;

b) an effective information strategy and communication strategy, appropriate to the needs of the public, service users and carers, staff and the size, functions and complexity of the organisation;

c) an effective and integrated information technology and information systems which support and enhance the quality and safety of care and provision of services;

d) system(s) and process(es) in place to ensure that urgent communications, safety alerts and notices, standards and good practice guidance are made available in a timely manner to relevant staff and partner organisations; these are monitored to ensure effectiveness;

e) clear communication principles for staff and service users, which include:

- openness and honesty;
- use of appropriate language and diversity in methods of communication;
- sensitivity and understanding;
- effective listening; and
- provision of feedback.

f) clear information principles for staff and service users, which include:

- person-centred information;
- integration of systems;
- delivery of management information from operational systems;
- security and confidentiality of information; and
- sharing of information across the HPSS, as appropriate;

g) the organisation has effective training for staff on how to communicate with service users and carers and, where needed, the public and the media;

h) effective records management policies and procedures covering access and the completion, use, storage, retrieval and safe disposal of records, which it monitors to assure compliance and takes account of Freedom of Information legislation;

i) procedures for protection of service user and carer information which include the timely sharing of information with other professionals, teams and partner organisations as appropriate, to ensure safe and effective provision of care, treatment and services, e.g. in relation to the protection of children or vulnerable adults, and the safe and efficient discharge of individuals from hospital care;

j) effective and efficient procedures for obtaining valid consent for examination, treatment and/or care;

k) an effective complaints and representation procedure and feedback arrangements, which is made available to service users, carers and staff and which is used to inform and improve care, treatment and service delivery; and

l) a range of published up-to-date information about services, conditions, treatment, care and support options available, and how to access them both in and out of service hours, which are subject to regular audit and review.

APPENDIX 1

GLOSSARY OF TERMS

Adverse incident	Any event or circumstance that could have or did lead to harm, loss or damage to people, property, environment or reputation.
Carer	Carers are people who, without payment, provide help and support to a family member or friend who may not be able to manage at home without this help because of frailty, illness or disability.
Care plan	The outcome of an assessment. A description of what an individual needs and how these needs will be met.
Care Standards	Care Standards are service specific standards currently being developed. They will cover a range of services provided by public, voluntary and private organisations such as nursing homes, residential homes, independent clinics etc.
Clinical and Social Care Governance	A framework within which HPSS is accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment.
Community care	Health and social services aimed at supporting individuals to remain safely in their own homes for as long as possible.
Community development	Consultation with, and involvement of local communities and groups in improving health and social well-being of the community.
Controls Assurance Standards	These standards focus on key areas of potential risk and help HPSS organisations demonstrate that they are doing their reasonable best to manage themselves and protect stakeholders from risk. They support effective governance.
Equality impact assessment	Consideration of a policy having regard to its impact on and the need to promote equality of opportunity between: persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation, men and women generally, persons with a disability and persons without and between persons with dependants and persons without.
Evidence based practice	Provision of services which are based on best practice as proven by research findings, scientific knowledge and evaluation of experience.
Family Practitioner Services (FPS)	The principal primary care services i.e. family doctors, opticians, dentists and pharmacists.
HPSS (Health and Personal Social Services)	An organisation which either commissions or provides health and social services, e.g. HSS Boards, Strategic Health and Social Care Authority, a Trust providing hospital and community services, a local commissioning body, and Family Practitioner Services.

NPSA	The National Patient Safety Agency promotes safe practice in clinical care and supports the development of solutions and the cascade of learning to reduce areas of high risk.
Person-centred assessment	An assessment, which places the individual at the centre of the process and which responds flexibly and sensitively to his/her needs.
Primary care	The many forms of health and social care and/or treatment accessed through a first point of contact provided outside hospitals e.g. family doctors, pharmacists, nurses, allied health professionals (physiotherapists, psychologists, dieticians etc) social workers, care assistants, dentists, opticians and so on.
Secondary care	Specialist services usually provided in an acute hospital setting following referral from a primary or community healthcare professional.
Statutory duty	A legal responsibility.
Statutory sector	Government-funded organisations e.g. HSS Boards, Strategic Health and Social Services Authority, Trusts, Special Agencies and Local Commissioning Groups.
Tertiary care	Highly specialised services usually provided in an acute hospital setting by medical and other staff with expertise in a particular medical specialty.

APPENDIX 2

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Safer Management of Controlled Drugs

A guide to good practice in secondary care (Northern Ireland)

Updated August 2012 mainly in respect of Misuse of Drugs Regulations amendments (Original version published 2009)

MAHI - STM - 089 - 4074

Safer Management of Controlled Drugs
A guide to good practice in secondary care (Northern Ireland)

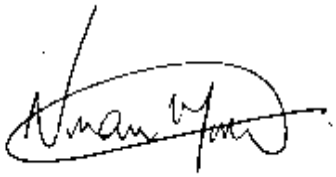
Foreword

There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.

In implementing better controls which support professionals and encourage good practice we must ensure that patients have appropriate and convenient access to controlled drugs to meet their clinical needs.

This document has been developed for secondary care in Northern Ireland and is designed to provide guidance on good practice for the management of controlled drugs. It seeks to take account of the important legislative changes and developments in professional practice and accountability.

In commending this guidance to secondary care organisations I wish to acknowledge the multidisciplinary input and the extent and quality of the responses to the consultative draft. The application of this guidance will, I believe, make a significant contribution to improving governance and patient safety.



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Contents

Changes to text in the August 2012 updated version include

Section 2.1: Table 1: BNF style of indication of CD schedule included
Section 2.2: Inclusion of Pharmacist Independent Prescribers
Section 2.2.1: Updating of PGD information
Section 2.2.2 and 5.8: Updating regarding Midwives
Section 4.10.5: Updating regarding Nurse Independent Prescribers; deletion of Table specifying Controlled Drugs and indications
Section 4.10.6: Updating regarding Pharmacist Independent Prescribers
Section 5 Index: Correction – omit “PGDs” include “Illicit Substances”
Section 6.1.1: Removal of word “doctor” to reflect lawful responsibility for controlled drugs in operating theatres
Section 7.9: Updating retention periods as in *Good Management Good Records*
Section 7.11: Implications of repeal of section 10(7) of the Medicines Act 1968
Glossary: Definitions -“Relevant Persons” changed; “Prescribe” updated
Appendix 1: Updating of description of legal provisions
Throughout document: Consequential page renumbering. Hyperlinks updated. Obsolete references to RPSGB removed.

1 Executive summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed from an original document published by the Department of Health. [*Safer Management of Controlled Drugs A guide to good practice in secondary care*, 17th October 2007, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618]. That document emerged following widespread consultation with key stakeholders, including representation from Northern Ireland, chaired by the Royal Pharmaceutical Society of Great Britain. The work of the Royal Pharmaceutical Society is acknowledged and appreciation is expressed to the Department of Health for permission to use the original document as the basis for the Northern Ireland version. The document, as revised for Northern Ireland, has been reviewed by professionals here. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in *Improving Patient Safety – Building Public Confidence.* [27th Nov 2006, www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf] The response identified ways for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

Improving Patient Safety – Building Public Confidence set out a substantial programme of work to improve the management of controlled drugs. As a result, a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1) (MDR). The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, came into operation on 1st October 2009.

This document is intended to provide guidance on good practice for the management of controlled drugs in secondary care in Northern Ireland. It aims to set out robust

systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of controlled drugs, whilst at the same time helping to ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of controlled drugs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The DHSSPS has published a guide to good practice in the management of controlled drugs in primary care which is available on its website.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs.

Controlled Drugs are those listed in Schedule 2 to the Misuse of Drugs Act 1971. For practical purposes they are classified in Schedules 1 to 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002 according to the controls necessary for their governance. Within this document the emphasis is placed on those contained in Schedule 2 to the MDR, as these are subject to the highest levels of control. On occasions, healthcare organisations choose to manage non-controlled drugs and controlled drugs in other Schedules in the same way as Schedule 2 controlled drugs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in two previous documents: *Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services* (April 2004, www.dhsspsni.gov.uk/use_control_of_medicines.pdf) and *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report), (March 2005, www.rpharms.com/support-pdfs/safsechandmeds.pdf - commended by the DHSSPS and endorsed by the Pharmaceutical Society of Northern Ireland). Neither of these documents is concerned specifically with controlled drugs and readers are also encouraged to refer to them for guidance on more general aspects of medicines management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of controlled drugs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of controlled drugs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases it is hoped that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the *Revised Duthie Report* (March 2005) has been adopted. The term “should” has been used for recommendations that relate to good practice and “must” for those governed by legal requirements. Recommendations have also been

inserted that “may” be followed as matters of good practice, if they are relevant to local circumstances.

This document has been designed both for those who are involved in management of controlled drugs in secondary care and for those who are responsible for ensuring that controlled drugs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where controlled drugs are used including:

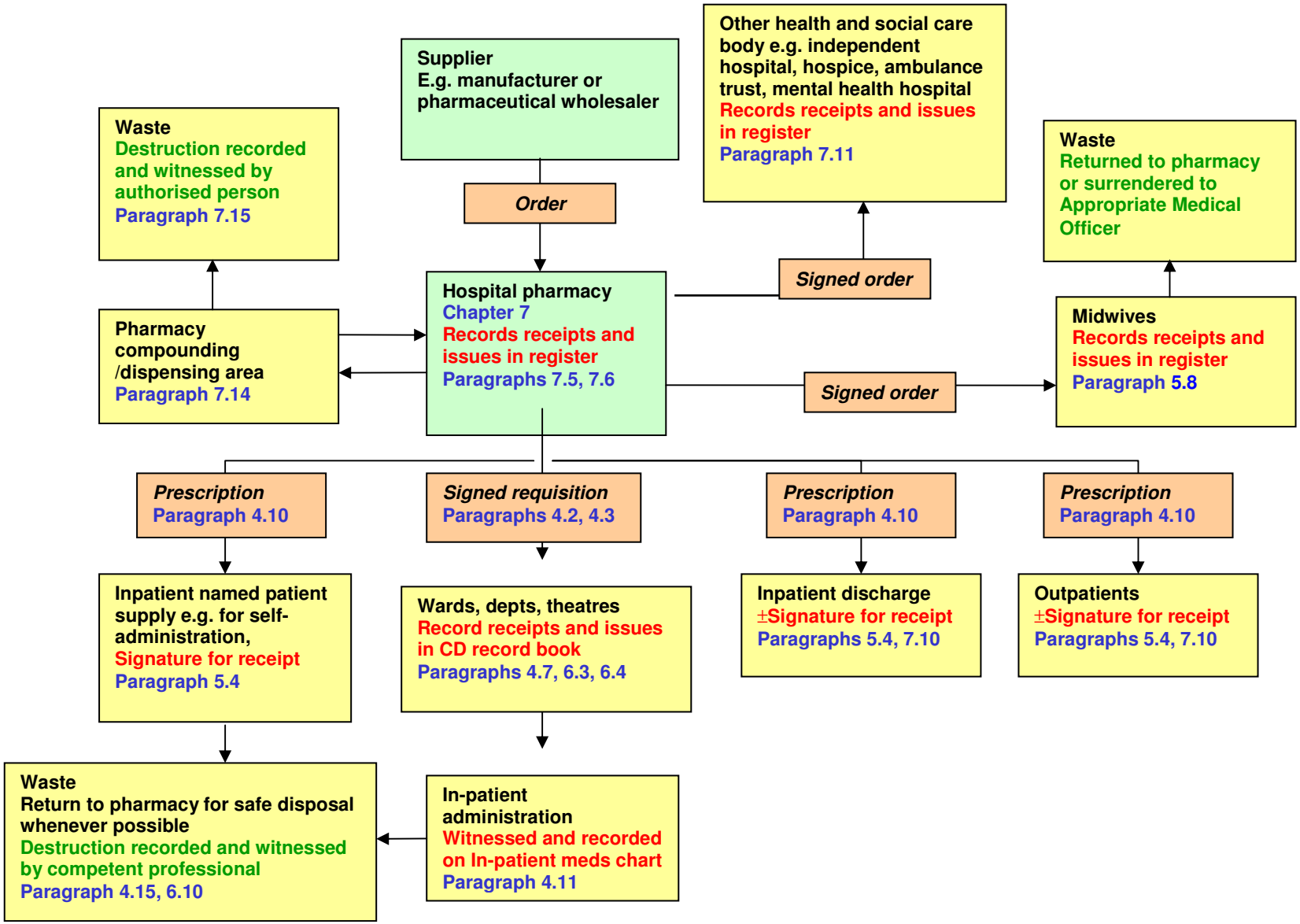
- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Other health and social care bodies

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where controlled drugs are used and managed.

Questions relating to the management of controlled drugs may often be resolved by referring to guidance published by professional bodies. Advice may also be sought from the Pharmaceutical Advice and Services Branch of the DHSSPS. Appendix 4 includes professional organisations that provide advice for their members. Regular reference should be made to the following websites to check for up-to-date information:

The Department’s website: www.dhsspsni.gov.uk
The Department of Health website: www.dh.gov.uk/controlleddrugs
The Home Office websites:
www.homeoffice.gov.uk and www.drugs.gov.uk/drugslaws
The Pharmaceutical Society of Northern Ireland website: www.psni.org.uk
The Royal Pharmaceutical Society website www.rpharms.com as available

Figure 1 The product journey – Controlled drugs in secondary care



2 Legislation and governance arrangements

Legislation

2.1 Legislative framework for controlled drugs

The management of controlled drugs is governed by the Misuse of Drugs Act (1971) and its associated Regulations.

Additional statutory measures for the management of controlled drugs are laid down in the Health Act (2006) - and its associated legislation the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer to the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the different Schedules of controlled drugs are summarised in Table 1. Schedule 1 drugs have been omitted from the table because drugs in this group have virtually no therapeutic uses.

Table 1: Summary of legal requirements applying to controlled drugs in Schedules 2, 3, 4 & 5 of the Misuse of Drugs Regulations

Schedule (refers to schedules of the Misuse of Drugs Regulations)	**Schedule 2** Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) remifentanil secobarbital	**Schedule 3** Includes minor stimulants, temazepam, buprenorphine, flunitrazepam, midazolam, barbiturates except secobarbital	**Schedule 4 pt I** Includes benzo-diazepines	**Schedule 4 pt II** Includes anabolic steroids, clenbuterol, growth hormones	**Schedule 5** Includes low strength opioids
Designation	CD or CD2 (BNF)	CD No Reg or CD3 (BNF)	CD Benz or CD4-1 (BNF)	CD Anab or CD4-2 (BNF)	CD Inv
Safe custody	Yes, except secobarbital	Yes, with certain exemptions (see MEP, details below)	No	No	No
Prescription requirements – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
CD Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy*	Yes*	Yes*	Yes*
Validity of prescription	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

Table adapted from (previous edition) Medicines, Ethics and Practice Guide (MEP). Further information can be found in the MEP, in the British National Formulary (www.bnf.org/bnf/) and on PSNI website www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

* Up to a quantity sufficient for 5 days treatment
** "Appropriate date" means the later of the date on which the prescription was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied.

2.2 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor, dentist, nurse independent prescriber or pharmacist independent prescriber
- Supplied and administered under Patient Group Directions
- Supplied and administered by a midwife

Certain restrictions apply to each of these routes of supply.

2.2.1 Supply and/or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified healthcare professionals to supply and/or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have received appropriate training for operating the PGD.

Named nurses, paramedics and other specified health professionals can supply and administer certain controlled drugs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 (SR 2003 No. 420) www.uk-legislation.hmso.gov.uk/sr/sr2003/nisr_20030420_en.pdf (See also for background information the *Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*.) www.homeoffice.gov.uk/about-us/corporate-publications-strategy/home-office-circulars/circulars-2003/049-2003/

There are currently only limited circumstances in which certain controlled drugs may be administered or supplied under a PGD by certain named health professionals. These are:

- Registered nurses and pharmacists (but no other healthcare practitioners) can supply or offer to supply diamorphine or morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 controlled drug or midazolam in accordance with a PGD, except

- The anabolic steroids in Schedule 4, part 2
- Injectable formulations for the purpose of treating a person who is addicted to a drug

2.2.2 Midwive's exemptions

Registered midwives may administer parenterally, a number of specified controlled drugs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pethidine hydrochloride

(See - The Human Medicines Regulations 2012 (SI 2012 No. 1916). The Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1))

(See also paragraph 5.8 Controlled drugs for midwives)

Governance arrangements

2.3 Accountability and responsibility

At local level, all healthcare organisations or designated bodies {see the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009; (SR 2009 No. 225) available at the website www.legislation.gov.uk} are accountable, through the Accountable Officer (AO, see below), for ensuring the safe management of controlled drugs. In Northern Ireland, the following are designated bodies:

- The Regional Health and Social Care Board
- A Health and Social Care Trust
- The Northern Ireland Ambulance Service Trust
- An Independent Hospital

All designated bodies, including HSC Trusts, and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the Controlled drugs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to

pay particular attention to and prioritise key areas of risk which will include the interface with other health and social care providers.
Each designated body may also consider establishing a Controlled Drug Review Group. Such groups may be part of the arrangements that AOs are required to have in place for analysing and responding to adverse incidents involving the management or use of controlled drugs.

2.4 The Accountable Officer

The Accountable Officer is responsible for all aspects of the safe and secure management of controlled drugs in his organisation. This includes ensuring that safe systems are in place for the management and use of controlled drugs, monitoring and auditing the management systems and investigation of concerns and incidents related to controlled drugs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations Northern Ireland) 2009; (SR 2009 No.225) and a summary of the main provisions is provided at Appendix 3 of this document. See also 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

2.5 Monitoring and inspection

Regular inspections of hospital pharmacies related to the management of controlled drugs are conducted by inspectors from the DHSSPS. Core activities examined include secure storage facilities, statutory and informal record keeping and the arrangements made for robust audit trails.

2.6 Standard operating procedures

Each of the activities that relate to controlled drugs, regardless of where in the organisation they occur, should be described in a standard operating procedure (SOP). SOPs for controlled drugs became mandatory in Northern Ireland, rather than good practice, with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, which came into operation on 1st October 2009. SOPs are particularly important if tasks are delegated to others. For example, issue and receipt of stock controlled drugs in the pharmacy may be delegated to a competent pharmacy technician. However, responsibility lies with the pharmacist who authorised the activity.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs must be familiar with the SOPs.

The standard operating procedures must, in particular, cover the following matters:

(a) who has access to the controlled drugs;

(b) where the controlled drugs are stored;

(c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;

(d) disposal and destruction of controlled drugs;

(e) who is to be alerted if complications arise; and

(f) record keeping, including:

(i) maintaining relevant controlled drugs registers under misuse of drugs legislation,

(ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2002 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer.

Additional Information

A comprehensive list of drugs included within the Schedules to the Misuse of Drug Regulations 2002 can be accessed at:

- www.legislation.gov.uk/
- Home Office www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-licences/controlled-drugs-list?view=Binary
- Medicines and Healthcare products Regulatory Agency (MHRA) www.mhra.gov.uk

Some of the following sites may contain material which may be useful to inform practice in Northern Ireland.

- DHSSPS will also publish guidance for the safer management of controlled drugs in primary care. www.dhsspsni.gov.uk/safer-management-of-controlled-drugs-a-guide-to-good-practice-in-primary-care-version-2-july-2011.pdf
- The Care Quality Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs: www.cqc.org.uk
- Department of Health Controlled Drugs pages: www.dh.gov.uk/controlleddrugs
- Pharmaceutical Society of Northern Ireland www.psni.org.uk

- Pharmaceutical Services Negotiating Committee (PSNC) www.psnc.org.uk
- Nursing and Midwifery Council (www.nmc-uk.org). Standards for Medicines Management (February 2008); NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives.*

3 General principles

There are a number of overarching principles that guide the use of medicines in general and controlled drugs in particular. They underpin and inform the decisions that are made about the safe management of controlled drugs within the current legal framework. The following principles should apply in relation to the management of controlled drugs.

3.1 Patients have timely access to the medicines prescribed for them

3.2 Organisations and individuals comply with the current legal requirements for controlled drugs

3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.

3.4 Patients are adequately informed about their treatment

3.5 Controlled drugs are used and managed safely and securely

3.6 There is a clear audit trail for the movement and use of all controlled drugs

3.7 The use of controlled drugs is audited and action is taken if necessary

3.8 Controlled drugs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of controlled drugs

3.9 Local procedures and protocols are designed to be as clear and accurate as possible. They should be practical in use and not impose an intolerable administrative burden

3.10 The stock levels of controlled drug preparations held in wards and departments match what is routinely used in that clinical area

3.11 Healthcare staff have access to up-to-date information about CD legislation and official (Home Office, DHSSPS, professional body and other) guidance

3.12 Healthcare staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work

3.13 Healthcare and appropriate ancillary staff receive adequate training and are competent in the management of controlled drugs (appropriate to their sphere of activity and level of responsibility)

3.14 Access to controlled drugs is restricted to appropriate, designated and legally authorised personnel

4 Management of controlled drugs in wards and departments

This chapter deals with the management of controlled drugs in wards and departments. The management of controlled drugs in operating theatres is covered in Chapter 6.

Contents of this chapter:

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

4.1 Accountability and responsibility

4.1.1 Accountable individuals

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management of controlled drugs in that area. The senior registered nurse or ODP in charge can delegate control of access (i.e. key-holding) to the CD cabinet to another, such as a registered nurse or another ODP. However, responsibility remains with the registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

4.1.2 Standard operating procedures

There must be standard operating procedures (SOPs) covering each of the activities concerned with controlled drugs such as requisitioning, receipt, administration, record keeping and destruction.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Relevant staff should be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

4.2 Controlled drug stocks

There should be a list of the controlled drugs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the ward or department and should be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the senior registered nurse or registered operating department practitioner in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

4.3 Requisitioning of controlled drugs

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The senior registered nurse or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP (See Chapter 6; The management of controlled drugs in operating theatres and Appendix 2). However, legal responsibility remains with the senior registered nurse or ODP in charge.

4.3.1.1 Orders must be in writing and should be on suitable stationery (e.g. a controlled drug requisition book with duplicate or triplicate pages) and must be signed by an authorised signatory. Stationery should be designed to facilitate a robust audit trail. (See also 4.3.3 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition controlled drugs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Name of Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity
- Signature of senior registered nurse or ODP in charge

The requisition should also contain:

- Date on which it was written
- The printed (as in a legible version) of the name of the senior registered nurse or ODP in charge who signed the requisition

When the drug has been supplied the requisition must:

- Be marked in such a manner to show that it has been complied with.

4.3.1.4 The person making the supply should sign and date the requisition when it has been complied with, if that has not been part of the compliance marking, above.

4.3.1.5 The person who accepts the controlled drugs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.1.6 The person who receives the controlled drugs on the ward should sign the duplicate copy of the requisition.

4.3.1.7 Requisitions must be retained at the dispensary at which the drug was supplied and a copy of the requisition or a note of it must be retained by the recipient (the senior registered nurse or ODP in charge.)

4.3.2 CD Top-up schemes

In some situations pharmacy-led CD top-up schemes for replenishing stocks of controlled drugs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1 When a CD top-up scheme is in operation, the responsibility for controlled drugs in a ward or department remains with the senior registered nurse or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward controlled drug record book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the senior registered nurse or ODP in charge.

4.3.3 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

4.4 Receipt of controlled drugs

When controlled drugs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of controlled drugs). A local procedure should define the appropriate persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs. The person receiving the supply should sign the duplicate sheet in the requisition book, having checked the items received.

4.4.1 As soon as possible after delivery the senior registered nurse or ODP in charge should:

- Check the controlled drugs against the requisition – including the quantity ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should

be countersigned in the "received by" section. If the controlled drugs received do not accord with the requisition then the pharmacy should be contacted immediately. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. (Note, however, that some pharmacies open sealed packs to check for breakage before issue to wards.) Intact seals will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.

- Place the controlled drugs in the appropriate CD cabinet
- Enter the controlled drugs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.
- If, when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the senior registered nurse or ODP in charge should contact the pharmacy department as soon as possible.
- Ensure that appropriate records are made in the ward controlled drug record book and all necessary action taken to resolve the discrepancy. See 5.9 Discrepancies and diversion.

4.4.2 Depending on local circumstances, some healthcare organisations may wish to stipulate that receipt of controlled drugs and updating of the controlled drugs record book should be witnessed by a second competent professional.

See also paragraph 6.4 Receipt of controlled drugs in Theatre

4.5 Storage of controlled drugs

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 (SR 1973 No 179) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs. Apart from specified excepted circumstances, the Regulations also require that all controlled drugs to which the Regulations apply, must be in locked storage which can only be opened by a person who can lawfully be in possession of the controlled drugs or a person working under their authority.

4.5.1 Ward CD cupboards should conform to the British Standard reference BS2881:1989 ("Specification for cupboards for the storage of medicines in healthcare premises" ISBN 058017216 3) or be otherwise approved by the pharmacy department. Cupboards should provide a level of security at least comparable to that laid down in the Safe Custody Regulations. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case further security measures should be introduced.

4.5.2 In certain circumstances, for example when controlled drug discharge medicines are sent to the ward several hours before the patient leaves, the medicines should be stored securely in the CD cupboard. These medicines should be segregated from the ward CD stock. (See paragraph 5.4 Management of controlled drugs that are patients' property)

4.5.3 General measures for the storage of controlled drugs include the following:

- Controlled drugs must be locked away when not in use
- Cupboards must be kept locked when not in use
- The lock must not be common to any other lock in the hospital
- Keys must only be available to authorised members of staff and at any time the key-holder should be readily identifiable
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances healthcare organisations may decide to allow other drugs that are not controlled drugs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this

4.6 Key-holding and access to controlled drugs

4.6.1 **Responsibility for CD keys**

The senior registered nurse or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding (in the sense of giving the key to another for immediate access to the cupboard) may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the senior registered nurse or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the senior registered nurse or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

4.6.2 Missing CD keys

If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting staff who have just gone off duty.

4.6.2.1 A procedure should be in place to ensure that an appropriate level of nursing/midwifery/theatre management and the duty pharmacist are informed as soon as possible. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded e.g. by issuing a spare key.

4.6.2.2 If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, a decision may be made to contact the police. The DHSSPS Head of Medicines Regulatory Group should be made aware of the situation. Locks may need to be replaced to prevent unauthorised access to the drugs.

4.7 Record-keeping

Each ward or department that holds stocks of controlled drugs should keep a record of controlled drugs received and administered in a controlled drug record book (CDRB).

The senior registered nurse, or ODP, in charge is responsible for keeping the CDRB up to date and in good order.

4.7.1 Controlled drug record books

4.7.1.1 The controlled drug record book (CDRB) should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be easily maintained. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist,) or by a pharmacy technician, or an appropriately trained healthcare assistant, who has been assessed as being competent for the purpose. In defining local policy NMC Medicines Management Standards may be consulted related to witnessing by student nurses or midwives.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The finished page number should be indicated

at the top of the new follow-on page. As a matter of good practice this transfer should be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by a second registered nurse, midwife, ODP or other registered professional or by an appropriately trained healthcare assistant. The witness should also sign the correction. An explanation may be made if necessary by a marginal note or footnote.

4.7.2. Records of controlled drugs received

A record should be kept of all Schedule 2 controlled drugs that are received or administered.

4.7.2.1 For controlled drugs received, the following details should be recorded on the appropriate page in the CDRB:

- Date on which the controlled drug was received.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording controlled drugs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the opportunity for entries to be altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the new balance recorded in the CDRB. The entry should be signed and dated.

For records of controlled drugs administered see paragraph 4.11 Administration

4.8 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CDRB should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. If reconciliation is being conducted related to shift change, where possible, a representative from each shift may be involved. In addition, regular documented stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The senior registered nurse or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives, ODPs or other registered health professionals should perform this check. Both must see the drugs and the records for witnessing to be meaningful. Where possible, the staff assigned to do this check should be changed periodically. The check should take account of the following points:

- Checking of controlled drugs involves the checking of the balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure that all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock-checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, “check of stock level” and be signed by the registered nurse, midwife, ODP or other registered health professional and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragrapht 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed.

4.9 Archiving of controlled drug records

Healthcare organisations must make arrangements to store records in accordance with legislation and the schedules in *Good Management Good Records*. www.dhsspsni.gov.uk/gmgr The current guidance that applies to retention of hospital pharmacy CD registers is eleven years. This retention period also applies to ward CDRBs. The retention period is reckoned from the date when the last entry was made.

Many local documents designed to track and/or monitor controlled drug usage should be kept for two years after the last entry/date of use.

See also paragraph 7.9 - Archiving of controlled drug records (and 4.3.1.7 and 5.1.5.2)

4.10 Prescribing

4.10.1 Prescribing for inpatients

For hospital inpatients directions for administration of controlled drugs from ward stocks may be written on the inpatient medicines chart or case sheet (sometimes called the inpatient prescription and administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines and include:

- Start date
- Drug name, form and strength where appropriate
- Route of administration, and where appropriate, the site of application
- Dose
- Time of administration or frequency (if prescribed "when required" e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum daily dose)
- Include a finish date where appropriate
- Signature of prescriber

The patient's name, date of birth, unit number and/or address and any known drug sensitivities or drug allergies should also be written on the chart.

4.10.1.2 If controlled drugs are administered or self-administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements of 4.10.1.1, in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the patient chart. (See section 5.4.4 Self-administration of controlled drugs.)

4.10.2 Prescribing for discharge patients

Prescriptions for controlled drugs for patients who are going home (discharge medicines) should be written on locally-approved prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe controlled drugs (and other POM medicines) on these prescription forms for

inpatient use so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983. In line with GMC guidance for general practice, it is recommended that such issues of delegation by supervising practitioners must be clearly documented to avoid any confusion. Further guidance with some explanation of the legislation is available from the GMC at www.gmc-uk.org/Provisionally_registered_doctors_on_GP_placements_prescribing_rights.pdf_26990223.pdf

4.10.2.2 A clinically appropriate amount, up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.3. Prescribing for outpatients

Prescriptions for controlled drugs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). Such prescribing must occur within locally agreed frameworks. The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or, in the case of Substitution Treatment for opiate dependence with methadone or buprenorphine, an SP1 or SP2 form for a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 controlled drugs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated

- The patient's full name and address
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

In addition, it is good practice to include the patient's age and NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his usual signature, in his own handwriting (this must be handwritten) and dated (the date does not have to be handwritten).

Amendments to the Misuse of Drugs Regulations 2002, which came into force on 16th January 2006, removed the requirement for prescriptions for Schedule 2 and 3 controlled drugs to be written in the prescriber's own handwriting (other than their signature).

CD prescriptions may be computer-generated but **do not have** to be computer-generated. Appropriate prescribers may issue computer-generated prescriptions for all controlled drugs in Schedules 2 and 3. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is produced, prior to signature by the prescriber, by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed adhesive labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for controlled drugs do not prevent the use of preprinted adhesive labels on prescriptions. If, and where, they are used, such labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If an adhesive label is used, prescribers should also sign across each label. This is a further safeguard to ensure that such labels are not tampered with or that another label is not placed on top of the one that the prescriber signed for. Relevant procedures should include measures to minimize further risks related to adhesive labels and copies of prescriptions.

4.10.3.5 A clinically appropriate amount up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to public safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

4.10.4 Supplementary prescribers

Regulations were amended in 2005 to permit supplementary prescribers, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

4.10.5 Non-medical independent prescribers

Nurse independent prescribers

Following amendments to the Prescription Only Medicines Order 1997 (SI 1997 No. 1830), the range of drugs that Nurse Independent Prescribers were able to prescribe independently was extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers were able to prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs for specific conditions. The Misuse of Drugs Regulations 2002 were again amended in May 2012 to allow a nurse independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.10.6 Pharmacist independent prescribers

The Misuse of Drugs Regulations 2002 were amended in May 2012 to allow a pharmacist independent prescriber to prescribe any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of controlled drugs should comply with all local policies and procedures for the administration of medicines.

Nurses and midwives must follow Nursing and Midwifery Council standards and guidance. (www.nmc-uk.org)

In terms of the Misuse of Drugs Regulations (MDR) any person can administer to a patient any drug specified in Schedule 2, 3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2002, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2002- Regulation 7 (1)

4.11.1 Healthcare organisations that do not have a system of double checking for administration of controlled drugs should carry out a risk assessment to determine whether the introduction of double checking as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of controlled drugs, one of them should be a registered nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the controlled drug to be administered.
- The controlled drug being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required).

A record should be made in the ward or department controlled drug record book (CDRB) when a controlled drug is removed from the CD cupboard.

4.11.1.2 For controlled drugs administered the following details should be recorded:

- Date and time when dose administered (or refused in the case of a controlled drug that was prepared for the patient)
- Name of patient
- Quantity administered and quantity wasted (see 4.11.1.3)
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or other registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted*." The destruction should be witnessed by a second registered nurse, midwife or other registered health professional who should also sign the record. If a second registered nurse, midwife or other registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist) or by an appropriately trained pharmacy technician or healthcare assistant. In defining local policy NMC Medicines Management

Standards may be consulted related to witnessing by student nurses or midwives.

4.11.1.4 Individual doses of controlled drugs which have been prepared but not administered should be destroyed by a registered nurse, midwife or other registered health professional on the ward or department in the presence of a witness and the reason documented in the CDRB.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of Controlled drugs).

4.12 Management of controlled drugs when patients are admitted

See paragraph 5.4 Management of Controlled Drugs that are the patient's property

4.13 Management of controlled drugs when patients are transferred to other wards or departments

See paragraph 5.2 Transfer of controlled drugs

The circumstances are limited where a controlled drug will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents controlled drugs being supplied from ward to ward. Patient controlled analgesia will be one of the cases where a controlled drug may need to move with the patient. There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved between theatre and/or wards
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

4.14 Management of controlled drugs when patients are discharged

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

4.15 Returning controlled drugs to the pharmacy

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock may be re-issued by the pharmacy provided it was initially issued by that pharmacy, is in good condition

and has at all times been under the control of that hospital. The pharmacy department should carry out an assessment of controlled drugs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

4.15.2 Records of controlled drugs returned

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice book with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

The following details should be recorded when controlled drugs are returned to the pharmacy:

- Date
- Name, form, strength and quantity of drug being returned
- Reason for return
- Name and signature of the senior registered nurse or ODP in charge

The top copy will be taken from the book and transported with the drugs to the pharmacy.

In addition, an entry should be made on the relevant page of the ward or department CDRB, showing:

- Date
- Reason for return
- Names and signatures of the senior registered nurse, or ODP responsible and a competent witness
- Quantity removed
- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 Transfer of controlled drugs)

4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of controlled drugs in pharmacies

In the interests of safety and containment of environmental pollution, controlled drugs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on wards and departments, the methods used should be those currently recommended by the Pharmaceutical Society of Northern Ireland
See the Pharmaceutical Society of Northern Ireland website:
www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf

Some healthcare organisations may wish to provide denaturing kits for use on wards to destroy controlled drugs that have been used for patients. This may be appropriate on wards or departments where large quantities of controlled drugs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on wards. Where denaturing kits are provided to wards or departments, an SOP should be developed for this practice.

4.16.1 Disposal of small amounts of Controlled drugs

4.16.1.1 In principle, only small amounts of Controlled drugs should be destroyed on wards and departments, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Policy should be agreed locally regarding denaturing and disposal of larger quantities of controlled drugs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes. An assessment should be made of risks involved in transport, and of the impact on infection control, prior to establishing any policy that indicates that these items be returned to the pharmacy for safe denaturing and disposal.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as a registered nurse, midwife or ODP. Both persons should sign the CD record book.

4.16.2 Method of disposal

Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.

5 Management of controlled drugs – general processes and specific circumstances

Contents of this chapter:

5.1 Controlled drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain controlled drugs for inappropriate purposes.

5.5.1 Definition of CD stationery

CD stationery includes:

- CD requisition books
- CD record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents
- Prescription forms

5.1.2 Secure storage of CD stationery

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

5.1.3 Supply of CD stationery

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. Local policy should define the form of requisition that is required to order such stationery. The local policy should also define the groups of staff who can sign requisitions for CD stationery. It may be appropriate to use the same duplicate book for ordering CD stationery that is used to order controlled drugs. This will ensure that the requisition forms themselves are stored securely.

5.1.3.1 A record should be kept in pharmacy of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the stationery supply record.

5.1.3.3 Healthcare organisations may wish to number CD requisition books to provide an additional means of tracking.

5.1.4 Loss or theft of CD stationery

Loss or theft of any controlled stationery which may be used to order controlled drugs should be reported immediately to the chief pharmacist and the Accountable Officer. The police should be informed, if appropriate.

5.1.5 Use of CD stationery

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of controlled drugs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife, ODP or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books must be retained for a minimum of two years from the date of the last entry. CD record books should be kept for a period of 13 years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

5.2 Transfer of controlled drugs within and outside the hospital

Transfer of controlled drugs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by commercial courier (e.g. taxi out-of-hours)
- Delivery using (trackable) recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

5.2.1 Methods of transfer

Wherever possible, controlled drugs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some healthcare organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whichever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 Controlled drugs may not be transported in pneumatic tubes. If consideration is being given to the use of such a system, prior discussion should take place with the Department inspectors.

5.2.2 Records of transfer

At each point where a controlled drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug and the person receiving it.

5.2.2.1 Healthcare organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.

5.2.3 Messengers

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Healthcare organisations may wish to stipulate that controlled drugs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a controlled drug he should be asked to show his valid company ID, as he would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that controlled drugs are being transported as this may increase the potential for diversion.
- As a matter of good practice the taxi registration or taxi licence number may also be recorded.

5.2.3.4 Healthcare organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

5.2.4 Transfer from ward to ward or theatre to ward

In general, the Misuse of Drugs Regulations 2002 prevent controlled drugs being supplied from ward to ward. However, local procedures should define safe, secure and auditable methods to transfer controlled drugs from ward to ward in circumstances where a controlled drug is required to move, for example, when a patient moves to another ward. The three situations in which this is most likely to arise are:

- When a patient is receiving a controlled drug by means of syringe pump (patient controlled analgesia) or infusion or a transdermal patch
- When a patient has his/her own controlled drugs for self-administration
- When a controlled drug has been dispensed on a “named-patient” basis

5.2.4.1 Patients' own controlled drugs should be transferred from ward to ward with the patients in line with local procedures for transferring all other medicines and property belonging to those patients.

5.2.4.2 There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) for all aspects of the management of patient controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

See also paragraph 5.4 Managing controlled drugs that are the patient's property

5.2.5 Transfer from ward to pharmacy

When controlled drugs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning controlled drugs to the pharmacy)

5.3 Clinical trials

The procedures for the use of controlled drugs in clinical trials must comply with the Misuse of Drugs Regulations 2002 and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and Medicines and Healthcare products Regulatory Agency (MHRA) guidance on clinical trials (www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/index.htm)

5.3.1 Storage and records

5.3.1.1 All clinical trial controlled drugs should be stored separately from stock controlled drugs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local

procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed and also the chief pharmacist and Accountable Officer. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a controlled drug, pharmacy staff may be unaware which packs contain controlled drugs. In this situation, all supplies should be treated as controlled drugs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 controlled drugs, such as cannabinoids, a licence from the DHSSPS must be obtained before the item is received into stock or supplied. The licence should normally be held by the chief pharmacist. A copy should be kept with the trial protocol.

5.3.2. Labelling

All clinical trial controlled drugs must be labelled and dispensed in accordance with the specific trial protocol in addition to the Misuse of Drugs Regulations 2002 requirements.

5.3.3 Disposal

Clinical trial controlled drugs must be destroyed in the same way as other controlled drugs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions from the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

5.3.4. Clinical trial controlled drugs returned by patients

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

5.3.5 Arrangements for research departments

If a hospital pharmacy supplies controlled drugs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

5.4 Management of controlled drugs that are the patient's property

A local procedure should be in place for the management of controlled drugs that are the patient's property.

5.4.1 Use of a patient's own controlled drugs on the ward

It may be appropriate to use a patient's own controlled drugs (i.e. controlled drugs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients' own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self-administration of controlled drugs)

5.4.1.1 If patients' own controlled drugs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's representative agrees, medicines may be sent to the pharmacy for safe destruction. Such assent may be recorded with the signature of the patient or their representative if appropriate. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. That adult should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them. If the medicines are no longer safe and/or appropriate for future use by the patient, then the patient and/or patient's representative should be advised, and they should be encouraged to allow them to be destroyed in the hospital pharmacy (or to take them to a community pharmacy for safe destruction.)

5.4.1.2 Patients' own controlled drugs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should be placed in the CD cupboard but should be clearly marked and kept separate from ward stock. The presence on, and departure from, the ward of these controlled drugs should be recorded according to local policy.

5.4.1.4 Patient's own controlled drugs must never be used to treat other patients.

5.4.2 Controlled drug discharge medicines

When CD discharge medicines are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag. Healthcare organisations may wish to stipulate that a record of the receipt and supply of these medicines from the ward should be maintained.

When Schedule 2 controlled drug discharge medicines are collected from the pharmacy, the person collecting them should be asked to sign for receipt as a matter of good practice.

5.4.3 Receipt of controlled drugs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs.

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

- **May** request evidence of that person's identity and
- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person
- Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must,** unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

From 1st February 2008, it has been a requirement to record the following information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address [*Guidance* – work address - not home]
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the supplier did not ask may be included, but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients receiving controlled drugs should sign for receipt of a specified number of doses.

5.4.4 Self-administration of controlled drugs

A local procedure should be in place for wards or departments where patients self-administer their own medicines including controlled drugs.

5.4.4.1 When patients who self-administer controlled drugs require additional supplies, these should be dispensed as for discharge controlled drugs. Prescription details must comply with the requirements of the Misuse of Drugs Regulations 2002. Healthcare organisations may wish to consider whether the administration of these controlled drugs is recorded in the CDRB or in a separate book for recording of controlled drugs that are self-administered.

5.4.4.2 Patients receiving controlled drugs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Healthcare organisations may wish to stipulate that these controlled drugs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the controlled drugs in the patient's individual medicines cabinet may be made by the registered nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB.

5.4.4.4 The controlled drugs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Healthcare organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high

level of security and a clear record of who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

5.5 Out-of-hours supply

Under the current Regulations, the senior registered nurse in charge of a ward can only supply controlled drugs to a patient on that ward or department, in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of controlled drugs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, a standard operating procedure should be developed.

5.6 Temporary ward closure and transfer of wards

5.6.1 Temporary ward closure

There should be a local procedure for the management of controlled drugs during short and long term ward closures. The procedure should ensure the security of the controlled drugs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Documented stock reconciliation conducted by senior registered nurse and ward pharmacist
- Arrangements for removal and temporary storage of controlled drugs by the pharmacy, if appropriate
- Arrangements for return of controlled drugs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of controlled drugs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy should be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the

ward reopens, to ensure that signatures are valid and up to date.

5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its controlled drugs and CDRBs may be transferred or, where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of controlled drugs during ward moves. This procedure should ensure the security of the controlled drugs and should be auditable.

5.6.2.2 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of controlled drugs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but controlled drugs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but controlled drugs and CDRBs are left in place

5.6.2.3 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

5.7 Paediatrics

The management of controlled drugs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of controlled drugs may require a slightly different approach.

5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule is used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, “2.5mg given and 2.5mg wasted.” This should be witnessed by a second registered health professional who should also sign the record.
- The controlled drug to be discarded should be rendered irretrievable, in the presence of a witness as above, by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.
- A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry in the CDRB and this must be done immediately or as soon as is practicable after administration.

- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

5.7.2 Child protection

Parents who are substance misusers sometimes bring their prescribed controlled drugs on to hospital premises. Healthcare organisations may wish to consider whether, on a parent's request, they may want to store the controlled drug in the CD cupboard and the parent requests the nurse to supply when a dose is required. These controlled drugs should be clearly labelled and kept separate from other controlled drugs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

5.8 Controlled drugs for midwives

A registered midwife may possess diamorphine, morphine and pethidine in her own right so far as is necessary for the practice of her profession.

5.8.1 Acquisition of controlled drugs by midwives

Supplies of diamorphine, morphine and pethidine may only be made to a midwife on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.

5.8.1.1 The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate).

5.8.1.2 The order must specify the name and occupation of the midwife, the purpose for which the controlled drug is required and the total quantity to be obtained.

5.8.1.3 Supplies of pethidine, morphine and diamorphine may be obtained from a hospital pharmacy if the midwife is engaged in the business of the Trust. (Matters of pharmacy registration or wholesale dealing must be considered if the midwife is not engaged in the business of the Trust.) The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacy must retain the midwife's supply order for two years.

5.8.2 Storage and records

Midwives must record full details of supplies of diamorphine, morphine and pethidine received and administered in their controlled drugs register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and must be stored safely and securely.

5.8.2.2 Where it is necessary for midwives to keep medicines in their homes, the medicines must be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.

5.8.2.3 Administration of controlled drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the controlled drugs should also be kept in the woman's records.

5.8.3 Returns and disposal

When a midwife is in possession of controlled drugs that are no longer required they may be surrendered to the Appropriate Medical Officer, who should make arrangements for safe disposal, or the drugs may be returned to the pharmacy from which they were obtained. (The Appropriate Medical Officer is a doctor authorised in writing by the Health and Social Care Board who may sign midwives' supply orders, or the person appointed by the Board to exercise supervision over registered midwives.) A record of the return should be made in the midwife's controlled drugs register.

5.8.3.1 When a Schedule 2 controlled drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current guidance. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's register. Some healthcare organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.2 Controlled drugs that have been prescribed for a woman by her doctor for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required they should not be removed by the midwife, but the woman should be advised to return them to a community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and

returning it to a pharmacy for safe disposal, on behalf of the woman.

5.9 Discrepancies and diversion

The balances in the controlled drug record books (CDRBs) should always tally with the amounts of controlled drugs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate diversion. There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance checks should be carefully made that:

- All requisitions received have been entered into the correct page of the CDRB
- All controlled drugs administered have been entered into the CDRB correctly
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic is correct, to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second registered health professional. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the chief pharmacist and the Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents. Depending on the seriousness of the discrepancy and the early investigation findings, the DHSSPS Inspectorate and the police should be informed.

5.10 Illicit substances

DHSSPS has issued guidelines to help in the development of local policy and associated documents with respect to suspected illicit controlled substances recovered from patients. Although the guidance was provided for mental healthcare settings it will be of relevance to any secondary care facility. The DHSSPS Head of Medicines Regulatory Group should be consulted with respect to destruction of illicit substances. Please refer to *Drug and Substance Misuse in Mental Healthcare Settings – Guidelines for Service Providers*, DHSSPS, September 2004
www.dhsspsni.gov.uk/substance-misuse-guidance.pdf

6 Management of controlled drugs in in-house operating theatres

Contents of this chapter:

This chapter describes measures for management of controlled drugs in in-house operating theatres and departments where controlled drugs are used primarily by anaesthetists.

6.1 Accountability and responsibility

6.1.1 Accountable individuals

The senior registered nurse or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of controlled drugs.

The senior registered nurse, or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or another ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the senior registered nurse or ODP in charge. Legal responsibility remains with the senior registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions).

Similar considerations apply to requisitioning and checking of controlled drugs.

6.1.2 Standard operating procedures

Healthcare organisations should ensure that all the procedures for the management of controlled drugs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working for, perhaps, only a small part of their working week. Relevant staff must be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains accountable for the safe management of controlled drugs

6.2 Controlled drug stocks

There should be a list of controlled drugs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the senior registered nurse or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

6.3 Requisitioning of controlled drugs

The senior registered nurse or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in the theatre. (See Appendix 2)

The senior registered nurse, or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP. However, legal responsibility remains with the senior registered nurse, or ODP in charge.

Wherever practicable, different persons should be responsible for requisitioning and receipt of controlled drugs.

Requisitions must comply with the requirements for stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Healthcare organisations may consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of controlled drugs in theatres

6.4 Receipt of controlled drugs

When controlled drugs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of Controlled drugs). A local procedure should define the persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of controlled drugs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

6.5 Storage of controlled drugs

The storage arrangements for controlled drugs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of controlled drugs.

6.6 Record-keeping

The records for controlled drugs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some healthcare organisations may wish to stipulate the use of stationery that permits more detailed records of controlled drugs issued, administered and destroyed.

6.7 Controlled drug stock checks

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The senior registered nurse or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. Pharmacy staff should carry out a documented stock check at regular intervals. This should be at least every three months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

6.8 Archiving of controlled drug records

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing controlled drugs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain.

Where separate charts are used e.g. epidural charts, anaesthetic charts, they should be cross-referenced on the patient's main medicines chart.

Prescribing of controlled drugs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006.* www.aagbi.org] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed e.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "*2.5mg given and 2.5mg wasted* "

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the controlled drug. This should include the identity of the person, the dose administered and the time of administration.

6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (e.g. pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

6.12 Returning controlled drugs to the pharmacy

The arrangements for return of controlled drugs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, date-expired or controlled drugs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15.

6.13 Disposal of controlled drugs

The disposal of controlled drugs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments.

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or ODP.

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in

a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “*contains mixed pharmaceutical waste and sharps – for incineration*”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.

- If large quantities of part used controlled drugs are routinely generated, some healthcare organisations may wish to provide denaturing kits for use in theatres to destroy controlled drugs that have been used for patients. A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

7 Management of controlled drugs in hospital pharmacies

Contents of this chapter:

This chapter deals with the management of controlled drugs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of controlled drugs in the pharmacy. Day-to-day management of controlled drugs (e.g. receipt into and issue from dispensary stock) in the pharmacy may be delegated to a suitably-trained, competent pharmacy technician or another pharmacist. Where technicians are delegated the management function, legal responsibility for the controlled drugs remains with the delegating pharmacist.

7.2 Security of controlled drugs/Standard Operating Procedures

The pharmacy should have standard operating procedures (SOPs – see also page 15) covering each of the aspects of the safe management of controlled drugs including: ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of Controlled drugs. (See Appendix 3)

Relevant staff should be conversant with the SOPs.

7.3 Ordering and receipt

Ordering of controlled drugs from wholesalers and manufacturers and receipt of controlled drugs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

7.3.1 Ordering

Routine orders to wholesalers and manufacturers for controlled drugs for stock are usually placed electronically. Some healthcare organisations may, for reconciliation and accounting purposes, make a decision to produce paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that demand may outstrip the normal supply arrangements, for example, during long holiday breaks.

7.3.2 Receipt

There should be a locally agreed procedure for the receipt of controlled drugs into the pharmacy department. The procedure should ensure the security of controlled drugs and should be auditable. It should include:

- Who should sign for receipt (- ideally not the same person who generated the order.)
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods and the original order) and appropriate stock control documentation completed. Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- What action is to be taken if a tamper evident seal is broken or the contents of a pack do not match the stated amount
- What action is to be taken if the item received is incorrect

- What arrangements are made for storage of incorrect items for return, if appropriate
- The specifications for the record required in the CD register, including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event the record must be made no later than the day next following the day of receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry.

7.3.2.3 The stock must be put away promptly into the appropriate section of the CD cabinet. Controlled drugs must never be left outside of the cabinet unsupervised.

7.4 Storage

Pharmacy CD cabinets must conform to, or exceed the requirements of the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973.

The Regulations should be regarded as a minimum security standard and may not be sufficient for areas where there are large amounts of controlled drugs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. When new hospital pharmacies are being designed, purpose built, compliant strong-rooms should be incorporated in the plans and it is essential to consult in this respect with the DHSSPS Head of Medicines Regulatory Group.

7.5 Issuing of Controlled drugs to wards and departments

There should be a local procedure for the issuing of controlled drugs to wards and departments. The procedure should ensure the security of the controlled drugs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the controlled drugs to the ward or department

7.5.1 Electronic systems

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

7.5.2 Labelling of Controlled drugs (Stock)

There should be a standardised procedure for labelling controlled drugs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- Manufacturer’s Batch Number if dispensed from bulk
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

7.6 Record-keeping

7.6.1 CD registers

Pharmacy departments are required to keep registers of receipts and supplies of Schedule 2 controlled drugs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. Correction must be made by footnote or marginal note. The note must specify the date on which it was made and should be accompanied by the signature of the person making the correction. It is acceptable to bracket the incorrect entry. The resulting record in the register must be unambiguous.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional, under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign the entry

7.6.1.4 The Misuse of Drugs Regulations 2002 were amended in 2007 with changes which came into force **from 1 February 2008**. The "Form of the Register" as specified in Schedule 6 of the 2002 Regulations was removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages for each strength and form of controlled drug are now required. The name, strength and form of the drug must be entered at the top of each page and the mandatory fields of information recorded under the specified headings. An index should be maintained, together with "carried forward to/from page" details on register pages where appropriate, to enable easy navigation through the register.

7.6.1.5. The fields of information are somewhat expanded from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register. The fields are as follows:

7.6.1.6 For controlled drugs **supplied** the register entry must include:

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess - prescriber or licence holder's details
- Quantity supplied
- Person collecting Schedule 2 controlled drug (patient/patient's rep/healthcare professional) and if healthcare professional, name and address *[Guidance – work address - not home address]*
- Was proof of identity requested of patient/patient's rep (Yes/No)
- Was proof of identity of person collecting provided (Yes/No)

7.6.1.7 For Controlled drugs **obtained** the following details must be recorded in the CD Register:

- Date supply received
- Name and address from whom received
- Quantity received

7.6.1.8 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.9 The Misuse of Drugs Regulations 2002 were amended in July 2006 to make clear that the details required to be kept in a controlled drug register are a minimum and do not prevent any person required to keep a register from including additional relevant information. This principle is unchanged.

7.6.1.10 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007 can be found at www.legislation.gov.uk/nisr/2007/348/pdfs/nisr_20070348_en.pdf

7.6.2 Liquid preparations

Discrepancies can arise with liquid controlled drugs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. In dealing with discrepancies, be alert to the possibility of, or potential for, diversion. Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one. Spilled product should be treated as controlled drug waste; denatured and rendered irretrievable.

7.6.3 Computerised registers

The Misuse of Drugs Regulations 2002 were amended in January 2006 to allow (not require) the CD register to be held on an approved computerised system. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date

- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made
- Systems are in place to minimize the risk of unauthorised access to the data
- Systems which permit inspection of the register by authorised persons without disruption to the workflow of the pharmacy.

For further details see The Misuse of Drugs and the Misuse of Drugs (Notification of and Supply to Addicts) (Amendment) Regulations (Northern Ireland) 2005. (SR 2005 No. 564)
www.opsi.gov.uk/**Sr**/**sr2005**/ni**sr_20050564**_en.pdf

7.7 Checks of CD stocks performed by pharmacy staff

7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined following a risk assessment by the pharmacist with operational responsibility for managing controlled drugs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for controlled drugs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded indelibly in the CD register by means of signature, date and an appropriate entry, e.g., "*Stock checked. Balance correct*".

7.7.1.3 Some healthcare organisations may also wish to stipulate periodic checks of controlled drugs by pharmacy managers who do not routinely work in the dispensary.

7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of controlled drugs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CDRB.
- A check of a sample of CD requisition originals (brought from pharmacy) together with sample supply/administration

information to ensure that records have been correctly made in the CDRB

- A review of the security and quality of record keeping
- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage or peculiar patterns of usage of controlled drugs
- A check of the physical security arrangement for the storage of controlled drugs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own controlled drugs held on the ward at the time.

7.7.2.3 A record of the stock check should be made clearly and indelibly in the CDRB. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate diversion. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and the Accountable Officer should be informed. They should decide what action to take.

7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a controlled drug is supplied must be preserved by the Pharmacy department in accordance with legislation **and** the guidance contained in *Good Management Good Records* (GMGR) (www.dhsspsni.gov.uk/gmgr). The extensive disposal schedule to the GMGR document contains detailed information about retention of records, not only in pharmacy, but throughout HPSS. It is important to be aware of the wider content in addition to the section on "Pharmacy". Healthcare organisations

should note that even though a short mandatory period of retention may be specified in regulations, cases often come to court at a much later date.

The time periods in GMGR for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	11 years from last entry
Extemporaneous preparation worksheets	6 years
Patient Controlled Analgesia worksheets	5 years (or 11 years after expiry where product liability exists)
Discharge and specialist medicines prescriptions	2 years
Clinical trials	See GMGR

Refer to GMGR for detailed guidance on retention of records relating to children. www.dhsspsni.gov.uk/gmgr

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to the DHSSPS website for up-to-date information.

7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

- Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

May request evidence of that person's identity and

- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must**, unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

From 1 February 2008, it has been a requirement to record the following extra information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients and discharge patients should not only sign for receipt of a dispensed item but also for receipt of a specific number of doses.

7.11 Supply to external units

Section 10(7) of the Medicines Act 1968 was repealed in August 2012 to comply with EU legislation. Section 10(7) provided an exemption for registered pharmacies from the requirement to hold a Wholesale Dealers Licence when medicines were traded in certain circumstances. A hospital pharmacy wishing to make a supply to an external organisation must now ensure that it follows the MHRA guidance for supply of medicines by pharmacy to healthcare professionals or it must hold a Wholesale Dealers Licence. The guidance may be found at: www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON152604

Before making a supply to an external unit the hospital should satisfy itself that it may lawfully supply the controlled drug and that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a DHSSPS Licence to hold schedule 2 CD stocks. The supplier should only make the supply if such a licence is held. (For further information see the Home Office Drug Laws and Licensing pages: www.homeoffice.gov.uk The DHSSPS Head of Medicines Regulatory Group may be consulted regarding local licence holders.

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of Controlled drugs. Where the external unit acts on behalf of, or provides services under arrangements made with, the Trust, the Trust's Accountable Officer must ensure that the external unit has established and operates appropriate arrangements for securing safe management and use of controlled drugs. These arrangements include adequate and up-to–date SOPs.

Where a service level agreement (SLA) is drawn up for a service to supply controlled drugs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

7.11.1 Supply to external units

External units include, for example, hospices, prisons and the ambulance trust.

The other unit must comply with the legislation for controlled drugs and should also follow the guidance in this document.

7.11.2 Written agreement (Service Level Agreement [SLA])

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (SLA):

- What is to be supplied; stock controlled drugs and/or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including controlled drugs).
- An outline of the ordering and supplying processes and the documentation used.
- The arrangements for obtaining supplies of controlled drugs in emergencies and out of hours.
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).

- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for controlled drugs.
- If two different Accountable Officers cover the issuing and receiving units then each Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any problems and agree any remedial action to resolve these and review services.
- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that processes and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

7.11.3 Ordering of stock controlled drugs by another hospital or a nursing home

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a doctor or dentist employed by or engaged by the body must countersign orders for controlled drugs raised by the person in charge or acting person in charge of the other hospital or nursing home.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only to another hospital or nursing home

The person or acting person in charge of a hospital or nursing home, can complete the controlled drugs requisition book and sign this order, which must also be countersigned – see below. The stock controlled drugs order must contain:

- Signature of the person to whom the drug is to be supplied (the recipient),
- The name, address and profession or occupation of the recipient
- Name, formulation, strength and quantity (whole pack sizes) of the controlled drug,
- Purpose for use,
- Countersignature of a doctor (or dentist) who is employed or engaged at the other hospital or nursing home.

The requisition should be dated and should include sufficient information to identify the hospital or nursing home and the ward or department.

The doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other hospital or nursing home. Responsibility and accountability should be written into the SLA and be in accordance with the Misuse of Drugs Regulations.

There are circumstances where a doctor may request controlled drugs and is also responsible for the management of the controlled drugs within the department of the other organisation.

7.11.4 Ordering of patient specific controlled drugs by external units

7.11.4.1 Ordering from a hospital pharmacy

Patient specific controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

It is acceptable for the external unit to use locally designed and approved prescription forms for prescribing a patient's medication. The hospital pharmacy should manage these prescription forms in the same way as they would internal prescription forms.

A full audit trail should be maintained when transferring the dispensed controlled drugs to the external unit.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.11.4.2 Ordering from a community pharmacy

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit such as a prison or hospice.

(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

7.12 Transfer of controlled drugs

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and
a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs

7.13 Controlled drugs returned from wards

There should be a local procedure and auditable documentation for the management of controlled drugs returned from wards.

See also paragraph 4.15 – Returns to Pharmacy

7.14 Production and Quality Control

Where pharmacy production or aseptic units are preparing products that contain controlled drugs, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted controlled drugs should be denatured in a pharmacy, and when required by legislation, in the presence of an authorised witness. Treated waste should be placed in appropriate containers for eventual incineration and should not be allowed to enter the sewerage system. [See *Handling and Disposal of Pharmaceutical and Clinical Waste* (Health Estates 2002) www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf] Reference has previously been made (e.g. section 4.16.2) to circumstances whereby small quantities of waste liquid controlled drugs at ward or department level may be disposed of to sewer. Note that this pertains where hospitals have individual agreements with Northern Ireland Water, and act within the parameters of those agreements.

Controlled drugs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of controlled drugs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment and Heritage Service guidance. The methods used for denaturing should be in accordance with PSNI guidance.

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management licence for denaturing Controlled drugs as this is seen by the EA as a 'low risk' activity. The Environment and Heritage Service in Northern Ireland has taken the following position: "EHS have considered the risks posed by the destruction of controlled drugs in a pharmacy and have concluded that it will not normally take enforcement action against persons carrying out this activity providing the subsequent movement and disposal of the denatured drugs is in compliance with all relevant waste legislation… Pharmacies must ensure that the activities they undertake to denature controlled drugs protect the environment, workers and others within the pharmacy." The EHS may take appropriate action where it considers that there is a risk to human health and/or the environment. It may also amend its position if there are regulatory changes, future government guidance or in the

light of experience of this type of activity. It is therefore essential that local policies and procedures for destruction of Controlled drugs not only ensure effective destruction but also protect the environment and people in the pharmacy.

7.15.1 Destruction of stock controlled drugs

Any pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs not returned by patients, that requires destruction can only be destroyed in the presence of a person authorised by the DHSSPS.

7.15.1.1 Authorised witnesses currently include pharmacy inspectors,and other named persons employed by Trusts, who have been authorised and trained by DHSSPS.

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock controlled drugs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other controlled drugs in the CD cupboard. Stock controlled drugs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 controlled drugs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

7.15.2 Destruction of controlled drugs returned by patients

These are controlled drugs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned controlled drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2002 it is good practice to keep a record.

7.15.2.2 A record of controlled drugs returned by patients should be kept as above and a record of their destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of these destructions should be made somewhere other than the CD register – for example in a separate "Destruction Book" designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the controlled drugs
- Name, quantity, strength and form of the controlled drugs
- Role of the person who returned the controlled drugs (if known)
- Name and signature of the person who received the controlled drugs
- Patient's name and address (if known)
- Names, positions and signatures of the person destroying the controlled drugs and the witness
- Date of destruction
- Any other comments relevant to the receipt or destruction of that particular dispensed medicine

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the CD cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur regularly and with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

7.15.3 Methods of disposal for Controlled drugs

Denatured controlled drugs for disposal should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers of waste should be labelled, "*contains pharmaceutical waste – for incineration*".

The Home Office has advised that Schedule 2, 3 and 4 Part I controlled drugs must be denatured before being placed into waste containers.

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature controlled drugs. Where this is not possible or practical other methods of denaturing may be used. Used denaturing kits should be placed in pharmaceutical waste bins that are destined for incineration. Regardless of the methods used, measures should be taken to ensure safety of personnel and non-contamination of the environment.

7.15.3.2 Details of suitable methods for destruction of Controlled drugs in different dosage forms can be found in Pharmaceutical Society of Northern Ireland guidance www.psni.org.uk/documents/600/GuideLegalRequirements+MedsHumanUseControlledDrugs.pdf and it is strongly recommended that these methods are used.

7.15.3.3 Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where denaturing kits are used, their use should be included in an SOP.

Small unrequired excesses are most likely to arise when products are being prepared. In these circumstances, the controlled drug has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: "2.5ml used 0.5ml wasted".

As a matter of good practice, the disposal of the part dose should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

8 Staff training for management of controlled drugs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally.

Staff should be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

Glossary of terms

Administer	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in medicines legislation as follows: “external use" means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations; "parenteral administration" means administration by breach of the skin or mucous membrane.
Chief Pharmacist	In the context of this document the term is used to describe the pharmacist with overall responsibility for the hospital pharmacy. In some circumstances consultation may be necessary with a higher level of pharmacy management.
Controlled Drugs (CDs)	The drugs listed in Schedule 2 to the Misuse of Drugs Act 1971. These drugs are categorised in schedules 1-5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended). Drugs listed in the different MDR schedules are subject to differing levels of control but all are controlled drugs.
CD record book (CDRB)	Bound book in which records are made of controlled drugs received and supplied in wards, theatres and departments.
CD register	A “register” as specified in the Misuse of Drugs Regulations 2002 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or an approved computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.
Discrepancy	Difference between the amount shown in the register or record book and the amount that is physically present.
Designated body/bodies	Health care organisations - the Board, HSC Trusts, the Northern Ireland Ambulance Service, Independent Hospitals – as defined in Regulation 3 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.
Dispense, dispensing	Dispensing of controlled drugs: preparation (including compounding, dissolving, diluting, packing and labelling.) In some contexts it may include the transfer (supply) of medicines to individual patients.

Diversion	Removal of controlled drugs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Healthcare organisations	Organisations responsible for the delivery of healthcare. Includes Trust hospitals and independent hospitals.
Local Intelligence Network	A network lawfully established by the Accountable Officers for sharing information regarding the management and use of controlled drugs.
"may"	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances.
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971).
"must"	Used in this document in connection with legal requirements e.g. "records of schedule 2 controlled drugs received and supplied by a pharmacy must be kept in a CD register."
Operating Department Practitioner (- Registered Operating Department Practitioner)	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners – see Appendix 2
Order	In the context of controlled drugs: To make a formal order for controlled drugs. Can only be done by someone who is entitled to be in possession of controlled drugs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving specified registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
Pharmacist (– Registered Pharmacist)	Person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland
Pharmacy technician	Pharmacy technicians in Northern Ireland are not currently registered with the Pharmaceutical Society of Northern Ireland and are not, therefore, regulated professionals. Their activities related to controlled drugs should be circumscribed by standard operating procedures and must be carried out under the authority of a pharmacist.
PODs	Patient's own drugs. In this context - controlled drugs brought into the hospital by the patient on admission.
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Human Medicines Regulations 2012. The term has however become commonly used to describe authorising - by means of an NHS prescription - the

	supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse in charge	The registered nurse who is in charge for the time being (senior registered nurse on duty) and is therefore responsible for management of controlled drugs.
Relevant persons	Are defined in the Health Act 2006 and see also the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
Requisition	In the context of controlled drugs: To make a formal, written request, compliant with Regulation 14(6) of the Misuse of Drugs Regs (NI) 2002, for a supply of a controlled drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made on stationery designed specifically for that purpose. Confusingly these books are often called "Controlled Drug Order Books".
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Includes: Designated bodies, the Department, the Regulation and Quality Improvement Authority, the Regional Business Services Organisation, the Police Service, Regulatory Bodies.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
"should"	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of controlled drugs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) www.hmso.gov.uk
Supply	In the context of legal supply of controlled drugs: making a supply against a signed order, requisition, Patient Group Direction or a prescription.
Transcribe	To copy the details of one document on to another.

Appendix 1: Legislation for the management of Controlled drugs

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of controlled drugs. The MDA 1971 makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies. A controlled drug is defined as any drug listed in Schedule 2 to the Act.

Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR)

The use of controlled drugs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website of the Office of Public Sector Information (www.opsi.gov.uk)

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. In Northern Ireland only certain persons can be licensed by the DHSSPS to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the DHSSPS.
The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product), for which there is an open general licence, is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody
Schedule 2 controlled drugs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973, (see below)). They must be stored in a locked receptacle, such as

an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the controlled drug or a person authorised by them**.**

Schedule 2 controlled drugs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4 and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with the regulations.

A pharmacist may supply schedule 2 controlled drugs to a patient only on the authority of a prescription in the required form issued by an appropriate prescriber.

Schedule 2 controlled drugs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 controlled drugs

Nurse Independent Prescribers and Pharmacist Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer any controlled drug in Schedule 2, 3, 4, and 5 of the Regulations, but not in relation to cocaine, diamorphine or dipipanone for addicts, otherwise than for the purpose of treating organic disease or injury.

Record-keeping
There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 controlled drugs and this register must comply with the requirements of the Misuse of Drugs Regulations 2002. Wards and departments should also keep a Controlled Drugs Record Book (often loosely referred to as a register) for Schedule 2 controlled drugs
Midwives must keep a register for the Schedule 2 controlled drugs that they are permitted to possess and administer.

A licence is required to import or export drugs in Schedule 2.

Destruction
The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person.

Schedule 3 (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody
Some Schedule 3 controlled drugs are exempt from safe custody requirements and may be stored on the open dispensary shelf. Non-exempt examples include flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Record keeping
There is no legal requirement to record transactions involving Schedule 3 controlled drugs in a CD register. Some organisations keep a non-statutory register as a matter of good practice.

Invoices must be retained for a minimum of two years.

Schedule 3 controlled drugs are subject to full import and export control.

Destruction
The requirements for destruction do not apply unless the controlled drugs are manufactured by the entity in legal possession. However, Home Office has advised that drugs in Schedules 3 and 4 Part 1 should be denatured before disposal.

Schedule 4 (CD Benz and CD Anab)

Schedule 4 is split into two parts.

Part 1 (CD Benz) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anab) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

Unauthorised possession or supply of a drug in Schedule 4 Part 1 (CD Benz) is an offence. Possession and supply by practitioners and pharmacists acting in their professional capacities is authorised.

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anab) drug. Unauthorised supply to a third party is unlawful.

Drugs in Part 1 (CD Benz) are subject to full import and export control and a DHSSPS licence is also required for the importation and exportation of substances in Part 2 (CD Anab) unless the substance is imported in person and is for administration by the person to himself.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers. It is good practice to store securely excess stock of Schedule 4 controlled drugs.

Prescription-writing requirements for these controlled drugs do not apply, except those requirements laid out in the Human Medicines Regulations 2012. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such controlled drugs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2002).

Schedule 5 (CD Invoice)

Schedule 5 contains preparations of certain controlled drugs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and Safe Custody Regulations do not apply.

Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.

A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any controlled drug in Schedule 5.
A nurse independent prescriber acting in her capacity as such, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2, 3, 4, and 5 for the purposes of administration in accordance with regulations and any person acting in accordance with the written directions of a doctor, a dentist, a nurse independent prescriber, a pharmacist independent prescriber, or a supplementary prescriber acting under and in accordance with the terms of a clinical management plan, may compound any drug specified in Schedule 2,3,4, and 5 for the purposes of administration in accordance with the regulations.

Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973

The Safe Custody Regulations 1973 impose controls on the storage of controlled drugs. The degree of control depends on the premises within which the drugs are being stored.

All Schedule 2 and certain non-exempted Schedule 3 controlled drugs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such controlled drugs must be stored in a cabinet or safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet.

Misuse of Drugs (Notification of and Supply to Addicts) (Northern Ireland) Regulations 1973

These Regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under DHSSPS licence. A licence is not required with such drugs for the treatment of organic disease or injury. Doctors must notify the DHSSPS of patients whom they consider to be addicted to specified controlled drugs.

Medicines Act 1968 and the Human Medicines Regulations 2012

This Act (much of it repealed in August 2012), and particularly the Human Medicines Regulations 2012 set out the requirements for the legal sale, supply and administration of medicines. They also allow certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, or pethidine. A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer controlled drugs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

The key provisions of the Act are:

- Designated bodies (as prescribed by regulations) are required to appoint an Accountable Officer with responsibilities (prescribed by regulations) in connection with the safe and effective management of controlled drugs
- A duty of collaboration is placed on responsible bodies (as prescribed by regulations) to share intelligence on controlled drug issues
- A power of entry and inspection is granted for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

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

These regulations, made under the Health Act 2006, set out the requirements for certain healthcare organisations and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers related to the management and use of controlled drugs.
The Regulations also require specified bodies to co-operate with each other, including with regard to sharing of information about concerns related to the use and management of controlled drugs, and set out further arrangements relating to powers of entry and inspection.

Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007

This Regulation amends the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973 to (among other matters):

Update the references to premises covered by the Safe Custody Regulations

Update references to “sister” to “senior registered nurse”

Replace the prescribed form of the CD register with prescribed headings for entries in the register

Permit ODPs to possess and supply Controlled drugs in accordance with prescriber directions

Appendix 2: Operating Department Practitioners

Operating Department Practitioner (ODP) is defined in the Misuse of Drugs Regulations 2002 (as amended by SR 2007/348) as a person who is registered under the Health Professions Order 2001 (SI 2001/254 as amended by SI 2004/2033) as an operating department practitioner. The amendment to the Misuse of Drugs Regulations afforded to this group of registered professionals similar (but not identical) authority to that already granted to the "senior register nurse (formerly 'sister') or acting senior registered nurse for the time being in charge of a ward, theatre or other department…" The ODP was granted authority to possess and supply controlled drugs supplied to him by the person responsible for dispensing and supply of medicines at the hospital. The ODP may supply to a patient in a ward, theatre or other department only in accordance with the directions of an appropriate prescriber who may legally prescribe that drug. The amendment to the Misuse of Drugs Regulations did not specify that the ODP had to produce the same requisition as required of the senior registered nurse in charge. Because the ODP's authority to "possess and supply" implies the ability to obtain the drugs, the Home Office has stated that the ODP's authority is sufficient to "order" controlled drugs from the hospital pharmacy. Until such time as the Misuse of Drugs Regulations are further amended to require the same requisition from the ODP as the nurse in charge of a ward, hospitals should ensure that, as a matter of good practice and/or in order to comply with SOPs, supply of controlled drugs to ODPs should still be dependant upon the receipt by the hospital pharmacy of a requisition of exactly the same nature that a nurse in charge of a ward would present. Furthermore hospitals should specify in policy and SOPs which registered professional (senior nurse in charge or ODP) is responsible for the stock of controlled drugs in the particular ward, theatre or other department. Whereas the legislation grants authority to the senior (or acting senior) registered nurse in charge, **any** ODP is permitted to possess and supply controlled drugs under certain conditions. This guidance document has followed the position of the Department of Health document in referring to the senior registered nurse in charge or **ODP in charge** although it is recognised that this goes beyond the actual wording of the legislation. The intention is to indicate that it should be crystal clear in policy and procedures who is responsible for the controlled drug stock held in any theatre, ward or other department.

Appendix 3: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR2009/225 ; www.legislation.gov.uk_ Further detail is also given in 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website www.dhsspsni.gov.uk

The following paragraphs provide a summary of the main provisions.

Persons who may be appointed as Accountable Officers

Each HSC Trust and other designated bodies must appoint an Accountable Officer who is a fit, proper and suitably experienced person in a senior role within the organisation. Where designated bodies are large organisations, the Accountable Officer may consider appointing Designated Officers to assist in the day-to-day discharge of responsibilities.

The Accountable Officer should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle Controlled drugs (for example, in emergencies), but if this is the case, their use of Controlled drugs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another body. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for an HSC Trust should liaise with the Chair of the Local Intelligence Network.

Responsibilities of the Accountable Officer

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.
The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his oversight (i.e. the organisation and those with which it contracts).

(For some of the following duties and responsibilities the regulations frequently use the form of words, "The Accountable Officer must ensure/establish …, or ensure that his designated body ensures/establishes …")

- Establish, operate and periodically review appropriate systems for the safe management of controlled drugs
- Ensure that all arrangements comply with relevant statutory requirements
- Ensure that adequate and up-to-date standard operating procedures are in place for the management and use of controlled drugs
- Establish and operate appropriate arrangements for securing the safe destruction and disposal of controlled drugs
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
    - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
    - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Establish and operate arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
    - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
    - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following:
    - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
    - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
    - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some Controlled drugs or unusually high numbers of breakages could indicate misuse.

The Accountable Officer in Secondary Care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable Officer must:
    - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
    - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
        - the date on which the concern was made known to the accountable officer;
        - dates on which the matters that led to the concern took place;
        - details regarding the nature of the concern;
        - details of the relevant individual in relation to whom the concern was expressed;
        - details of the person who, or body which, made known the concern;
        - details of any action taken by the designated body in relation to the concern;
        - the assessment of whether information in relation to the concern should be disclosed to another responsible body
        - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.

- Assess and investigate concerns. The accountable officer must:
    - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
    - Take appropriate action if there are well-founded concerns

  - Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.
- Establish arrangements for sharing information. The Accountable Officer must:
  - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs
  - Provide a quarterly report to the Chair of the Local Intelligence Network
  - Cooperate with other organisations including the Department, the RQIA, the Business Services Organisation and the police as circumstances require.

- Participate in the Local Intelligence Network

Appendix 4: Useful contacts

British Medical Association
BMA House
Tavistock Square
London
WC1H 9JP
Tel: 0207 387 4499
Fax: 0207 383 6400
Website: www.bma.org.uk/

Community Practitioners' and Health Visitors Association
33-37 Moreland Street
London
EC1V 8HA
Tel: 0207 505 3000
Website:
www.amicustheunion.org/cphva/

Council for Healthcare Regulatory Excellence
157-197 Buckingham Palace Road
London
SW1W 9SP
Tel: 0207 389 8030
Fax: 0207 389 8040
Website: www.chre.org.uk

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS
Tel: 0207 210 4850
Website: www.dh.gov.uk

Department of Health, Social Services and Public Safety
Pharmaceutical Advice and Services
Room D4.5,
Castle Buildings
Stormont
Belfast
BT4 3SQ
Tel: 028 9052 8688
Fax: 028 9052 2335
Website: www.dhsspsni.gov.uk

Dispensing Doctors' Association
Low Hagg Farm
Starfitts Lane
Kirbymoorside
North Yorkshire
YO62 7JF
Tel: 01751 430835
Fax: 01751 430836
Website: www.dispensingdoctor.org

General Medical Council
Regent's Place
350 Euston Road
London
NW1 3JN
Tel: 0845 357 3456
Website: www.gmc-uk.org

Health and Social Care Board
Headquarters
12-22 Linenhall Street
Belfast
BT2 8BS
Tel: 028 9032 1313
Website: www.hscboard.hscni.net

Home Office Drugs Licensing Branch
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0483
Website: www.homeoffice.gov.uk/drugs/licensing/

Home Office Drug Legislation Team
2 Marsham Street
London
SW1P 4DF
Tel: 0207 035 0464
Website: www.homeoffice.gov.uk

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Tel: 0207 084 2000
Fax: 0207 084 2353
Website: www.mhra.gov.uk

National Clinical Assessment Service
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn BT28 1TW
Tel: 02892663241
Website: www.ncas.nhs.uk

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD
Tel: 0207 927 9500
Website: www.npsa.nhs.uk

National Pharmacy Association
Mallinson House
38-42 St Peter's Street
St Albans
Hertfordshire
AL1 3NP
Tel: 01727 832161
Fax: 01727 840858
Website: www.npa.co.uk

National Prescribing Centre
The Infirmary
70 Pembroke Place
Liverpool
L69 3GF
Tel: 0151 794 8134
Fax: 0151 794 8139
Website: www.npc.co.uk (Internet)
www.npc.nhs.uk (NHSNet)

National Treatment Agency
8th Floor, Hercules House
Hercules Road
London
SE1 7DU
Tel: 020 7261 8801
Fax: 020 7261 8883
Website: www.nta.nhs.uk

Nursing and Midwifery Council
23 Portland Place
London
W1B 1PZ
Tel: 020 7637 7181
Fax: 020 7436 2924
Website: www.nmc-uk.org

Pharmaceutical Society of Northern Ireland
73 University Street
Belfast
BT7 1HL
Tel: 028 9032 6927
Fax: 028 9043 9919
Website: www.psni.org.uk

Prescribing Support Unit
The Health and Social Care
Information Centre
1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE
Tel: 0113 254 7041
Fax: 0113 254 7097
Website: www.ic.nhs.uk/psu

Regional Business Services Organisation
2 Franklin Street
Belfast
BT2 8DQ
Tel: 028 9032 4431
Website: www.hscbusiness.hscni.net/

The Regulation and Quality Improvement Authority
9th Floor Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT
Tel: 028 9051 7500
Website: www.rqia.org.uk

Royal Pharmaceutical Society
1 Lambeth High Street
London
SE1 7JN
Tel: 0207 572 2737
Fax: 020 7735 7629
Website: www.rpharms.com

Appendix 5: Patient Information

NHS Direct

The NHS Direct website has developed a Common Health Question about Controlled drugs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at
www.nhs.uk/chq/Pages/1391.aspx?CategoryID=73&SubCategoryID=101
The text defines a controlled drug in legal terms, how the Regulations apply to them and directs patients to information about requirements for travelling abroad.

HOME OFFICE
Useful advice for patients travelling with controlled drugs can be accessed at
www.homeoffice.gov.uk/drugs/licensing/personal/

Medicines Guides

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on controlled drugs can be found on the www.medicines.org.uk website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the controlled drugs that have been published to date can be accessed at www.medguides.medicines.org.uk/cd.

Appendix 6: Contributors

The following individuals and organisations are among those who contributed to the design and content of this guidance and/or the original Department of Health document:

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Appendix 7

Suggestions for Future Revisions

Name:	
Organisation:	
Section number Indicate **page/section heading** or **'general'** if your comment relates to the whole document	**Comments** **Please insert each new comment in a new row.**
P.24, Record keeping	*In our hospital we refer to…*

Safer Management of Controlled Drugs

Guidance on Standard Operating Procedures for Northern Ireland

Department of Health, Social Services and Public Safety

October 2009

Guidance on Standard Operating Procedures (SOPs) for Controlled Drugs

Introduction

1. The purpose of this guidance is to promote the safe, secure and effective use of all controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. Strengthened measures have been introduced to make sure controlled drugs are managed safely. These governance arrangements need to be implemented in a way that supports professionals, and encourages good practice around the management and use of these important medicines when clinically required by patients.

2. This Department has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006[1]. These will work within and alongside existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[2] ("Regulations") made under the Health Act 2006 will require each Designated Body to appoint an Accountable Officer, responsible for the safe and effective use of controlled drugs in their organisation. The Regulations also introduce Standard Operating Procedures (SOPs) for the use and management of controlled drugs, as one of the practical measures that will help to ensure good practice throughout the health and social care system.

3. The Regulations require Accountable Officers to ensure that his or her organisation, or a body or person acting on behalf of, or providing services under contract with his or her organisation, has adequate and up to date SOPs in relation to the use of controlled drugs.

4. The Standard Operating Procedures must in particular cover the following matters as stated in the Regulations:

    - who has access to the controlled drugs
    - where the controlled drugs are stored
    - security in relation to the storage and transportation of controlled drugs as required by Misuse of Drugs legislation
    - disposal and destruction of controlled drugs
    - who is to be alerted if complications arise
    - record keeping, including maintaining controlled drugs registers under Misuse of Drugs legislation and maintaining a record of Schedule 2 controlled drugs that have been returned by patients.

[1] Health Act 2006
[2] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Definition

5 A SOP is an unambiguous document, describing the responsibilities and the procedures necessary to safely and accountably manage any set of processes, in this case around the total management of controlled drugs. A SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of controlled drugs in an individual setting. The responsibilities should be assigned to individuals where possible to ensure accountability.

6 This guidance is intended to provide base line advice on the areas that might be considered for inclusion in the SOP. Different health and social care settings may have practice areas in addition to those outlined below.

Principles

7 Why are SOPs needed for controlled drugs?

- To improve governance of controlled drugs within the organisation
- To ensure practice is in line with the regulatory frameworks
- To improve clarity and consistency for all staff handling controlled drugs
- To define accountability and responsibilities and clarify where responsibility can be delegated
- As a training tool for new and existing staff.

Validation within the organisation

8 A large organisation will require an overarching policy for SOPs, and smaller organisations such as GP practices will need to have an appropriate process in place to agree, adopt and review SOPs for use.

9 SOPs will need to be agreed at a senior level on behalf of the organisation, usually through the Accountable Officer for designated organisations (as defined in the Health Act Regulations and will include the HSC Board, Trusts, Northern Ireland Ambulance Service and Independent Hospitals) and/or involving other relevant stakeholders such as senior practitioners, senior partners, senior pharmacists, prescribing advisers, medical advisers, superintendent pharmacists, and Clinical Governance Leads as appropriate to the organisation.

10 A common template needs to consider inclusion of the following:

- Organisation/Area/Service to which the SOP applies
- Objective/purpose
- Scope
- Stages of the process for example other committees that need to agree such a document
- Responsibilities
- Other useful information such as interaction with other SOPs, what to do if circumstances change
- Validation by organisation and date
- Review period. e.g. one, two or three years
- Lead author and named people contributing to SOP

11 The SOP policy should take account of:

- Training considerations for new and existing staff including ownership and awareness training
- The review criteria, for example:
  - After a given time period
  - Following a critical incident, to include the learning from such incidents
  - Significant change in legislation or best practice
  - Where a specified named person is included in a SOP then the SOP will need to be changed if personnel circumstances change.
- Cascade mechanism of changes to all staff
- Staff responsibilities – requirement to notify variation/inability to follow SOP
- Opportunity to comment and be part of review process.

Scope of SOPs

12 SOPs are needed for every stage of the controlled drug's journey from procurement (ordering, receipt, and transport), safe storage, supply, administration, destruction and guidance for dealing with an incident. Most will require multi-disciplinary collaboration.

13 The organisation will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.

14 The following is to assist in identifying the steps in handling controlled drugs that need to be considered in the SOP and what is appropriate for each organisation.

15 SOPs need to be accessible to staff at all times.

Areas to consider

Receiving into organisation/unit/individual practitioner

Activity	Detail	Comment
Ordering	Assessment of necessity for a licence/authority to produce, supply or possess the stock of controlled drugs.	Refer to Home Office web-site Refer to DHSSPS web-site Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care"
	Format of requisitions including descriptions of other forms and stationery to be used	See Reg 14 of Misuse of Drugs (Northern Ireland) 2002 [MDR (NI) 2002]
	Named person(s) (consider deputy/locum) with authority to order	See Reg 14 of MDR (NI) 2002
	Organisational tendering processes	
Transport and secure transfer of stock	Ensure secure arrangement in place, particularly if not from wholesaler/manufacturer	To be risk assessed depending upon the drugs, amounts, frequency and distance of movement
Receipt	Personnel authorised within organisation to receive	
	Physical check of order for accuracy and completeness	Who is responsible for this and what happens if a deficiency is identified?
	Record keeping of receipt	Is a Proof of Delivery provided? How is the invoice stored and for how long? Refer to DHSS guidance – Good management, good records.
	Security on receipt	Who, where and when is responsible for this once the consignment is accepted?

Activity	Detail	Comment
Storage	Security and key/code security Personnel with access	Refer to Safe Custody Regulations. Does the storage meet the legislative requirements? Is key storage secure and is access limited to nominated individuals? Is there an updated list of those with authority to access?
	Appropriateness for product e.g. temperature	
	Out of Hours access	Can the person lawfully supply a controlled drug under the legislation? Refer to Guidance on Out of Hours procedures.
	Contingency for extended closure	Where are the drugs stored? Who has responsibility?
Register entry	Ensure entries are made in accordance with legislation and best practice guidance.	Who makes entries? When are entries made?
Stationery	Arrangements for controlled stationery including ordering and disposal	Who is responsible? Is a list of who holds what stationery maintained?
Audit	Regular(need to specify when) checks/audits Personnel involved.	To be risk assessed on drugs, amounts held and frequency of transactions. Is there a standard report format
Discrepancies	Action to take if any discrepancies noted	Cross check register entries and physical stocks. Formal investigation to be undertaken by whom and within what time scale.
	Identify chain of interested parties.	Who is to be informed and timescale for reporting. Who is accountable within the organisation? Do the police or other regulatory bodies need to be informed? Role of Accountable Officer.
Process for reconciliation when necessary	Standard format of report. Retention period of report.	Does the organisation have this? Where and how long is it stored?

Transfer within organisation/to practitioners

Activity	Detail	Comment
Request	Prescription	See Regs 15 and 16 of MDR (NI) 2002
	Signed order (correct stationery) by known signatory	See Reg 14 of MDR (NI) 2002
	Checking authority to order	Supplier able to check against specimen signature
Assembly and supply	Authorised personnel (responsible person)	Training/competency/qualifications
	Labelling issues	
	Register entry	
Hand over	Record keeping	To whom
Transport	Authorised personnel	Some organisations may require specific SOPs relating to transport.
	Audit trail on leaving department	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Security	
Audit trail by receiving unit	Personnel authorised to receive	To be risk, assessed depending on drugs, amounts held and frequency of transactions.
	Record keeping of receipt	
	Security on receipt	

Prescribing

Activity	Detail	Comment
Prescribing	Authority to prescribe	Refer to legal position of who can prescribe which controlled drugs. Supplementary prescriber status, existing and new independent prescribers, private or NHS.
	Prescription stationery	Hospital charts
		HS21 types including SP1 and SP2
	Private prescribing	Prescriber Identification Number – PCD1
	Local restrictions	

Administration

Administration	Authority to prescribe	Consider supplementary prescriber status, existing and new independent prescribers
	Authority to administer	PGD considerations, legal and clinical check
	Assembly	Removal from cupboard/store
		Reconstitution/assembly
		Trained personnel
	Patient	Verification of patient/treatment. Use of clinical notes.
	Register Entry	Entry in patient's notes
	Special precautions	IV, calculations
	Patient specific documentation	
	Disposal/recording arrangements for any unused portion	Refer to "A guide to good practice in secondary care" Refer to "A guide to good practice in primary care" Refer to NMC Standards and Professional Guidance.

Records and Register

Record keeping	Record document management	Refer to DHSS guidance – Good management, good records.
	Retention of hard copies/back-up of records	Time period/location/responsible person
	Supplier of register	Contact details of supplier of register
	Record keeping (legal)	Requirements under Misuse of Drugs(Northern Ireland) Regulations 2002
	Record keeping	Patient returned controlled drugs – PDRCs Where is information recorded? By who? Storage of records?

Individual patient supplies

Supply to patient	Authority to supply	Legal and clinical check of prescription
	Assembly and supply	Removal from cupboard
		Training, competency/qualifications
		Standards of equipment used
		Authorised personnel (responsible person)
		Labelling
	Patient/representative	Verification of patient/treatment. Use of clinical notes.
		ID arrangements
	Delivery service	Transfer to delivery driver. Procedures on delivery to patient, consider if patient not at home, counselling.
	Register entry	
	Prescription forms	Arrangements for sending to the Business Services Organisation

Disposal

To include agreed record keeping requirements

Disposal	Unused portions (e.g. ampoules, syringe driver)	How is this undertaken and by whom?
	Out of date stock (ward and pharmacy)	How is this undertaken and by whom?
	Excess stock	Disposal
		Legal return to stock
	Patient Own	
	Denaturing	What is the process for this and what happens to clinical waste?
	Record keeping	
	Authorised witnesses if required	
	Disposal	Carrier and destination? Contact name, address and telephone number.

Illicit substances

Illicit substances	Removal	Who may lawfully undertake this activity?
	Storage	Where are drugs held until removal?
	Recording	How are they recorded?
	Reporting	Relevant contact numbers

Incidents

Incidents	Reporting mechanisms	Who has investigative responsibility? How is this documented?
	Review procedures	On-going reviews held when? Need to review in light of experience.

Audit of SOP

Audit	By whom	
	Format	
	Frequency	
	Reporting route	
	Record management	

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Safer Management of Controlled Drugs

A Guide to Strengthened Governance Arrangements in Northern Ireland

Introduction

1. This guidance sets out strengthened governance arrangements for the management and use of controlled drugs in Northern Ireland. These arrangements are underpinned by the Health Act 2006 and the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 as amended by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 (the Regulations).

The guidance has been developed from original guidance issued by Department of Health (DH) (England) and the Scottish Executive to support the work of their Accountable Officers. The Department of Health, Social Services and Public Safety (the Department) is grateful to DH (England) and the Scottish Executive for the use of their guidance documents and for the support provided to the Department in the preparation of this document.

Please note that the Department does not accept responsibility for inaccuracies in this guidance. Organisations must seek their own independent legal advice.

2. The Fourth Report of the Shipman Inquiry[1] identified a number of serious shortcomings in the systems used for the management of controlled drugs and made recommendations to improve their management. The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in "Improving Patient Safety – Building Public Confidence"[2]. It is recognised that the recommendations within the Fourth Report related, in the main, to the situation in Great Britain at the time of the Inquiry and that the controlled drug monitoring arrangements operating in Northern Ireland were most favourably commented upon by the Inquiry Chair at that time.

3. The Shipman Inquiry identified the key strengths of the current Department's Medicines Regulatory Group (formerly known as the Medicines Inspection and Investigation Team) as its centralised nature, integration within the Department, expertise and multi-disciplinary nature, existing integration and collaboration with other professional bodies and investigation/enforcement authorities.

4. The Department favoured a system which would work within and alongside the existing governance arrangements and build on, and use, the expertise of the current inspection and investigation resources.

5. It was anticipated that the procedures would result in a significant improvement to existing arrangements, being better co-ordinated and integrated within the overall framework for improving quality in healthcare. They are intended to encourage good practice in the management of

[1] See *The Regulation of Controlled Drugs in the Community, The Fourth Report of the Shipman Inquiry* (http://www.the-shipman-inquiry.org.uk/4rpage.asp)
[2] "Improving Patient Safety – Building Public Confidence" www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf

controlled drugs as well as help to detect unusual or poor clinical practice or systems, criminal activity or risk to patients.

Legislative changes

6. Parliament considered that new legislation was necessary to respond to a number of the recommendations in the Shipman Inquiry report. Therefore, the Health Act 2006, which received Royal Assent in July 2006, included measures to improve and strengthen the management and use of controlled drugs.

7. The Regulations made under the Health Act 2006 are called The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009[3] which came into operation on 1 October 2009. These Regulations were subsequently amended by the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations (Northern Ireland) 2015 which came into operation on 16 July 2015.

8. The governance arrangements have been implemented in a way that supports healthcare professionals, encourages good practice and does not deter the use of controlled drugs when clinically required by patients. Furthermore it is essential that the arrangements ensure potential criminality is identified and reported to the police at the earliest opportunity.

9. This guidance describes the arrangements in Northern Ireland.

Implementation

10. The three key elements of the legislation are:

- Accountable Officers and their duties
- Powers of entry and periodic inspections
- Co-operation between health bodies and other organisations

11. The Health Act 2006 requires “Designated Bodies” to appoint or nominate an Accountable Officer, either one per organisation or, within parameters, shared between organisations. For the purposes of the Act, “Designated Bodies” are those that are “directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service)”, or “otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs”.

12. Designated Bodies include:

- the Health and Social Care Board (HSCB)
- Health and Social Care Trusts

[3] The Regulations can be accessed at http://www.opsi.gov.uk/sr/sr2009/nisr_20090225_en_1

- relevant independent Hospitals
- the headquarters in Northern Ireland of regular or reserve forces (armed forces)

13. The Act also introduces a duty of co-operation which requires Responsible Bodies to share information and concerns about the management and use of controlled drugs. Responsible Bodies include:

- Designated Bodies, as above
- the Department
- the Regulation and Quality Improvement Authority (RQIA)
- Police Service of Northern Ireland
- The Counter Fraud Unit of Business Services Organisation (BSO)
- regulatory bodies (including the Pharmaceutical Society of Northern Ireland, General Dental Council, General Medical Council, Nursing and Midwifery Council, Health and Care Professions Council and the Northern Ireland Social Care Council)

(Refer to Annex B for full list of Responsible Bodies).

14. The Act contains a power of entry and inspection for certain authorised persons to inspect controlled drugs and associated records. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development. It may identify concerns which will be brought to the attention of the Accountable Officer.

15. More detailed information on the above aspects of the legislation can be found in the following Annexes.

Annex A - Accountable Officer
Annex B - Duty of Co-operation/Local Intelligence Network
Annex C - Monitoring
Annex D - Entry and Inspection
Annex E - Investigations
Annex F - Controlled drug declarations and self-assessments

Annex A

Accountable Officer

1. The Health Act 2006 and the Regulations require Designated Bodies to nominate or appoint an Accountable Officer (regulation 4 (as amended)) to be responsible for a range of measures relating to the monitoring of the safe management and use of controlled drugs within the organisation and take appropriate action where necessary. Designated Bodies include the Health and Social Care Board, Health and Social Care Trusts, relevant independent hospitals and the armed forces.

2. An Accountable Officer must be an officer or employee of the Designated Body who is a fit, proper and suitably experienced person and, other than for the armed forces, be a senior manager, or someone who is answerable to a senior manager, of the Designated Body.

3. In the case of the armed forces the Accountable Officer must be a senior officer with rank of lieutenant colonel, or a person of equivalent or superior rank.

4. For relevant independent hospitals it is likely that the Accountable Officer will be the registered manager. The decision will however be dependent on the person meeting the three conditions for appointment (regulation 4 (as amended).

5. Two or more Designated Bodies which are of the same type may jointly nominate or appoint one person to be their Accountable Officer so long as that person meets the requirements of regulation 4 (as amended). Each Designated Body must be satisfied that the Accountable Officer can discharge his/her responsibilities in relation to both.

6. The Accountable Officer must only exceptionally prescribe, supply, administer or dispose of controlled drugs as part of their duties. A Designated Body can nominate or appoint an Accountable Officer who has an occasional, exceptional role in the use of controlled drugs (for example, in emergencies). However, their use of controlled drugs should be open to the scrutiny of another person to whom they are answerable. They should have credibility with all healthcare and social care professionals and be of a sufficient seniority to be able to take action regardless of how a concern is raised. Individuals at levels equivalent to Medical Directors, Pharmacy Directors or Directors of Nursing, can be appointed as Accountable Officers if they meet the above criteria. The Accountable Officer can be a stand-alone or additional role depending on local circumstances. Designated Bodies should make it clear, as part of their monitoring systems whom people should approach if they have concerns about the practice of their own Accountable Officer.

7. A Designated Body (or, in the case of a joint appointment, the Designated Bodies acting jointly) must remove its Accountable Officer if he no longer satisfies the conditions set out above or if he is no longer considered fit to be an Accountable Officer (regulation 6 (as amended)). For the purposes of the Regulations, an Accountable Officer is found to be unfit if he wilfully,

negligently or through lack of competence breaches his duties as an Accountable Officer. A Designated Body must have in place a procedure (which may be part of its internal disciplinary procedures) for due consideration of matters which may lead to the removal of its Accountable Officer.

8. The Regulations set out Accountable Officers' responsibilities. The Accountable Officer will hold a senior post in the Designated Body and will carry overall responsibility for ensuring compliance with the arrangements in relation to the management of controlled drugs. Regulation 4 (as amended) requires that a Designated Body must provide its Accountable Officer with the funds and other resources necessary to enable him to carry out his responsibilities. Resources may include staff and it is anticipated that the Accountable Officer may identify individuals to assist them in the day-to-day discharge of their responsibilities.

9. Designated Bodies must inform the Department in writing of their nominations or appointments of Accountable Officers and of any subsequent changes. The Department maintains an up to date list of Accountable Officers in Northern Ireland which is published on the Departmental website (regulation 6A) and can be accessed at
www.dhsspsni.gov.uk/accountable-officer-contact-list.pdf
.

Accountable Officer Responsibilities

10. As set out in Regulations 8-18 (as amended), Accountable Officers need to ensure that they have systems in place for routinely monitoring the management and use of controlled drugs through pro-active analysis, identification of triggers for concern, and taking action (regulation 11). They also need to ensure that appropriate arrangements are in place for assessing and investigating concerns and that they are alerted to any significant findings (regulations 11 and 16). Where criminality is suspected the police should be notified.

11. Accountable Officers must have arrangements in place for the review of the management and use of controlled drugs within their Designated Body or ensure that the Designated Body does so. They must also ensure that any person or body acting on behalf of, or providing services under arrangements made with their Designated Body, establishes, operates and reviews appropriate arrangements for the management and use of controlled drugs.

12. The Accountable Officer will need to have or be able to access certain skills and expertise, including data analysis, investigative skills and networking. They may require investigative and administrative support and support from others such as the clinical governance lead, Medicines Management Adviser, the Department or the police as appropriate (see Annex C).

13. Designated Bodies may wish to consider consortia arrangements to support Accountable Officers in areas such as data analysis and investigative skills. These arrangements will be for local determination and should take into

account any previous history of concerns about controlled drugs misuse and predictions of the likely workload.

14. The Accountable Officer should also make sure that their Designated Body and contractors have suitable arrangements in place for the disposal of controlled drugs (regulation 10).

15. Accountable Officers are required to ensure that appropriate training is received by those carrying out their responsibilities under the Regulations and this should include regular and comprehensive training applicable to the role of the person involved in the prescribing, supplying, administering and disposal of controlled drugs.

16. Accountable Officers shall provide appropriate training on local standard operating procedures and ensure that anyone involved in working under the standard operating procedures is informed when a formal review takes place e.g. after the designated time period or after a critical incident.

17. The structures set up for the Accountable Officer should integrate with existing local performance structures and should relate to groups such as Drug and Therapeutic Committees and clinical governance committees. Accountable Officers are encouraged to share best practice and learn from each other through contact with other Accountable Officers.

Annex B

Duty of Co-operation

1. To maximise the effectiveness of the Regulations it is important that healthcare organisations, the police service, and others work together to share concerns on controlled drugs issues. The Regulations place a duty of co-operation on specified organisations ("Responsible Bodies" set out in regulation 22) permitting them to share information giving rise to concerns about the management or use of controlled drugs by any "relevant person".

The Health Act 2006 (Section 19) and the Regulations (regulation 23 (as amended)) made under the Act define the term "relevant person" and include any individuals, whether or not health care professionals, who are involved in any way with the management or use of controlled drugs on behalf of or providing services under arrangements with a designated body.

Furthermore the term "relevant person" includes any health care professional who provides services to private patients which involves the supply or administration of controlled drugs. Additionally any individual, whether or not they are a health care professional, who is engaged in any activity carried on with or on behalf of that health care professional is included in the definition of a "relevant person".

2. Under the arrangements the following are Responsible Bodies:

Primary Care

- Health and Social Care Board

The Accountable Officer may liaise with key members of staff including prescribing, medical, dental, nursing advisers and HR where appropriate to collate detailed information for the Local Intelligence Network (LIN).

Secondary Care

- Belfast Health and Social Care Trust
- Northern Health and Social Care Trust
- Southern Health and Social Care Trust
- South - Eastern Health and Social Care Trust
- Western Health and Social Care Trust

The Accountable Officer may liaise with key members of staff including clinical directors, pharmaceutical directors and HR, where appropriate, to collate detailed information for the LIN.

Other Designated Bodies

- Northern Ireland Ambulance Service Trust
- relevant independent hospitals
- armed forces

The Accountable Officer may liaise with key members of staff within their Designated Body to collate detailed information for the LIN.

Other Responsible Bodies

- Department
- RQIA
- Counter Fraud Unit of BSO
- Police Service of Northern Ireland
- Pharmaceutical Society of Northern Ireland
- General Medical Council
- General Dental Council
- Nursing and Midwifery Council
- Health and Care Professions Council
- Northern Ireland Social Care Council

Information-Sharing

3. A Responsible Body may disclose to any other Responsible Body any information which may help identify cases where action may need to be taken in respect of the management or use of controlled drugs. This enables bodies that have a concern to share it as soon as possible with any other bodies who may be affected or who may have complementary information.

4. Confidential information about patients must be removed where possible. If it is not possible to remove patient identifying details from confidential information, then the patient's consent should be sought wherever practicable (regulations 25 & 26 (as amended)).

5. In sharing such information, Responsible Bodies must have regard to the Data Protection Act 1998 and codes of practice on confidentiality - in particular the Caldicott principles i.e.

- Justify the purpose
- Do not use patient identifiable information unless it is absolutely necessary
- Use the minimum necessary patient identifiable information
- Access to patient identifiable information should be on a strict need to know basis
- Everyone should be aware of their responsibilities
- Understand and comply with the law.

6. Care should also be taken when sharing information about identifiable relevant persons and, where possible, individuals should be made aware of concerns raised about them unless, for example, disclosure would jeopardise the conduct of an investigation.

The Code of Practice on Protecting the Confidentiality of Service User Information www.dhsspsni.gov.uk/confidentiality-code-of-practice0109.pdf may be a helpful resource.

Local Intelligence Network (LIN)

7. The HSCB Accountable Officer is required to establish a network (a Local Intelligence Network) in which Responsible Bodies participate for sharing information regarding the management and use of controlled drugs. There is a single Local Intelligence Network, covering Northern Ireland.

8. The LIN will facilitate timely and appropriate sharing of information, and enable bodies that have a concern about the activities covered by this legislation to liaise at an early stage with other local agencies who may be affected or who have complementary information.

9. Members of the LIN may also want to involve others as appropriate such as Drug Action Teams and Local Supervising Authority Midwifery Officers. However, this list is not exhaustive and it is crucial that this forum takes account of the diversity of interests both within and outwith the health service including manufacturers, wholesalers and Veterinary Practitioners.

10. The LIN meets on a quarterly basis and members have agreed their Terms of Reference and guidance to support the managing and sharing of concerns. An Accountable Officer may request that an incident panel be convened by the HSCB Accountable Officer to investigate a concern and to

make recommendations. Each body will retain responsibility for taking appropriate action where required.

11. In addition to the quarterly meetings, members of the LIN may develop a centrally maintained, confidential database to support the effective sharing of information throughout the network.

Occurrence Reports

12. Accountable Officers must provide the HSCB Accountable Officer with a quarterly occurrence report (regulation 29 (as amended)). The HSCB Accountable Officer may require an Accountable Officer to provide occurrence reports more often than quarterly should he have a concern about that Designated Body. This report shall provide details of any concerns that the Designated Body may have identified regarding the management or use of controlled drugs or confirm that it has not identified any such concerns.

Request for Additional Information

13. There may be instances when a Responsible Body considers that it may require additional information from another Responsible Body in order to determine whether or not action is necessary (regulation 26 (as amended)). This additional information may be specific to the management or use of controlled drugs or could be, for example, fitness to practise information. Where a Responsible Body has received such a request in writing it must decide within a reasonable period of time whether or not to disclose the additional information. The decision about disclosure should take account of issues of confidentiality.

Restrictions Relating to Disclosures

14. Where a Responsible Body has an Accountable Officer, any information disclosed under the Regulations must ONLY be made by or to the Accountable Officer or his staff. The information may ONLY be used for identifying cases, considering and taking action in respect of concerns relating to the management or use of controlled drugs (regulation 27). In particular, the Responsible Body must ensure that appropriate measures are taken to prevent unauthorised access, processing, or disclosure of the information.

Record Keeping

15. Responsible Bodies must keep records (either paper or electronic) of any decisions to disclose information, details of the nature of the information disclosed, details of the Responsible Body to which the information was disclosed and any other relevant details (regulation 28).

16. Responsible Bodies must also keep a record (either paper or electronic) of any requests received from another Responsible Body to disclose information, details of the nature of the information disclosed, details

of the Responsible Body to which the information was disclosed and any other details considered to be relevant (regulation 28).

17. Responsible Bodies should refer to "Good Management, Good Records" for guidance on managing records in Health and Personal Social Services organisations in Northern Ireland.
http://www.dhsspsni.gov.uk/index/gmgr.htm

Taking Action

18. Responsible Bodies have a duty to co-operate in identifying cases, considering action and taking action, in respect of matters arising in relation to the management or use of controlled drugs by a relevant person (regulation 24). Action might include further investigation of issues of concern or the initiation of processes to protect the safety of the public, including professional disciplinary processes. Each organisation will be separately accountable for action within its own remit.

19. If a Responsible Body shares information under Regulations 25 and 26 (as amended) that indicates a concern about inappropriate or unsafe use of controlled drugs by a "relevant person", the Accountable Officer(s) concerned may make recommendations to the Responsible Body as to the actions that should be taken. For these purposes, the relevant Accountable Officer would be the Accountable Officer of the Designated Body responsible for entering into any arrangements (either directly or through another individual or body) with the person to provide services. The Responsible Body is any Responsible Body that could take appropriate action, including regulatory bodies and the police. Where the person does not provide services to a Designated Body, the HSCB Accountable Officer must seek to take reasonable steps to protect the safety of patients and the general public. If appropriate, the HSCB Accountable Officer must refer the matter to a relevant Responsible Body, e.g. a regulatory body or the police (regulation 30 (as amended)). Further information about undertaking investigations can be found in Annex E.

Annex C

Monitoring

Routine monitoring

1. Accountable Officers must establish and operate or ensure that their Designated Body and any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body, establishes and operates arrangements for monitoring and auditing the management and use of controlled drugs (regulation 11). This can be through normal governance and management arrangements. Where one organisation provides services to another, the commissioner of the services has responsibility for ensuring that appropriate governance arrangements are specified in the contract.

2. The arrangements made by the Accountable Officer in relation to controlled drugs must include provision for the following:

- monitoring and analysing of prescribing
- ensuring that the Designated Body (or its service providers[4]) has systems in place to alert the Accountable Officer of any complaints or concerns
- ensuring that the Designated Body (or it's service providers[4]) has an incident reporting system in place for untoward incidents
- ensuring that the Designated Body (or it's service providers[4]) has appropriate arrangements in place for analysing or responding to untoward incidents

Monitoring of prescribing may include COMPASS Prescribing Reports and allied data analysis tools. The COMPASS prescribing reports are produced from data that are captured by the Business Services Organisation from dispensed prescriptions. Prescribing reports are generated for individual practices, locality groups and the HSCB as a whole for each quarter and each financial year. Practice reports are circulated to all practices each quarter. The report allows practices to see how their prescribing compares to that of other practices in NI and how they have changed compared to the previous year. The COMPASS system is also used to generate control charts which allow Medicines Management Advisers to identify "out-lying" practices which require follow up in relation to their prescribing of Controlled Drugs.

Monitoring in secondary care can include, but is not restricted to, analysing:

- ward/department usage
- in-patient/out-patient discharge dispensing
- use in out of hours services.

The responsibility for prisons lies with the AO of the South Eastern Health and Social Care Trust

[4] any persons or bodies acting on behalf of, or providing services under arrangements made with the Designated Body

3. The Care Quality Commission produced a Controlled Drug Governance Self-Assessment Toolkit[5] to allow Designated Bodies to assess how they are doing in terms of controlled drug governance and to suggest actions for areas of improvement. The toolkit was developed predominantly for general practice in England, but can be used in other settings.

Controlled drug declarations and self assessments

See Annex F

Standard Operating Procedures (SOPs)

4. The Accountable Officer must ensure that his Designated Body (and service providers[4]) has adequate and up-to-date SOPs in place in relation to the management and use of controlled drugs.

Regulation 9 (as amended) requires the SOPs to cover (unless not applicable to the Designated Body):

- who has access to the controlled drugs;
- where the controlled drugs are stored;
- security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- disposal and destruction of controlled drugs;
- who is to be alerted if complications arise, and
- record-keeping, including –

  (i) maintaining relevant controlled drugs registers under the misuse of drugs legislation, and

  (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002[6] (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

Accountable Officers must also ensure that they have in place sufficient and up to date SOPs which cover prescribing, supply and administration of CDs and the clinical monitoring of patients who have been prescribed controlled drugs.

[5] See http://www.cqc.org.uk/content/controlled-drugs

[6] SR 2002/1 as amended

Annex D

Entry and Inspection

Routine periodic inspections

1. Inspections of a wide range of relevant premises are already undertaken by the Department's Medicines Regulatory Group and the Regulation and Quality Improvement Authority (RQIA). In addition to this, the Health Act 2006 contains a power of entry and inspection, subject to certain criteria, for constables and certain authorised persons to enter any relevant premises to inspect controlled drugs and any associated records. These authorised persons include Accountable Officers and persons authorised by the Designated Body.

2. Formal inspection involving an 'on-site' visit is only part of the monitoring and inspection arrangements which also include controlled drug declarations and self assessments. Nonetheless, inspection remains a useful tool to check physical arrangements for the storage, record keeping and management of controlled drugs. The inspection process is intended to monitor compliance, improve quality and support individual and organisational development.

3. For those premises that are periodically inspected by RQIA and the Department, the Accountable Officer does not have a duty to undertake **periodic** inspections (regulation 19(as amended)). However, as part of his monitoring, the Accountable Officer may undertake additional inspections to give assurance that controlled drugs are being managed and used safely. The number and frequency of these additional inspections are at the discretion of the Accountable Officer. In undertaking any additional inspections, the Accountable Officer should take account of the Government's policy that the inspection process should not be over burdensome and should avoid duplication. RQIA and the Department will inform relevant Designated Bodies on the frequency of the routine inspections and also the format and frequency of assurances following such visits.

Primary Care

4. As part of their monitoring and auditing arrangements, the HSCB Accountable Officer should arrange for a small number of inspections of a random sample of "relevant premises"[7] where controlled drugs are stored, dispensed, supplied or used. Inspections will be informed by information received by the Accountable Officer including inspection reports, declarations, and other monitoring of data. The Accountable Officer may choose to integrate controlled drug inspections into the current monitoring activities. Adverse issues may be investigated as detailed in Annex E.

5. The Department's Medicines Regulatory Group will undertake periodic inspections of community pharmacies and these will include stock audits of

[7] See clause 20 of the Health Act 2006 and Regulations 19 and 20 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (as amended).

controlled drugs. The HSCB will undertake periodic inspections of General Practitioners who are commissioned by the HSCB to provide medical services under the health service and of those Dental Practitioners who provide exclusively health and social care services. The RQIA undertakes inspections of private Dental Practitioners. These inspections may be informed by self assessment and other available information.
The inspecting authority will advise the relevant Accountable Officer of any issues in relation to controlled drugs.

Secondary Care

6. In secondary care pharmacies, periodic inspections will be carried out by the Department's Medicines Regulatory Group and these will include stock audits of controlled drugs. Inspection of other wards and departments will be the subject of agreement between RQIA/Department and the Trust.

These inspections will be informed by self assessment and other available information. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits

Independent Healthcare and Care Homes

7. In Independent Hospitals the RQIA, as part of their existing inspection processes, will carry out periodic inspections. The Department also carry out controlled drug visits to some Independent Hospitals. The inspecting authority and the relevant Accountable Officer will determine the level and frequency of feedback following such visits.

8. The Regulations enable an Accountable Officer to request in writing that another Accountable Officer from a Designated Body of the same type inspects any premises of his Designated Body (regulation 20(6). This is intended to provide Accountable Officers with a system of mutual audit and support.

Records

9. Inspecting authorities must keep a record, either paper or electronic, of all inspections (regulation 19 (as amended)). Where reports of routine inspections are made available to the premises concerned these may give assurance of existing good practice and may high-light areas where improvement is necessary. The relevant Accountable Officer should make arrangements with the inspecting body in relation to the sharing of reports following inspection visits.

Annex E

Investigations

1. Accountable Officers must ensure that robust systems are in place across their areas of responsibility to enable concerns or incidents involving controlled drugs to be identified and, where appropriate, investigated (regulations 15 and 16).

Adequate records must be compiled and kept, in either paper or electronic form, in relation to any concerns expressed. Access to these records must be restricted to:

- the Accountable Officer and his staff; and
- others who need access for the purpose of ensuring the safe management and use of controlled drugs

The record must include, but is not limited to, as appropriate:

- the date on which the concern was made known to the Accountable Officer
- any dates on which the matters that led to the concern took place
- details regarding the nature of the concern
- details of the relevant individual in relation to which the concern was expressed
- details of the person who, or body which, made known the concern
- details of any action taken by the Designated Body (or a body or person acting on behalf of, or providing services under arrangements made with , the Designated Body) in relation to the concern
- the assessment of whether information in relation to the concern should be disclosed to another Responsible Body under regulation 25 (as amended) or 26 (as amended); and
- if information regarding the concern is disclosed to another Responsible Body under regulation 25 (as amended) or 26 (as amended) the details of any such disclosure, including the name of the Responsible Body to which the disclosure was made and the nature of the information disclosed to the body.

2. Where a concern involves a registered professional's fitness to practise or where patient safety may be compromised, information should be passed immediately to the appropriate Regulatory Body. Guidance can be found on the Regulatory Bodies websites, examples of which are listed below.

General Dental Council (www.gdc-uk.org) *Our Guide to Local Practitioner Advice and Support Schemes*

General Medical Council (www.gmc-uk.org) *Referring a doctor to the GMC: A guide for individual doctors, medical directors and clinical governance managers*

Nursing and Midwifery Council (www.nmc-uk.org) *Reporting unfitness to practise: A guide for employers and managers*

Health and Care Professions Council (www.hpc-uk.org) *Making a complaint about a health professional*

The Pharmaceutical Society of Northern Ireland (www.psni.org.uk)

The Northern Ireland Social Care Council (www.niscc.info/index.php) *Referring a Complaint to NISCC - Employer's Guide*

3 Regulation 17 details where advice may be sought and what actions should be taken in response to well-founded concerns.

Incident Panel

4 Where concerns have come to light, initial consultation with the members of the Local Intelligence Network (LIN) may be helpful as an alternative or prior step to requesting the HSCB Accountable Officer to establish an Incident Panel. An Incident Panel would be convened by the HSCB Accountable Officer. The membership is drawn from the LIN and will depend on local circumstances and the nature of the concern. The Incident Panel can recommend a number of actions as detailed in regulation 17(3) (as amended), including ongoing monitoring, referral of concerns to the Regulatory Body or the police.

5 In all cases, care should be taken that any evidence gathered during the course of an investigation is preserved in an appropriate manner to ensure its integrity. Such evidence may be required for proceedings instituted by the police, other enforcement agencies, Disciplinary Committees or Regulatory Bodies.

Escalating concerns

6 There may be cases where concerns cannot be resolved locally and need to be escalated or passed to another organisation. The table below summarises where issues should normally be referred. On occasion concerns may need to be passed to more than one organisation.

Concern	**Consider referring to:**
Criminality suspected (including fraud and theft)	Police / Department / Counter Fraud Unit (BSO) (where appropriate)
Individual fitness to practise issue	Regulatory Body
Organisational/systems issue	Department

7 If a concern is passed to another organisation(s) the relevant Accountable Officer must record the referral (regulation 28).

8 When patient safety is thought to be at risk, immediate action must be taken. HSC bodies should follow their local serious untoward incident

procedures. Immediate referral to the relevant regulatory body should be considered where there are serious concerns about an individual's fitness to practise.

9 Actions taken consequent upon the investigation findings and relevant policies in the Designated Body should be clearly documented.

Targeted inspection

10. Either following an Incident Panel or as a direct result of a concern, the Accountable Officer may decide that a formal inspection at the premises is required. The Accountable Officer can seek support from the Department's Medicines Regulatory Group and RQIA in conducting such an inspection to provide independent assurance.

Raising concerns

11 Individuals raising concerns should be supported in doing so. Cases where health service fraud is suspected can be reported to Counter Fraud Unit either by contacting cfps@hscni.net or 08000 963396.

12 Individuals should also be supported where concerns have been raised about them or where they wish to raise concerns about their own performance.

Closure of cases

13. Cases considered by an Accountable Officer should be recorded with a clear account of the findings and any action taken (regulation 15). The Accountable Officer should ensure that concerns, and any lessons learned, are shared across the Local Intelligence Network. Wider sharing of information (excluding the names of relevant persons) may be appropriate through the Cross Border Group[8]. Where there is evidence that a controlled drug has been diverted, it may also be appropriate to inform the manufacturer or wholesaler.

14 Reports containing information about the storage and movement of controlled drugs should not normally be disclosed under Freedom of Information legislation as this could aid criminal activity and so would come within the "law enforcement" exemption.

[8] The Cross Border Intelligence Group comprises representatives from the UK and the Republic of Ireland. This Group has been formed as a result of the 5 Nations meeting in 2007 (under the Health Act 2006). The remit of the Group is to support the development of appropriate systems through dissemination of information and sharing of good practice in order to achieve statutory compliance and to feed back this information to members' home organisations.

Annex F

Controlled Drugs declarations and self-assessments

Those who will send declarations and self-assessments can devise forms to suit their needs. The declaration and self-assessment form for registered pharmacies can be found below (Regulation 12 (as amended))

	Yes/No		Yes/No
1. Do you have specific written SOPs covering the management of CDs, appropriate to the activities carried out at the premises and as required by the Accountable Officer regulations?		7. Do you transport CDs in accordance with an SOP (e.g. patient deliveries)?	
2. Are the staff involved in activities related to CDs appropriately trained and competent?		8. Are all CDs appropriately labelled?	
3. Do you have procedures in place to identify, deal with and learn from significant incidents involving CDs?		9. Are regular date checks of CD stock carried out?	
4a. Have you noted any signs of unusual, excessive or inappropriate supply or prescribing patterns?		10. Is the CD Register maintained in accordance with the Misuse of Drugs Regulations and any relevant guidance?	
4b. **If yes,** have these issues been fully addressed?		11. Are running balances of CDs maintained in the CD register and is there evidence that they are audited?	
5a. Are there any signs of, or do you have concerns about, the diversion of CDs?		12. Are all relevant CDs stored in accordance with the Safe Custody Regulations and are procedures in place to prevent unauthorised access to CDs?	
5b. **If yes,** have these issues been fully addressed?		13. Is date expired and patient returned medication appropriately marked and segregated?	
6a. Have there been any complaints or significant incidents involving CDs in the last 12 months of which you are aware?		14. Are out of date or patient returned CDs destroyed in accordance with legislation and published guidance?	
6b. **If yes,** have these issues been fully addressed?		15. Are prescriptions for Schedule 2 & 3 CDs endorsed with the date of supply at the time of supply?	

DECLARATION

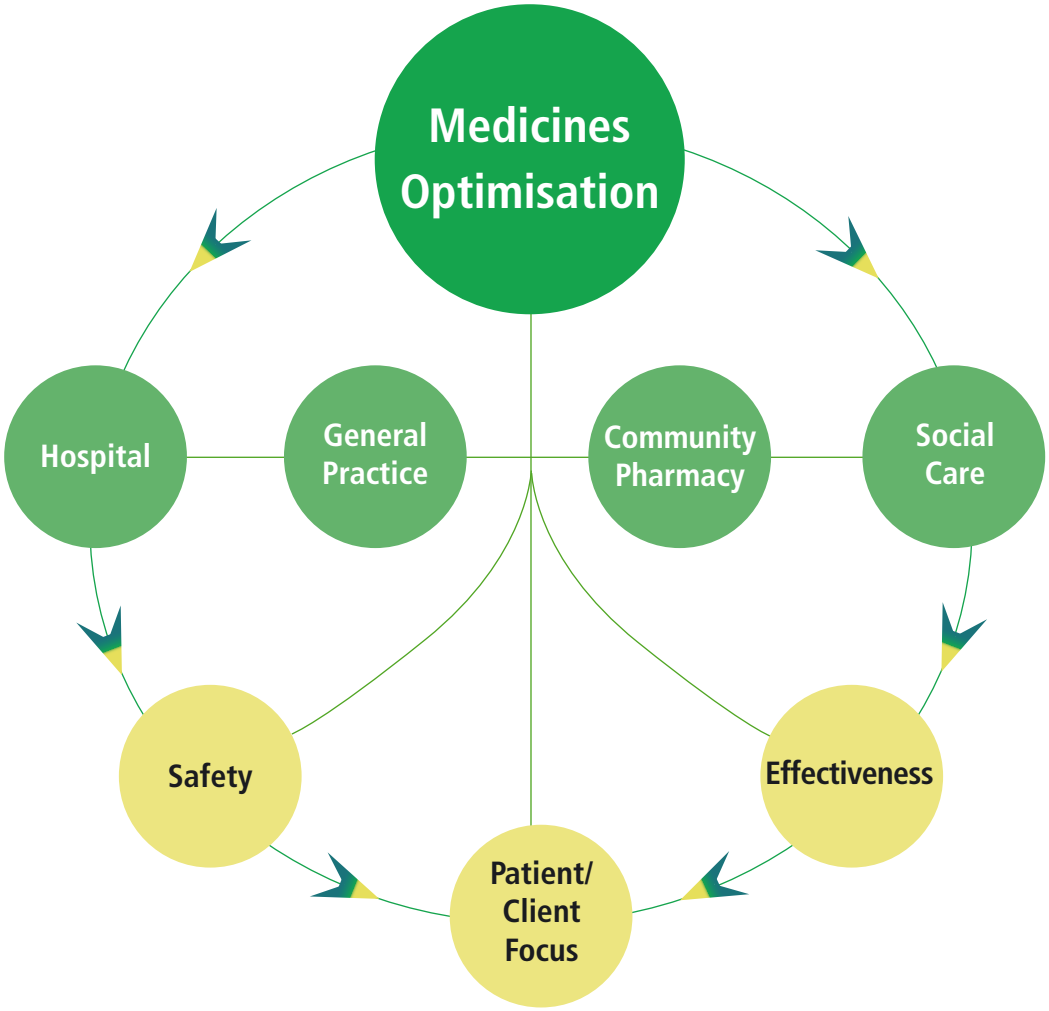
I declare that to the best of my knowledge and belief that the handling, management and use of Schedules 2 and 3 controlled drugs at these premises complies with the provisions of the Misuse of Drugs Act 1971, its associated regulations and the Health Act 2006 and its associated controlled drugs regulations.

Signed **Date**

Name		**Registration Number**	
Position within organisation		**Name of organisation and address of premises**	

Department of
Health, Social Services and Public Safety
www.dhsspsni.gov.uk

Northern Ireland Medicines Optimisation Quality Framework



March 2016

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FOREWORD

Minister for Health, Social Services and Public Safety

As Minister for Health, Social Services and Public Safety, my mission is to improve the health and well-being of all people of Northern Ireland. Whilst healthier lifestyle choices may be all that is required for some people to maintain health, most will need medicines at some stage to treat or prevent illness.

Medicines are the most common medical intervention used in the health service with an annual expenditure of over £550m. In comparison with other UK countries the volume and cost of medicines used per head of population in Northern Ireland is high. With an aging population and a rising number of people with long term conditions, demand is expected to increase.

Unfortunately evidence shows variance in best practices relating to the appropriate, safe and effective use of medicines and many people do not take their medicines as prescribed resulting in sub optimal health outcomes, wasted medicines and pressure on acute health and social care services.

The Medicines Optimisation Quality Framework aims to support better health outcomes for our population by focusing attention on gaining the best possible outcome from medicines every time that they are prescribed, dispensed or administered.

The Framework supports quality improvement through the consistent delivery of recognised best practice and supports the development and implementation of new, evidence based best practice. Implementation will involve an innovation and change programme involving multi-disciplinary professionals working together and with patients.

Much has been done in recent years to improve the way medicines are used and Northern Ireland is recognised as one of the leading regions in Europe in addressing the health and social care needs of the older population through innovation in medicines management. However, more action is needed to gain optimal outcomes from medicines and provide a sustainable approach to clinical and cost-effectiveness whilst reducing avoidable adverse events and waste.

Everyone has a responsibility to improve medicines use and patients need to become more involved in decisions about their treatment and better informed about the role of medicines in their care. By encouraging dialogue and listening to patients' concerns about their medicines, we can empower them to make informed decisions to improve health outcomes.

The Framework promotes multidisciplinary working and recognises the role of pharmacists in integrated teams within primary and secondary care. I welcome this and would like to see an increased utilisation of pharmacists' clinical skills working collaboratively with other health and social care professionals optimising patients' medicines use.

The development of the Framework has been overseen by a multi-disciplinary and multi-agency Steering Group established by the Department of Health, Social Services and Public Safety. Members of the Steering Group included representatives from the Health and Social Care Board, Public Health Agency, Business Services Organisation, Royal College of General Practitioners, the Pharmaceutical Industry, Community and Hospital Pharmacy, Nursing, Social Care, Patient Client Council, RQIA, Local Commissioning Groups, and the Community Development Health Network.

I wish to thank the contribution made by all those individuals involved in its development. It establishes a solid foundation from which the application of good practice and continuous improvement and innovation in medicines use will ensure the best outcomes for the citizens of Northern Ireland.

SIMON HAMILTON MLA
Minister for Health, Social Services and Public Safety

EXECUTIVE SUMMARY

Introduction

In continuing to provide a world class Health Service, the Department is committed to supporting innovative ways of ensuring that services are safe, that they improve the health and wellbeing of our population and at the same time make the best use of available resources. As medicines are a critical element of what the health service delivers to help patients[1], the Department has developed this Medicines Optimisation Quality Framework so that patients and health care professionals can work together to make the most of their medicines.

This Medicines Optimisation Quality Framework provides strategic direction for actions to improve the use of medicines for the benefit of the health and wellbeing of people in Northern Ireland. The framework builds on existing quality systems and infrastructure to deliver improvements through evidence based services and technologies and seeks to consolidate good practice and support consistency and quality improvement across Health and Social Care (HSC).

Some people maintain a healthy lifestyle without using medicines but for others, medicines play an important part in maintaining their health and treating or preventing illness. However, there is evidence that patients do not always gain the optimal benefit from their medicines and a new approach is needed that focuses on optimising health outcomes when medicines are prescribed, dispensed or administered. Medicines Optimisation is defined by the National Institute of Health and Care Excellence (NICE) as "a person centred approach to safe and effective medicines use to ensure that people gain the best possible outcomes from their medicines."

The overall aim of this Framework is to maximise health gain for patients through the appropriate, safe and optimum use of their medicines. It is split into five main sections.

Section 1: The Quality Framework – summarising what the framework is designed to do, who it is aimed at, what it seeks to deliver and lists its key recommendations. The Framework supports a patient focused approach in which patients are involved in decisions about their medicines and are supported by multidisciplinary[2] professionals working together to deliver best practice.

Section 2: The NI Regional Medicines Optimisation Model – outlining what should be done at each stage of the patient pathway in each of four different settings (hospital, general practice, community pharmacy, social care) to help gain the best outcomes from medicines.

Section 3: 10 Quality Standards – addressing the priority issues for medicines optimisation in Northern Ireland within the three overarching quality domains of safety, effectiveness and patient/client focus. The Quality Standards describe the best practices that should be delivered in each setting, identify gaps in best practices and the actions needed to address them.

1 Throughout the Quality Framework when patients are referred to this also refers to their families and carers.

2 Multidisciplinary includes all health and social care professionals involved in the prescribing, dispensing and administration of medicines. This includes specialist and generalist roles in medicine, nursing, pharmacy, allied health and social care.

Section 4: Implementation through an Integrated Innovation and Change Programme – applying a strategic approach to support and drive continuous improvement through the development and implementation of best practices in medicines optimisation with four components:

- a regional action plan for medicines optimisation;
- a medicines optimisation innovation centre;
- a medicines optimisation network; and
- a regional database to monitor improvement.

Section 5: Contains a summary of the nine overarching key recommendations to introduce and support the Regional Model for Medicines Optimisation.

1. A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in HSC settings.
2. The model should be delivered by a mutli-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.
3. The medicines optimisation workforce should deliver regional services and roles which are commissioned and co-ordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administering of medicines.
4. The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.
5. Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).
6. An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.
7. Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.
8. Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information service, Medicines Optimisation Innovation Centre (MOIC)[3].
9. A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

3 www.themoic.com

JOINT INTRODUCTION

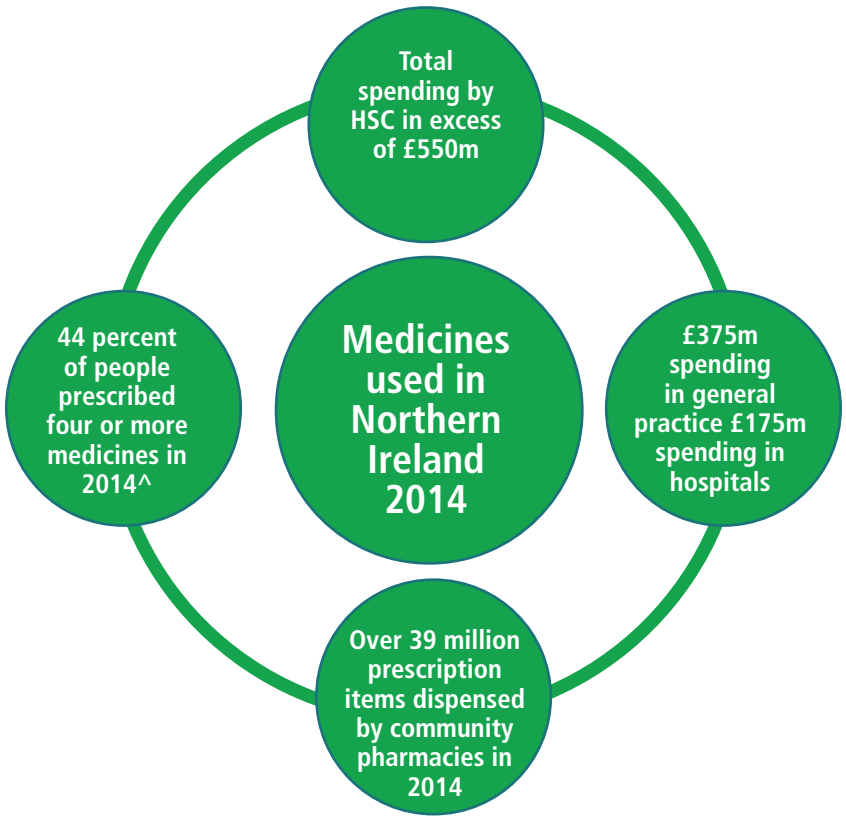
Chief Medical Officer and Chief Pharmaceutical Officer

1. Medicines play an important role in maintaining wellbeing, preventing illness and managing disease. Most people will take a medicine at some point in their lives. This could be a short term curative treatment, for example, a course of antibiotics for an infection or long term treatment for high blood pressure to prevent heart disease.

2. Medicines are the most common medical intervention within our population and at any one time 70% of the population[4] is taking prescribed or over the counter medicines to treat or prevent ill-health.

3. From a financial aspect, medicines expenditure equates to over £550m/annum in Northern Ireland, representing 14% of the total HSC budget and is the second largest cost after salaries.

Figure 1: Medicines Use in Northern Ireland 2014



4 Office of National Statistics Health Statistics 1997
^ Figure based on the definition of a medicine as having a unique number used in the dictionary of medicines and devices (DM+D)

4. As the population ages and the prevalence of chronic disease increases the need for medicines is expected to rise. This will place direct pressure on prescribing budgets and lead to an increased demand across HSC services, particularly those involved with the prescribing, dispensing and administration of medicines.

5. To date, health policy has sought to address these challenges by supporting regional best practice relating to Pharmaceutical Care[5] and Medicines Management[6]. This has introduced a range of services and systems[7] for the safe and effective use of medicines, often associated with the 'five rights'.

Table 1: The Five Rights of Medicines Administration[8]

• The Right Patient
• The Right Medication
• The Right Dose
• The Right Time and Frequency of Administration
• The Right Route

6. With over 14 years of expertise in developing good practice in the area of Pharmaceutical Care and Medicines Management, Northern Ireland was recognised in 2013 as one of the leading regions in Europe with 3 star reference site status for medicines management[9].

7. However, evidence shows that medicines use remains sub-optimal, with patients failing to gain the expected benefits of treatment and services coming under increasing pressure as their care needs escalate. For example:

5 Hepler CD & Strand LM. Opportunities and responsibilities in pharmaceutical care. American Journal of Health Systems Pharmacy 1990; 47: 533-543

6 Medicines management has been defined as "encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.

7 See Annex A, Table 12 – Examples of regional best practice in medicines management.

8 Jones and Bartlett, Nurse's Drug Handbook, 2009

9 European Innovation Programme- https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/rs_catalogue.pdf

Table 2: Examples of Sub-optimal Medicines Use

Ten days after starting a new medicine, 61% of patients feel they are lacking information and only 16% of patients who are prescribed a new medicine are taking it as prescribed, experiencing no problems and receiving as much information as they believe they need[10].
One in 15 hospital admissions are medication related, with two-thirds of these being preventable[11].
One in 20 prescriptions in General Practice contains an error, with a higher prevalence associated with prescriptions for the elderly and those taking 10 or more medications[12].
Prescribing errors in hospital in-patients affect 7% of medication orders, 2% of patient days and 50% of hospital admissions[13].
An estimated £18m of medicines are wasted annually in Northern Ireland[14].

8. To address these challenges and the demands of an aging population with increasingly complex medicines needs, a new approach is needed which shifts the focus to Medicines Optimisation. This will ensure that patient facing medicines services are provided in support of improving care and to enable transformation of HSC services through closer cooperation between multidisciplinary professionals and HSC organisations.

9. **Medicines optimisation** is defined by the National Institute for Health and Care Excellence (NICE) as "a person centred approach to safe and effective medicines use to ensure that people obtain the best possible outcomes from their medicines". This has evolved from the four principles of medicines optimisation developed by the Royal Pharmaceutical Society in 2013.

10 Barber et al. Patients' problems with new medication for chronic conditions. Quality and safety in healthcare 2004.

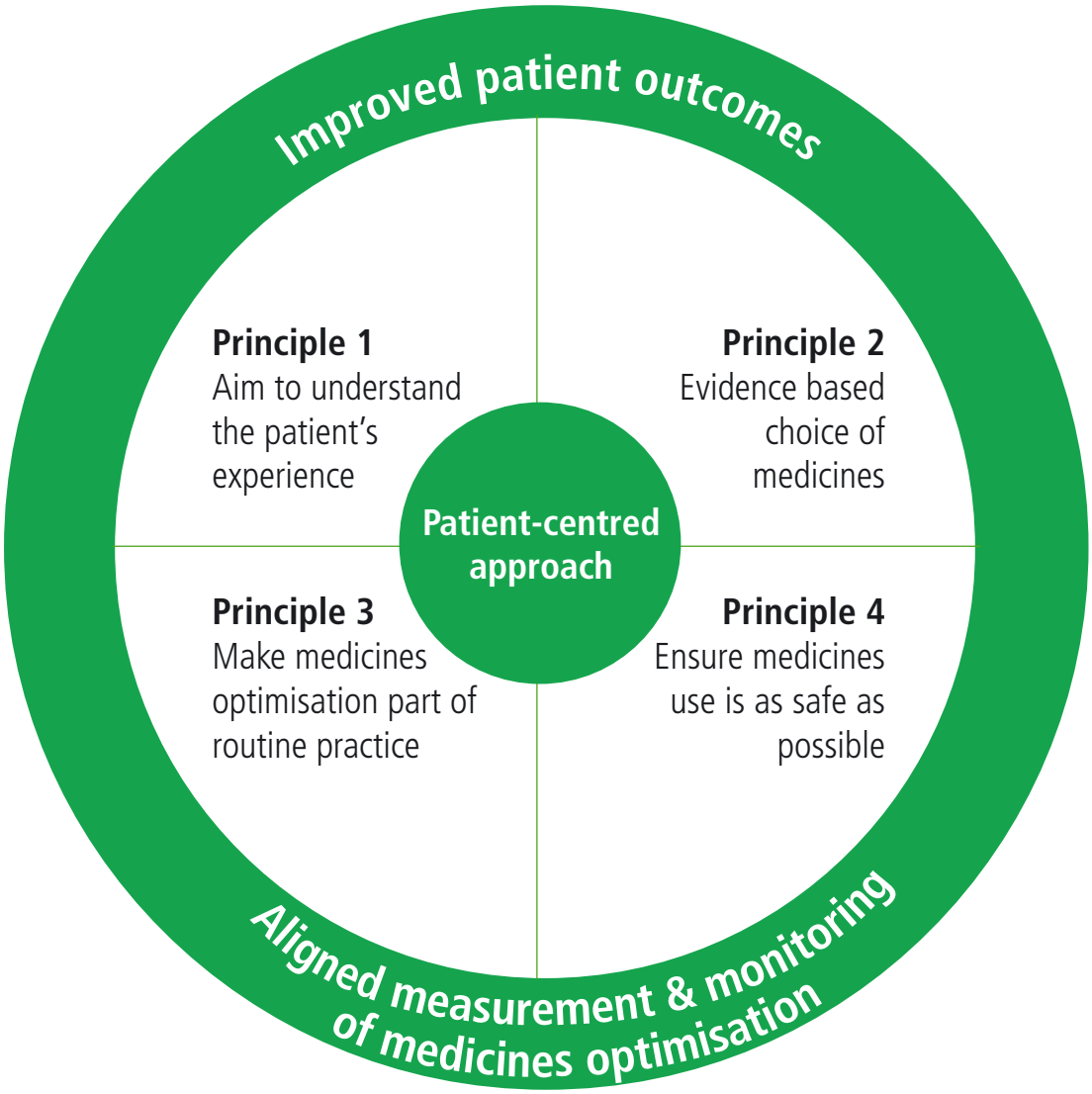
11 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

12 http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

13 Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf 2009; 32(5):379-389.

14 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010.

Figure 2: Patient Centred Approach Model[15]



10. In Northern Ireland the shift to medicines optimisation has started with the implementation of NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes[16] and the recommendations of the Regulation and Quality Improvement Authority (RQIA) Review of Medicines Optimisation in Primary Care[17].

11. However, to deliver sustainable and measurable improvements at a regional level a strategic approach is needed and the Medicines Optimisation Quality Framework has been developed to provide the necessary direction to support this.

15 https://www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf

16 https://www.nice.org.uk/guidance/ng5

17 http://www.rqia.org.uk/cms_resources/RQIA%20Medicines%20Optimisation%20in%20Primary%20Care%20Review%20July%202015.pdf

SECTION 1

THE QUALITY FRAMEWORK

1.1 The Medicines Optimisation Quality Framework provides a roadmap for improving how medicines are used across the HSC system (HSC). Building on existing quality systems and infrastructure, it seeks to deliver improvements in care through evidence based services and technologies that lead to better health outcomes for patients.

1.2 Primarily aimed at those with responsibility for, and influence on, commissioning decisions and front line service delivery in Northern Ireland, the Framework is underpinned by existing HSC responsibilities for ensuring the efficient use of resources and facilitating integration.

1.3 The Framework aims to support both patient care and the transformation of the HSC system by helping to deliver:

- better health outcomes for patients through the appropriate use of medicines, taken as prescribed;
- better informed patients who are engaged and involved in decisions about their medicines;
- improved medicines safety at transitions of care;
- an active medicines safety culture within HSC organisations;
- reduced variance in medicines use through the consistent delivery of medicines management best practices;
- improved intra and inter professional collaboration and a HSC workforce who recognise their role in medicines optimisation and are trained and competent to deliver it as part of routine practice;
- better use of resources through the consistent, evidence based and cost effective prescribing of medicines; and
- the development and implementation of best practice solutions in medicines optimisation across the HSC.

1.4 The Framework introduces a Regional[18] Model for Medicines Optimisation to engage health and social care professionals across the HSC in delivering best practices, supported by quality standards and an integrated innovation and change programme.

1.5 The Framework makes nine key recommendations to introduce and support the Regional Model for Medicines Optimisation.

18 Regional relates to the whole of Northern Ireland

Table 3: Recommendations

1.	A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in HSC settings.
2.	The model should be delivered by a multi-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.
3.	The medicines optimisation workforce should deliver regional services and roles which are commissioned and coordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administration of medicines.
4.	The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.
5.	Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).
6.	An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.
7.	Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.
8.	Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates, the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information Service, Medicines Optimisation Innovation Centre (MOIC).
9.	A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

1.6 The Framework complements existing health policy, Transforming Your Care[19] principles, recommendations in the Donaldson report[20] and is specifically aligned with the Quality 2020[21] strategic themes of safety, effectiveness and patient/client focus.

1.7 It promotes multidisciplinary approaches which include all health and social care professionals

19 https://www.dhsspsni.gov.uk/topics/health-policy/transforming-your-care

20 https://www.dhsspsni.gov.uk/topics/health-policy/donaldson-report

21 https://www.dhsspsni.gov.uk/publications/quality-2020-ten-year-strategy-protect-and-improve-quality-health-and-social-care

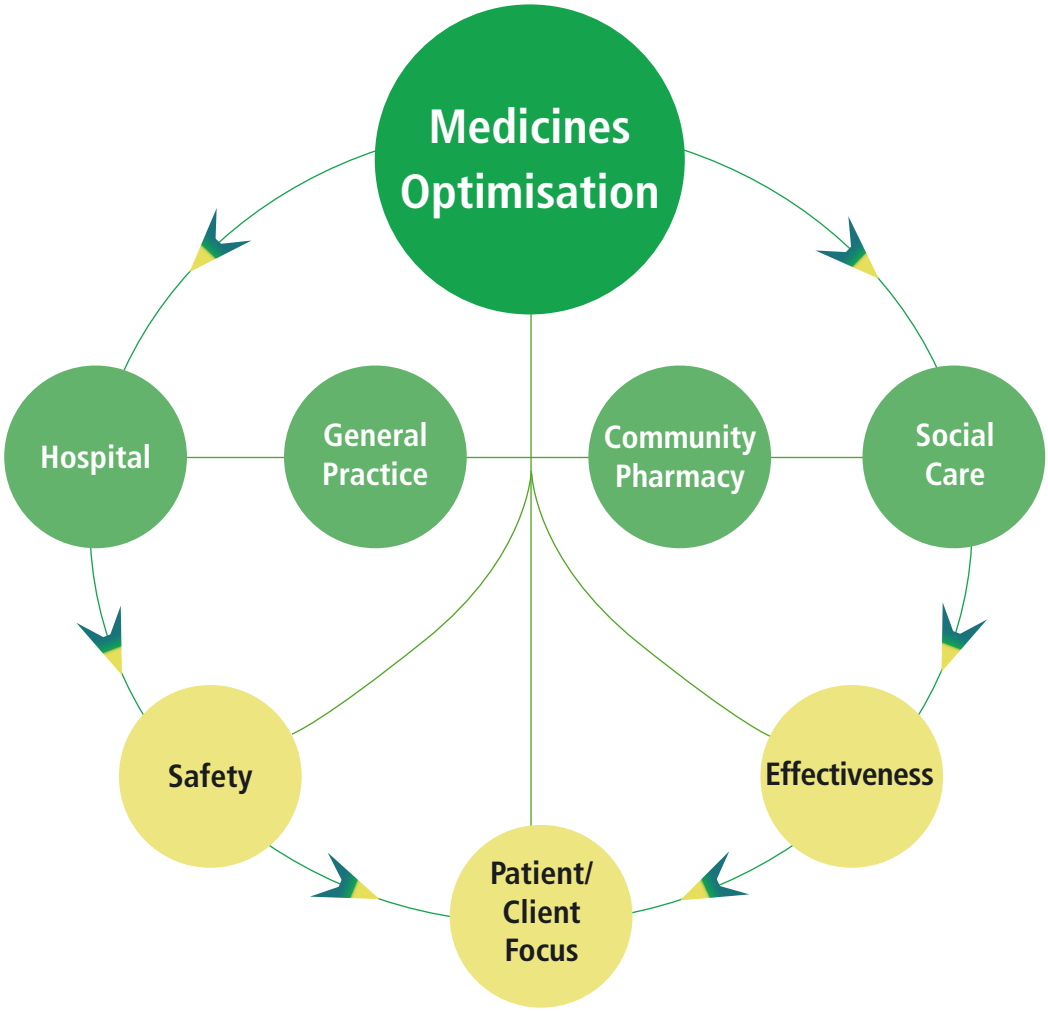
involved in the prescribing, dispensing and administration of medicines. This includes specialist and generalist roles in medicine, nursing, pharmacy, allied health and social care. NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes recommends that organisations consider a multidisciplinary team approach to improve patient outcomes with the integration of pharmacists. Historically this has not always been the case and the Framework addresses gaps in pharmacist to patient facing interventions in HSC settings.

1.8 The Framework seeks to build on the experience of the past, using existing medicines management services across the HSC as the foundation for improvement where possible. These services and the history of medicines management in Northern Ireland in the period 2000 - 2014 is described in detail in Annex A.

1.9 It has been developed in anticipation of demographic and financial challenges facing the HSC which require a renewed focus on gaining the best possible outcomes for patients from medicines at an affordable cost for the HSC. A detailed description of these challenges is included in Annex B.

SECTION 2

The Northern Ireland Medicines Optimisation Model



2.1 When medicines are prescribed patients should be involved in decisions about their use, know why the medicine is needed, understand the expected outcome, the duration of treatment and be informed of any risks or side effects.

2.2 When medicines are supplied, pharmacists should ensure that they are dispensed safely, that patients receive appropriate information to enable safe and effective use and are offered support to help them take their medicines as prescribed and on time, if needed. Pharmacists are also well placed to advise patients when the presentation of their medicine changes and provide reassurance of continued efficacy.

2.3 During treatment, patients should have their medicines reviewed on a regular basis and if a GP or other authorised health professional involved in assessing the patient makes a clinical decision that there is no health benefit or clinical need for the patient to continue taking the medication, the medication should be stopped.

2.4 When medicines for long term conditions are started, stopped or changed, patients should have their treatment regimen checked to ensure it remains safe and effective.

2.5 In day to day practice, medicines optimisation relies on partnerships between patients and health and social care professionals and aims to help more patients to self manage, to take their medicines correctly, reduce harm, avoid taking unnecessary medicines, cut down on waste and improve medicines safety. Ultimately it can help encourage patients to take increased ownership of their treatment and support care closer to home.

2.6 Within the HSC, success in medicines optimisation is reliant on multidisciplinary teams with the correct skill mix working collaboratively, delivering best practices, supported by quality systems and the necessary regional organisational infrastructure as illustrated by the diagram at the beginning of section 1.

2.7 The model is based on the principles of the Integrated Medicines Management[22] (IMM) service in secondary care which targets the work of pharmacists at specific points in the patient journey on admission, during the hospital stay and at discharge.

2.8 The model seeks to deliver IMM consistently across secondary care and expand the pharmacist role into the interface and intermediate care[23], to general practice, community pharmacy and social care.

22 https://www.dhsspsni.gov.uk/sites/default/files/publications/dhssps/northern-ireland-clinical-pharmacy-standards-2013.pdf

23 Intermediate care means step up/step down beds

2.9 It supports the integration of pharmacists in multidisciplinary teams, providing support with medicines at key points of the patient's journey based on an assessment of need, for example, when a new treatment is started, after discharge from hospital or during a medication review.

2.10 At the interface the model includes roles for consultant pharmacists[24] and specialist outreach pharmacists[25] working with intermediate care, nursing home settings and GP practices, with links to community pharmacy.

2.11 The model introduces a new role for pharmacists working in General Practice. 'Practice-based' pharmacists integrated with and working collaboratively with pharmacists in community pharmacy and secondary care will utilise more fully the clinical skills of the profession to improve patient outcomes.

2.12 In community pharmacy the model includes enhanced roles for pharmacists that will support better outcomes from medicines by working with patients to provide appropriate information and advice when medicines are dispensed and to support adherence and safer transitions through services such as Medicines Use Reviews[26] [27].

2.13 The model recognises the role of nurses and care workers in helping people with their medicines in residential, nursing and domiciliary care settings and the need for regional best practices that support role clarification, accredited training and support systems for staff.

2.14 The model recommends the optimal delivery of existing roles and commissioned services which are already supported by HSC contractual or service level agreements and funding streams as well as the need for new roles and services.

2.15 To deliver the model consistently in all settings additional recurrent funding will need to be targeted to support new roles and infrastructure which demonstrate clinical and cost effectiveness outcomes.

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24 The term consultant pharmacist refers to a pharmacist who has advanced roles in patient care, research and education in a specific medical speciality or expert area of practice.

25 Specialist outreach pharmacists are pharmacists in secondary care who carry out patient medication reviews and follow up in GP practices and are linked with specialist secondary care clinical teams.

26 www.cpwales.org.uk/Contractors-Area/Pharmacy-Contact---Services/DMR/DMR-Evaluation_Final-Report_13082014.aspx

27 http://www.elht.nhs.uk/Downloads-docs/Departmental/Refer-to-Pharmacy/Electonic%20referral%20from%20hospital%20to%20community%20pharmacy%20NWC%20AHSN%20report.pdf

2.16 To monitor progress a regional medicines optimisation database is proposed, based on NHS England's medicines optimisation dashboard,[28] to identify outcome measurements. This will largely bring together existing data related to medicines use from different sources across the region to monitor trends, enable benchmarking and help drive quality improvements using baselines established in recent years from, for example, health surveys. Categories of outcome measurements will include:

- patient/client satisfaction;
- medicines safety incident reporting;
- cost effective use of medicines;
- impact on acute health services; and
- achievement of expected therapeutic outcomes.

Table 4: Examples of Outcome Measurements

Outcome Measure	Examples of Indicators	Source for baseline data
Patient/client satisfaction	• On admission to hospital did a member of pharmacy staff discuss/ check what medicines you were currently taking?	• Northern Ireland Inpatient Survey 2014 [29]
	• Percentage of people prescribed medicines in the previous 12 months involved as much as they wanted to be in decisions about prescribed medicines	• Northern Ireland Health Survey 2012/13 & 2014/15 [30]
Medicines safety incident reporting	• Levels of reported medication incidents and yellow card reporting	• Northern Ireland Medicines Governance network [31] • Medicines and Healthcare Products Regulatory Agency (MHRA) [32]
Cost effective use of medicines	• Percentage compliance with the Northern Ireland Medicines Formulary and generic dispensing rates	• DHSSPS Commissioning Plan Direction 2015/16 [33]

28 https://www.england.nhs.uk/ourwork/pe/mo-dash/
29 https://www.dhsspsni.gov.uk/sites/default/files/publications/dhssps/inpatient-patient-experience-survey-2014.pdf
30 https://www.dhsspsni.gov.uk/articles/health-survey-northern-ireland#toc-0
31 http://www.medicinesgovernance.hscni.net
32 https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
33 https://www.dhsspsni.gov.uk/publications/ministerial-priorities

Outcome Measure	Examples of Indicators	Source for baseline data
Impact on acute health services	• Number and proportion of unplanned admissions to hospital for medicines related factors and non-adherence	• DHSSPS Commissioning Plan Direction 2015/16
Achievement of expected therapeutic outcomes	• Percentage underlying achievement for Quality and Outcomes Framework (QOF) clinical indicators	• QOF [34]

2.17 The Northern Ireland Medicines Optimisation Quality Framework is a 'living document' with examples of current best practice medicines optimisation in each of the four settings in Tables 5 to 8. This will provide a necessary short term focus on improving standards and reducing variance and provide a firm foundation on which to build the evidence base and develop services in all settings.

The Medicines Optimisation Model

What patients can expect when medicines are included in their treatment

Tables 5-8 below provide a summary of what patients can expect as routine practice with regards to medicines optimisation in different settings – Hospital, General Practice, Community Pharmacy and Social Care. The activities described are generic and can be applied across different areas of practice in each setting.

34 https://www.dhsspsni.gov.uk/topics/dhssps-statistics-and-research/quality-outcomes-framework-qof

Table 5: What you should expect when you are admitted to hospital as routine practice

Hospital

On Admission

- Patients bring their medicines to hospital so that they can be checked and used where possible.
- Within 24 hours of admission or sooner if clinically necessary, patients have their medicines reconciled by a trained and competent healthcare professional, ideally by a pharmacist. Medicines reconciliation[35] involves collecting information about current medicines, checking for omissions, duplications and other discrepancies and then documenting and communicating any changes. Patients, family members or carers should be involved in this process.
- Within 24 hours of admission, a clinical management plan is developed which includes discharge planning to help prevent delays on discharge.
- If patients move from one ward to another within a hospital, medicines reconciliation may need to occur again.

Following Medical Assessment/Accurate Diagnosis

- Patients are involved in decisions about their current and any new medicines, their needs, preferences and values taken into account and receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients have the opportunity to speak to a healthcare professional and ask questions about their medicines.
- During the inpatient stay, prescription charts are monitored by a pharmacist and reviewed in conjunction with medical notes and relevant medical laboratory results.
- Patient responses to medication therapy are monitored and best practices relating to 'high risk medicines' are followed.

Administration of medicines

- On some wards patients may be able to administer their own medicines. However, if this is not possible medicines are administered on time following a check that the direction to administer is appropriate and other related factors are taken into consideration.

35 Medicines reconciliation, as defined by the Institute for Healthcare Improvement, is the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated. The term 'medicines' also includes over the counter or complementary medicines, and any discrepancies should be resolved. The medicines reconciliation process will vary depending on the care setting that the person has just moved into – for example, from primary care into hospital, or from hospital to a care home.

On discharge

- Prior to discharge the medicines reconciliation process is repeated.
- Patients receive an appropriate supply of their prescribed medicines which may be a combination of inpatient and discharge medicines dispensed as a single supply labelled for discharge. They are provided with accurate, up-to date information about their ongoing treatment where necessary.
- Patients are educated to ensure that they can use their medicines and devices for example inhalers appropriately.
- Patients know who to contact if they have a query about their medicines after discharge.
- Accurate and up-to date information about medicines is shared with healthcare professionals and communicated in the most effective and secure way such as electronically, ideally within 24 hours of discharge.
- Following discharge from hospital, patients are followed up to ensure that they are completely clear about their medicine regimens.

Other Hospital/Trust Services

- Patients attending outpatient clinics should expect:
  - to be involved in decisions about their medicines with their needs, preferences and values taken into account;
  - their response to medicines to be reviewed;
  - to have the opportunity to speak to a healthcare professional and ask questions about their medicines; and
  - to receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients in Intermediate Care settings (i.e. step up/step down beds) should have the same quality of care as in hospital.
- Patients receiving specialist outreach services and other services at the interface should expect:
  - links to be established between specialist secondary care clinical teams and primary care;
  - to be followed up in primary care; and
  - to have clinical medication reviews carried out.
- Patients in nursing, residential and children's homes (see table 7)

Table 6: What you should expect from general practice as routine practice

General Practice

- Patients registering with the practice for the first time have a medicines reconciliation check.
- During consultations, patients are involved in decisions about their current and any new medicines, their needs, preferences and values taken into account and receive appropriate, tailored information about new medicines and the expected health outcomes.
- Patients taking multiple medicines or taking 'high risk medicines' are identified and, where appropriate, receive additional information and advice to help take their medicines safely and effectively.
- Patients on repeat medications have checks carried out before issue of prescriptions to reduce the risk of waste.
- All patients on repeat medication have an annual clinical medication review with a GP or pharmacist. (This may be more frequent depending on the individual's care plan or type of medication).
- Patient responses to medication therapy are monitored. Medicines that are not beneficial and not evidence based are not continued.
- Patients with problems taking their medicines as prescribed (non-adherent) are referred for an adherence assessment.
- Patients are involved in decisions about their medicines and are encouraged to ask questions about their treatment and to be open about stopping medication.
- Patients discharged from hospital/other care setting have their medicines reconciled by a trained and competent healthcare professional as soon as possible, before a prescription or new supply of medicines is issued and within one week of the GP practice receiving the information. Patients, family members or carers should be involved in this process and any changes documented.
- Prescribers have up to date information to support clinically appropriate and safe prescribing.
- Prescribers have access to a pharmacist for information and advice about polypharmacy patients taking multiple medicines.
- Practices provide information about prescribed medicines to hospitals and other appropriately authorised health and social care professionals to assist medicines safety during transitions of care.

Table 7: What you should expect from your community pharmacy as routine practice

Community Pharmacy

- On presentation of a prescription the pharmacist will carry out a clinical check of the prescription using the patient's medication record before it is dispensed. This will inform the level of information and advice that is needed for the patient to take their medicines safely and effectively.
- High quality medicines are dispensed safely.
- Patients receive appropriate information and advice with the supply of medicines, particularly if a new medicine or a 'high risk medicine' is supplied.
- If the presentation of a repeat medicine changes, the patient is advised of this change and reassured of continued efficacy.
- Patients are offered a medicines use review after a significant change in their medication. For example, following discharge from hospital or after starting a new treatment regimen.
- Patients having problems taking their medicines as prescribed have their adherence needs assessed and appropriate support provided.
- Patients are asked if they need all their repeat medicines before they are supplied to reduce the risk of waste.
- Pharmacists work closely with other health and social care professionals to ensure patients are on the most appropriate medication and have contact with pharmacists working in local GP practices and hospitals.
- To support safe transitions, pharmacies provide information about medicines supplies to the pharmacist or pharmacy technician conducting a medicines reconciliation check after admission to hospital or to appropriately authorised health and social care professionals in a nursing or residential home.
- On discharge from hospital, community pharmacy receives information on the patient's current medication and medication changes to support safe transfer.
- Pharmacies may provide other services such as clinical medication reviews and monitor health outcomes from medicines to support medicines optimisation.

Table 8: What you should expect from social care as routine practice

Nursing homes

- When individuals first move into a nursing home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- Individuals with specific medication needs such as Parkinson's Disease or Diabetes or those taking multiple or 'high risk medicines' are identified and receive the appropriate care in line with best practice.
- Individuals who take their own medicines are monitored to ensure they are taking them as prescribed.
- Medicines are administered on time following a check that the direction to administer is appropriate.
- Individuals taking repeat medication have an annual clinical medication review; the frequency of the review may vary depending on the care plan.
- Staff in nursing homes have contact with pharmacists in the community to assist with queries about medication.

Residential homes

- When individuals first move into a residential home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- Residential care home staff who manage medicines are trained and competent.
- Residents self-administer their own medicines where the risks have been assessed and the competence of the resident to self-administer is confirmed. Any changes to the risk assessment are recorded and the arrangements for self-administering medicines are kept under review.
- Residential care home staff receive training on 'High Risk Medicines' and have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.

Children's homes

- When a child/young person first moves into a children's home and at each transition of care thereafter their medicines are checked with their GP Practice and Community Pharmacy.
- Adequate supplies of medicines are always available and prescription ordering systems in homes are carefully managed and monitored to avoid over-ordering and waste.
- The management of medicines is undertaken by trained and competent staff and systems are in place to review staff competency.
- Robust systems are in place for the management of self-administered medicines.
- Prior written consent is obtained from a person holding parental responsibility for each child or young person for the administration of any prescribed or non-prescribed medicine.
- Staff receive training on 'High Risk Medicines' and have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.

Domiciliary care

- Nurses and care workers have clearly defined roles in helping with medicines taking.
- Administration of, or assistance with, medication is facilitated when requested in situations where an individual is unable to self-administer.
- Administration or assistance with medication is detailed in a care plan and forms part of a risk assessment.
- Policies and procedures identify the parameters and circumstances for care workers administering or assisting with medication. They identify the limits and tasks that may not be undertaken without additional training.
- Care workers who administer medicines are trained and competent. A record is kept of all medicines management training completed by care workers and retained for inspection
- When necessary, training in specific techniques (e.g. the administration of eye/ear drops or the application of prescribed creams/lotions) is provided for named care workers by a qualified healthcare professional.

- The care worker documents, on each occasion, the administration or assistance with medication.
- Care workers involved in the management of an individual's medication agree the arrangements for the safe storage within the individual's home. Appropriate information is available about the individual's current medication and staff are aware of any changes following a transition of care, such as discharge from hospital.
- Training on 'High Risk Medicines' is provided and staff have easy access to information about all medicines.
- Staff have contact with pharmacists in the community to assist with queries about medication.
- If an individual is having difficulties in managing their medicines, staff can refer them to the community pharmacist for assistance.

SECTION 3

Quality Standards for Medicines Optimisation

Quality Domain	Medicines Optimisation Standards
Patient/Client Focus Patients are involved in decisions about their treatment with medicines.	1. Safer Prescribing with Patient Involvement
	2. Better Information about Medicines
	3. Supporting Adherence and Independence
Safety Preventing and minimising harm related to medicines use.	4. Safer Transitions of Care
	5. Risk Stratification of Medicines
	6. Safety/Reporting and Learning Culture
Effectiveness Right patient, right medicine, right time, right outcome, right cost.	7. Access to Medicines you Need
	8. Clinical and Cost Effective Use of Medicines and Reduced Waste
	9. Clinical Medication Review
	10. Administration

3.1 In support of the Regional Medicines Optimisation Model new minimum quality standards will drive consistency and bring about a common understanding about what service providers are expected to provide and what patients can expect to receive when medicines are included as part of their treatment.

3.2 The ten standards address the priority issues for medicines optimisation in Northern Ireland within the three overarching quality domains of safety, effectiveness and patient/client focus and are compatible with the draft NICE Quality Standard on Medicines Optimisation[36].

3.3 The standards support delivery of best practice which should be developed and implemented in partnership with patients on an ongoing basis, actively seeking their views and listening to their experiences. For example via the Public Health Agency's 10,000 Voices[37] initiative, involving patients in hospital and learning from their experience through projects like ThinkSAFE[38] and through regular health surveys which can be useful in determining behaviours and attitudes.

36 A NICE Quality Standard for Medicines Optimisation is expected in March 2016. NICE quality standards may be used to inform best practice in Northern Ireland but are not currently formally endorsed by DHSSPS or mandatory within the HSC.

37 http://www.publichealth.hscni.net/publications/10000-voices-improving-patient-experience

38 http://www.thinksafe.care/

STANDARDS

Standard 1 - Safer Prescribing with Patient Involvement
Prescribing is carried out in a manner which promotes safety and optimal health outcomes, with patients involved in decisions about their treatment.

Standard 2 – Better Information about Medicines
Patients/carers receive the information they need to take their medicines safely and effectively.

Standard 3 – Supporting Adherence and Independence
People are helped to remain independent and self manage their medicines where possible but receive support with adherence when needed.

Standard 4 – Safer Transitions of Care
Checks occur at each transition of care to ensure that the transfer of medicines and medicines information between patients, carers and health and social care workers is safe, accurate and timely.

Standard 5 – Risk Stratification of Medicines
Patients who may be at risk because of the medicines that they use receive the appropriate help to take their medicines safely.

Standard 6 – Safety/Reporting and Learning Culture
Organisations promote an open and transparent culture with evidence of processes for the reporting, prevention, detection, communication and cascade of learning from medication incidents and adverse drug reactions.

Standard 7 – Access to Medicines you Need
Patients have appropriate, equitable and timely access to quality assured, evidence-based and cost-effective medicines.

Standard 8 - Clinical and Cost Effective Use of Medicines and Reduced Waste
Within organisations a culture exists promoting a shared responsibility for the appropriate, clinical and cost effective use of medicines supported by systems for avoiding unnecessary waste.

Standard 9 – Clinical Medication Review
Clinical medication reviews are carried out with the patient and occur on a regular basis, at least annually.

Standard 10 – Administration
Following an initial check that the direction to administer a medicine is appropriate, patients who have their medicines administered receive them on time and as prescribed.

Quality Theme – Patient/Client Focus

Standard 1 - Safer Prescribing with Patient Involvement

Prescribing is carried out in a manner which promotes safety and optimal health outcomes, with patients involved in decisions about their treatment.

Why is the standard needed?

UK studies have highlighted the prevalence of prescribing errors in primary and secondary care showing that medication errors are common and are associated with considerable risk of potentially avoidable patient harm[39] [40]. Studies have also shown that the prevalence of error and potentially inappropriate prescribing are greater for people taking multiple medicines (polypharmacy); generally older people and those living in residential and nursing homes[41] [42]. A range of safer prescribing initiatives are in place to address these issues and a number of tools are available and in development for prescribing support. For example, the pharmacy-led technology intervention (PINCER)[43] has been demonstrated as an effective method for reducing the range of medication errors in general practice. In secondary care, computerised prescriber order entry and decision support have also been shown to improve safety[44].

Modern prescribing practice recognises the importance of involving patients in decisions about their treatment and medication. In this area prescribers are guided by the 2009 NICE Clinical Guideline 76, '*Involving patients in decisions about prescribed medicines and supporting adherence*' which recommends improving communication and increasing patient involvement in decisions about prescribed medicines; a better understanding of the patient's perspective and the provision of more information for patients[45]. This guideline now overlaps with the NICE Guideline NG5 Medicines optimisation. Patients having problems because of

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39 Investigating the prevalence and cause of prescribing errors in general practice http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf.

40 Dornan et al. An in depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education. EQIP Study. 2009 A report to the GMC

41 Bradley et al. Potentially Inappropriate Prescribing and cost outcomes for older people: a cross-sectional study using the Northern Ireland Enhanced Prescribing Database. Eur J Clin Pharmacol, 2012

42 Alldred et al. Care homes' use of medicines study: prevalence, causes and potential harm of medication errors in care homes for older people. Quality and Safety in Health Care. 2009

43 Avery et al: A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. Lancet 2012

44 Bates D W. Using information technology to reduce rates of medication errors in hospitals. BMJ 2000 Mar 18; 320(7237): 788-791

45 https://www.nice.org.uk/guidance/cg76

language barriers need the support of advocates and language formats that they understand to ensure they are involved in decision making. Health and social care professionals who don't have English as their first language may also need support to ensure they have the necessary communication skills.

Doctors also comply with the GMC Good Practice in Prescribing Medicines and Devices 2013 which provides comprehensive advice on the prescribing of medicines to serve the patient's needs with agreement for the treatment proposed. In addition, the Service Frameworks for older people, mental health, learning disability and children all include standards for patient choice and shared decision making. However, time pressures for doctors may make this difficult to achieve and support from other healthcare professionals in supporting patients in decision making is needed.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Patients are involved in decisions about their treatment. • To support clinically appropriate and safe prescribing, prescribers have access to end to end paperless prescribing and administration systems.	• Sufficient time to enable an informed discussion with the patient/carer can be an issue. • An ePrescribing & Medicines Administration (EPMA) system should be developed.
General Practice	• Patients are involved in decisions about their treatment. • Prescribers have access to pharmaceutical advice and up to date information to support clinically appropriate and safe prescribing.	• Routine GP consultation times may be insufficient for some patients. • Pharmacists and electronic prescribing support systems such as PINCER are not available in all GP practices.
Community pharmacy	• Increase in number of pharmacists trained as Independent Prescribers, built on a strong clinical foundation and working in Community Pharmacy settings. • Access to Electronic Care Record (ECR).	• Low numbers of Pharmacist Independent Prescribers working in community pharmacies. • No access currently to ECRs.
Patients	• Patients are involved in decisions about their prescribed medicines.	• Patients do not see themselves as equal partners in decision making.

Actions needed to address the gaps

- In secondary care an ePrescribing & Medicines Administration (EPMA) system and the computerisation of records and processes should be introduced, linked to general practice and community pharmacy (see standard 10).
- GP practices should have pharmacists available to advise on complex medicines and polypharmacy, to conduct clinical medication reviews and to help patients with information and advice to take their medicines safely and effectively.
- In GP practices the role of technology enabled screening tools and clinical decision support systems during prescribing for optimising medicines selection and reducing medication errors should be considered. See NICE Guideline NG5 recommendation 1.7, clinical decision support.
- The Northern Ireland Formulary should be integrated within GP and community pharmacy systems and an EPMA system.
- Greater awareness of the patient's role in decision making should be promoted.
- The use of patient decision aids in consultations involving medicines should be explored. See NICE NG5 recommendation 1.6, patient decision aids.
- Consideration should be given to how patients with low health literacy, where there are language barriers and those patients with mental health incapacity will be more readily included in their treatment decisions where possible.
- Community pharmacists should develop clinically and train as independent prescribers.
- Community pharmacists should have access to ECRs.
- The hybrid independent prescribing model should be expanded where doctors diagnose and routine prescribing is then carried out by non-medical prescribers.
- There should be a greater multi-disciplinary approach to prescribing in the most appropriate setting for the patient to ensure medicines use is optimised.

Standard 2 – Better Information about Medicines

Patients/carers receive the information they need to take their medicines safely and effectively.

Why is the standard needed?

Ten days after starting a new medicine, 61% of patients feel they are lacking information and only 16% of patients who are prescribed a new medicine are taking it as prescribed, experiencing no problems and receiving as much information as they believe they need[46]. Good quality information is essential for greater patient involvement and shared clinical decision making and sufficient high quality information alongside good professional interaction is key to helping clinical decision making[47]. In December 2009 NICE was certified as a quality provider of health and social care information by the Information Standard[48] - a certification scheme for health and social care information aimed at the public. When NICE guidelines are being developed the principles of the Information Standard are followed to ensure key messages of the guideline are summarised in everyday language for users of health and care services, carers and the public. The regional public health strategy Making Life Better states that we need to empower people to make informed decisions about their health by improving health literacy which includes providing appropriate and accessible health information (making greater use of modern communication technology) and advice to all, which is evidence informed and tailored to meet specific needs[49].

Information needs to be accessible to all and communicated effectively at a level that will help patients to manage their condition effectively as opposed to just providing information. Limited health literacy capabilities have implications regarding medicines use and not having English as a first language can also impact significantly on the ability to assimilate and use information related to medicines.

The timing and method of communicating information to enable patients to understand their medicines needs to be considered and the medicines optimisation model allows clarification of the roles of health and social care professionals at particular points in the patient journey.

46 Barber et al. Patients' problems with new medication for chronic conditions. Quality and safety in healthcare 2004.

47 Coulter et al. Assessing the quality of information to support people in making decisions about their health and healthcare. Picker Institute, 2006.

48 https://www.england.nhs.uk/tis/

49 https://www.dhsspsni.gov.uk/articles/making-life-better-strategic-framework-public-health

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Patients receive appropriate, tailored, reliable information about their medicines and support during pre admission clinics and pre discharge counseling. • Patients on specialist medicines have access to a healthcare professional for appropriate advice and tailored, reliable information and support.	• Sufficient time to enable healthcare professionals provide patients with appropriate, tailored, reliable information and support can be an issue • There is no regionally agreed support system for patients post discharge.
General Practice	• Patients receive appropriate, tailored, reliable information and support about medicines when first prescribed and during clinical medication reviews. • Better integration of existing services for example GP referral to Community Pharmacy for medicines use reviews (MURs)/managing your medicines service	• GP consultation times may not be sufficient to provide appropriate, tailored, reliable information and support about medicines required by the patient.
Community pharmacy	• Patients receive appropriate, tailored, reliable advice, information and support when medicines are supplied. • MURs are provided to improve patient knowledge, adherence and use of their medicines. • It is a legal requirement that all medicines are supplied with a Patient Information Leaflet (PIL) provided by the pharmaceutical manufacturer.	• The provision of appropriate, tailored advice, information and support with medicines supplies is inconsistent. • MURs available in community pharmacies while offered by over 90% of community pharmacies, are currently capped in number and limited by patient condition. • The content of the PIL can be both difficult to read and comprehend and supplies with split packs can be problematic.
Social Care	• Nursing and social care staff have access to appropriate up to date information sources for medicines.	• Access to accessible and appropriate up to date information about medicines is limited especially for domiciliary care workers.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Patients	• Patients are aware of where to access the recommended, reliable sources of information on medicines. • Patients have access to information about medicines via the patient zone on the Northern Ireland Formulary website, a patient portal on the NIDirect website and other websites, for example NHS choices. Patients with mental illness have access to information about their medicines via the Choice and Medication website. • Patient helpline available for advice and information.	• Patient awareness of recommended, reliable sources of information is low. • There isn't a regional patient helpline however a helpline pilot is underway in BHSCT and WHSCT.

Actions needed to address the gaps

- A regional system should be agreed to support patients with their medicines after discharge from hospital.
- In GP practices, pharmacists should be available so that patients can be referred to them for appropriate, tailored, reliable information, advice and support to help them take their medicines safely and effectively.
- Community pharmacies should follow a Standard Operating Procedure (SOP) for the risk stratified provision of appropriate support, information and advice with supply of medicines. Information sources for patients should be promoted [patient portal].
- Increased use of technology to direct patients to information resources.
- If the pilot demonstrates benefits a regional patient helpline should be available for advice and information with appropriate signposting to existing national help lines.
- There should be increased availability of the current MUR service in community pharmacy and it should be developed further to include other conditions in particular for those patients prescribed new medications or recently discharged from hospital.
- Health and social care professionals should be trained on how to communicate information effectively to patients.
- Any information provided on internet sites for patients should be in a style accredited by the Plain English Campaign[50] or the Information Standard.

50 http://www.plainenglish.co.uk/

Standard 3 – Supporting Adherence and Independence

People are helped to remain independent and self manage their medicines where possible but receive support with adherence when needed.

Why is the standard needed?

UK evidence shows that 30-50% of long term conditions sufferers do not take their medicines as prescribed[51]. Consequences of non-adherence include poorer than expected clinical outcomes; reduced quality of life; deterioration of health and unplanned admissions to hospital. In the UK the NHS costs of hospital admissions resulting from people not taking medicines as recommended were estimated at £36-196 m in 2006-7[52]. A Cochrane review 'Interventions for enhancing medication adherence' concluded that improving medicines-taking may have a far greater impact on clinical outcomes than improvements in treatments[53].

It is important that people are helped to remain independent and self-manage their medicines for as long as they are able, with the confidence that they will be supported if the time comes when they need more help. Self management should provide people with the knowledge and skills they need to manage their own condition more confidently and to make daily decisions which can maintain or enhance their health and well-being as well as their clinical, emotional and social outcomes[54]. The King's fund paper, 'supporting people to manage their health – an introduction to patient activation describes the patient activation measure (PAM) which measures an individual's knowledge, skill and confidence for self-management. It is stated that patient activation is a better predictor of health outcomes than known socio-demographic factors such as ethnicity and age[55]. Good communication and effective systems can help support people, particularly as they age, to stay in control of ordering, collecting and taking their prescribed medicines.

51 Horne R, Weinman J, Barber N, Elliott R, Morgan M. Concordance, adherence and compliance in medicine-taking. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D. 2005.

52 NICE Costing Statement: Medicines Adherence: involving patients in decisions about prescribed medicines

53 Cochrane review: Interventions for enhancing medication adherence, 2008

54 DHSSPS Living with Long Term Conditions Strategy, 2012

55 Supporting People to Manage Their Health – An Introduction to Patient Activation. The King's Fund, 2014

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• On admission to hospital, patients with sub-optimal adherence are identified through the NI Single Assessment Tool (NISAT) and/or IMM Medicines Reconciliation. Their needs are assessed and appropriate post-discharge support is arranged prior to discharge. • Improved clinical coding of the incidence of unplanned admissions to hospital associated with non-concordance.	• There is no common approach to using NISAT, identifying and assessing non-adherence and to the provision of solutions or support at discharge. • The IMM service is currently only available for 50% of beds. • The clinical coding of medicines related admissions including non-concordance is under reported.
General Practice	• Patients who are experiencing problems adhering to their medicines are identified and referred for assessment.	• There is no common regional approach to identifying and assessing non-adherence and to the provision of solutions.
Community pharmacy	• Patients with sub-optimal adherence are identified through the targeted medication use review (MUR) service which is offered by over 90% of community pharmacies and the Manage Your Medicines Service. • Adjustments are made to medicines packs and adherence aids provided to assist patients to take their medicines more effectively. • On the request of GPs community pharmacies can supply medicines weekly for high risk patients when it is essential to protect the patient and prevent life-threatening non-compliance.	• The targeted MUR Service is limited to patients with respiratory disease and/or diabetes and MURs are currently capped in number. • The Manage Your Medicines Service has low uptake. • There is no common regional approach to identifying and assessing non-adherence and to the provision of solutions. However a Medicines Adherence Support Service (MASS) pilot has been carried out and is currently being evaluated.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Patients should have the necessary support to remain independent and manage their medicines for as long as possible without the need for interventions such as Monitored Dosage Systems (MDS).	• Although healthcare professionals undertake many specialist clinics and invest significantly in supporting patients in medicine adherence and independence including for example inhaler techniques and discussions regarding adverse drug reactions (ADRs) there is still a heavy reliance on a one size fits all approach through MDS.
Patients	• Patients have access to a wide range of patient education/self management and training programmes provided within the HSC and by voluntary and community organisations to help provide the skills and tools they need to self-care/manage for example the Pain Toolkit[56] and Beating the Blues[57] • Patients have self-management plans to support self management of their chronic or long term condition using medicines	• There is low awareness of the resources available. • There is no regional approach to self-management plans to empower patients to be more involved in managing their chronic or long term condition(s).
Other	• Patients have access to tele-monitoring services which enable them to monitor e.g. BP at home, avoiding visits to GP or A&E with their readings being monitored remotely and help available if required.	• Tele-monitoring services are still under development.

56 http://www.paintoolkit.org/

57 http://www.beatingtheblues.co.uk/

Actions needed to address the gaps

- An integrated regional system for identifying and assessing non-adherence and providing solutions should be agreed with defined roles for secondary care, general practice, community pharmacy services and social care.
- Appropriate clinical pharmacy staffing levels particularly in emergency departments to identify and help manage adherence/ adverse drug reaction related admissions.
- Guidance for health and social care professionals on the availability of adherence solutions other than MDS.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- A range of low and high tech solutions to support adherence should be developed with patient involvement and commissioned.
- The MUR service should be developed for patients with multi-morbidities and polypharmacy.
- Development of new referral mechanisms to community pharmacists for patients who require adherence support..
- A regional system for improving the quality of coding for medicines related factors to identify admissions due to poor adherence should be developed and implemented.
- The availability of self help information relating to medicines and adherence should be promoted.
- Self-management plans should be developed to support patients with a chronic or long term condition(s). See NICE Guideline NG5 recommendation 1.5, self-management plans.

Standard 4 – Safer Transitions of Care

Checks occur at each transition of care to ensure that the transfer of medicines and medicines information between patients, carers and health and social care workers is safe, accurate and timely.

Why is the standard needed?

When patients move between care settings it is important that their medicines and information about their medicines transfers safely and accurately with them, to avoid harm. Over half of all hospital medication errors occur at interfaces of care, most commonly on admission to hospital[58]. A report for the General Medical Council in 2012 investigating the prevalence of prescribing errors in general practice highlighted risks at the primary/secondary care interface with significant problems concerning correspondence about medications particularly at the time of hospital discharge[59]. Older people, those taking multiple and higher risk medicines are most at risk. Risks also exist at transitions of care with intermediate care, community settings including residential, nursing or children's homes, transfers between GP practices and entering or leaving prison. The Donaldson Report highlighted the role that pharmacy can offer at transitions between hospital and the community.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Integrated Medicines Management (IMM) Service providing electronic medicines reconciliation at transitions; post-discharge communication with GPs, community pharmacies and other health and social care workers.	• The IMM service is limited to around 50% of hospital beds mainly during weekdays from 8:00am to 6:00 pm and delivery of the service varies between HSC Trusts. • Electronic medicines reconciliation is not available in all Trusts.

58 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

59 Investigating the prevalence and cause of prescribing errors in general practice http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital contd	• Consultant pharmacists led services/Senior Clinical Pharmacists supporting appropriate polypharmacy in older people in intermediate care and nursing/ residential homes. • Regional Guidelines for the Supply of 'Take Home Medication' from Northern Ireland Emergency Departments [60] developed by GAIN • Regional Guidelines for Immediate Discharge Documentation for Patients Being Discharged from Secondary into Primary Care[61] developed by GAIN, 2011	• Consultant Pharmacist-led services for older people are not available in all Trusts.
General Practice	• GP practices provide information relating to prescribed medicines to secondary care and to appropriately authorised health and social care professionals looking after patients in care homes[62] or their own homes. • GPs receive timely notification electronically when their patients are admitted to hospital and receive timely and accurate information about medication changes on discharge.	• There is no agreed approach to the timely provision of this information. • GPs do not always receive timely notification that their patients have been admitted to hospital and post discharge medicines information is not always reconciled to the GP list before a prescription or new supply of medicines are issued and within 1 week of the GP practice receiving the information. • No process currently in place to ensure that GP practices are advised if any of their patients are admitted to prison.

60 http://www.gain-ni.org/images/Uploads/Guidelines/Regional_Guidelines_for_the_supply_of_Take_Home_Medication_from_Northern_Ireland_Emergency_Departments_DEC_2014.pdf

61 http://www.gain-ni.org/images/Uploads/Guidelines/Immediate-Discharge-secondary-into-primary.pdf

62 Where reference is made to' care homes 'this means Nursing Home, Residential Home and Children's Homes.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice contd	• People discharged from an acute care setting to primary care have their medicines documented in the discharge summary and reconciled in the GP list as soon as is practically possible, before a prescription or new supply of medicines is issued and within 1 week of the GP practice receiving the information. • GP practices are notified if a patient is admitted to prison and on release. Prescribing information from the Prison health GP IT EMIS system should be uploaded onto, and available on, the ECR.	• Prison health can see ECR when prisoner arrives in prison, but cannot add to it, so that no information about prescribing during the prison stay is available to the patient's GP on release of the patient.
Community pharmacy	• With patient agreement a nominated community pharmacy receives post discharge medicines information from secondary care electronically. • The Royal Pharmaceutical Society Innovators' Forum has produced a toolkit[63] to support safer transition from secondary care to community pharmacy. • Information relating to medicines supplied is provided on request to secondary care and to appropriately authorised health and social care professionals in care homes. • There is a defined role for community pharmacy to support safer transitions at discharge.	• HSC Trusts do not routinely provide information to community pharmacies post discharge. • There is no specific role or service for community pharmacy to support safer transitions for patients at discharge. • The ECR is not yet accessible to community pharmacies.

63 http://www.rpharms.com/support-pdfs/3649---rps---hospital-toolkit-brochure-web.pdf

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Nursing staff conduct medicines checks for new patients in nursing homes and independent healthcare settings. • Medicines checks are completed by social care workers when children move into a children's home or change day care setting[64]. • Domiciliary care staff are made aware of changes to patients' medicines following transitions of care. • Community nurses and appropriately authorised health and social care staff have visibility of medicines prescribed through access to ECR.	• Community Nurses can contact GPs to discuss a patient's medication on transfers of care however the ECR is not accessible to them. • The ECR is not accessible to appropriately authorised health and social care professionals in care homes. • When patients are discharged from hospital or return home from a care setting there is no system to make domiciliary care workers, who assist them with their medicines aware of changes to their medication.
Patients	• Patients bring their current medication and related information with them to hospital and all Trusts have policies for using patients own drugs where possible. • Patients are responsible for knowing what medicines they are currently prescribed and why. • Patients have access wherever possible to ECR and/ or a patient passport and are aware of who else has what information, under what circumstances and with what safeguards.	• The patient's role in managing their own medicines and medicines information during transitions of care is not well understood. • Patients are not involved in decisions about their medicines as much as they should be to enable them to take responsibility for knowing what they are prescribed and why. • Patient view allows patients internet access to their own records but access to the ECR is needed to improve co-ordination of care

64 https://www.dhsspsni.gov.uk/articles/care-standards

Actions needed to address the gaps

- An Integrated Medicines Management Service with electronic medicines reconciliation should be delivered consistently across HSC Trusts which includes hospital attendance without admission for example at outpatient clinics. See also NICE Guideline NG5 recommendation 1.3, medicines reconciliation.
- A regional consultant pharmacist led service should be commissioned for managing polypharmacy in older people in intermediate care, nursing and residential care settings.
- There should be 'one single source of truth' for example ECR regarding patient's medications which is up to date and can be accessed by patients and shared by all healthcare professionals. See also NICE Guideline NG5 recommendation 1.2, medicines-related communications systems when patients move from one care setting to another.
- A regional protocol for safe transitions in the community should be developed to ensure that medicines checks occur at each transition of care with defined roles for GPs, Community Pharmacists, and health and social care workers in care settings, facilitated by appropriate access to the ECR.
- Electronic communication between hospitals and GPs should be improved to notify when patients are admitted to hospital and provide timely and accurate medicines information on discharge
- A process should be established to ensure that GP practices are advised if a patient is admitted to prison.
- Information about prescribing during a prison stay should be uploaded onto the ECR for the patient's GP to see on release of the patient.
- The patient's role in managing their own medicines and related information during transitions of care should be promoted.

Standard 5 – Risk Stratification of Medicines

Patients who may be at risk because of the medicines that they use receive the appropriate help to take their medicines safely.

Why is the standard needed?

Although the use of all medicines is associated with a level of risk, some medicines are known to carry a greater risk of side effects, adverse events and/or admission to hospital than others. A systematic review of medicines related admissions to hospital found that four groups of drugs account for more than 50% of the drug groups associated with preventable drug-related hospital admissions - antiplatelets, diuretics, NSAIDs and anticoagulants[65]. In addition, a review was carried out of medication incidents reported to the National Reporting and Learning System in England and Wales over a 6 year period. The top 5 medicines for which the clinical outcome was death or severe harm were opioids, antibiotics, warfarin, low molecular weight heparins and insulin[66]. Antimicrobial resistance is among the civil emergencies listed in the Cabinet Office's National Risk Register of Civil Emergencies[67]. In Northern Ireland, antimicrobial prescribing is high and the prevalence of systemic antimicrobial prescribing in residential homes was found to be relatively high compared with care homes (particularly nursing homes) in other countries[68]. By measuring and addressing performance indicators, the quality of antibiotic prescribing could be improved[69]. The misuse of prescription and over the counter drugs is a significant public health and social issue in Northern Ireland, resulting in negative impacts on physical and mental health, and there have been an increasing number of deaths related to the misuse of a range of prescription drugs. There are particular issues in relation to poly-drug use, especially when combined with alcohol and the use of hypnotics which are associated with increased mortality, even in patients taking fewer than 18 Doses/Year[70]. Other medicines also require caution in use including some specialist 'red and amber list' medicines which may need ongoing patient monitoring. These are initiated by a hospital prescriber and may be delivered directly to a patient's home with associated services (homecare services). Risks of harm are higher for some patient groups, for example, older people, those taking multiple medicines (polypharmacy), and for whom careful adherence is critical for example in the treatment of diabetes, Parkinson's Disease and some mental health conditions. A useful tool, SPARRA[71] (Scottish Patients at Risk of Readmission and Admission) has been developed by the Information Services Department, Scotland which can be used to predict an individual's risk of being admitted to hospital as an emergency inpatient within the next year.

65 Which drugs cause preventable admissions to hospital? A systematic review. www.ncbi.nlm.nih.gov/pubmed/16803468

66 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct; 74(4):597-604

67 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419549/20150331_2015-NRR-WA_Final.pdf

68 McClean et al. Antimicrobial prescribing in residential homes. J Antimicrob Chemother, 2012.

69 Maripu H et al. An audit of antimicrobial treatment of lower respiratory and urinary tract infections in a hospital setting. Eur J Hosp Pharm 2014;21:139-144

70 Kripke DF et al. Hypnotics' association with mortality or cancer: a matched cohort study. Pharmacology and therapeutics, 2012

71 http://www.isdscotland.org/Health-Topics/Health-and-Social-Community-Care/SPARRA/

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• There is an agreed approach across Trusts for the management of patients taking high risk or specialist medicines which includes specialist pharmacists with a strategic responsibility for high risk medicines across Trusts. • Clinicians record medicines related issues as causative factors for admission/ re-admission in patients' notes, supporting accurate clinical coding and monitoring trends across Trusts. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship. • The pharmacy management system (JAC) has high risk medicines flagged	• The interface pharmacist network provides pharmaceutical care for some groups of patients on specialist medicines. This varies depending on service delivery and capacity and would not encompass all medicines on the red amber list. Other specialist pharmacists also play a significant role. There is inconsistency in the level of information provided to patients, carers and social care workers when high risk medicines are prescribed and dispensed. • There is low awareness among medical staff of medicines related issues as causative factors for admission/ re-admission leading to under reporting in patient's notes, incomplete clinical coding and lack of data for monitoring trends. • A system for surveillance and monitoring of antimicrobial resistance and antimicrobial stewardship with alert functionality is not available in all Trusts. • High risk medicines are not highlighted on JAC, the pharmacy management system.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Patient safety tools are in use for example PINCER, STOPP/START and the GRASP suite of tools • Proactive case management and targeting care to those most at risk through a primary care enhanced service for risk stratification is included in the work of ICPs. • All patients on high risk medicines receive appropriate help to take their medicines safely. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship which collects data from GP practices across the region. • Patients' records including the ECR highlight the use of high risk and specialist medicines. • A local enhanced service (LES) for those patients in nursing and residential homes supports those who may have more complex needs supported by pharmacist prescribers and case management nurses in primary care.	• There is no regional multi-disciplinary approach to the management of patients on high risk medicines. • A surveillance system to capture microbiological data in general practice is not available across the region. • Examples of high risk medicines are available on a poster for practices however there is no agreed system for highlighting high risk and specialist medicines on patient records and ECR. • The LES for nursing and residential homes does not currently specify management of patients on high risk medicines.
Community pharmacy	• Risk stratified provision of appropriate support, information and advice with supply of medicines. • Community pharmacies have access to up to date information relating to patient medication including high risk and specialist medicines.	• Examples of high risk medicines are available on a poster for community pharmacies however there is no protocol which they use to stratify risk. • Community pharmacies do not currently have access to the ECR.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Social Care	• Patients in nursing and residential homes taking high risk medicines are identified and receive appropriate care. • In domiciliary care there is compliance aid support for at risk patients based on a person's physical capability/cognitive ability/mental health difficulties. • The roles of nurses and care staff support patients on high risk medicines in domiciliary care settings agreed regionally with accredited training and competency based assessments for care staff. • Consistent provision to social care workers of information regarding patients on high risk medicines. • A regional electronic antimicrobial surveillance system is in operation which includes resistance tracking, alert functionality and antimicrobial stewardship which collects data from nursing and residential homes across the region.	• The roles of nurses and care staff supporting patients on high risk medicines in domiciliary care settings is unclear. • A surveillance system to capture microbiological data in nursing/residential homes is not available across the region.
Patients	• Patients with a greater awareness of high risk medicines and empowered to seek support, information and advice in the use of these medicines.	• There is a lack of knowledge among patients regarding high risk medicines to enable them to manage them appropriately.

Actions needed to address the gaps

- A regional risk stratification tool should be developed and implemented in primary and secondary care which includes outpatients to identify patients who may be at risk because of the medicines they use.
- Patients and carers should be made aware when high risk medicines are prescribed and dispensed and receive the necessary support and information to assist safe and effective use.
- An ePrescribing & Medicines Administration (EPMA) system and JAC in hospitals should highlight when high risk medicines are being used.
- Increased use of patient safety tools for example PINCER, STOPP/START and the GRASP suite of tools.
- The ECR should highlight when high risk and specialist medicines are being used.
- Information to patients and their GPs regarding specialist medicines should be consistently provided.
- A regional plan to improve reporting/clinical coding of the incidence of unplanned admissions to hospital associated with medicines should be developed and implemented.
- GP and community pharmacy computer systems should have high risk and specialist medicines highlighted.
- High risk patients should be prioritised for regular clinical medication reviews (See Standard 9).
- Roles and responsibilities relating to risk stratification and medicines optimisation should be included in ICP patient pathways for at risk patient groups.
- A regional antimicrobial prescribing and surveillance system should be established which includes resistance tracking, an alert functionality and antimicrobial stewardship.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- For high risk drugs there should be shared care guidelines not only with the GP but also with the patients chosen community pharmacist.

Standard 6 – Safety/Reporting and Learning Culture

Organisations promote an open and transparent culture with evidence of processes for the reporting, prevention, detection, communication and cascade of learning from medication incidents and adverse drug reactions.

Why is the standard needed?

The medicines governance teams in primary and secondary care are well established in promoting medication incident reporting, developing risk management processes, implementing regional best practice policies and risk education. However there is variance in the degree to which medicines incidents are reported across the HSC and reluctance from community pharmacies to report due to current legislative penalties for errors. One of the recommendations of the Donaldson Report was a need to make incident reports really count.

The MHRA has received over 700,000 UK spontaneous adverse drug reactions (ADRs) since the scheme was first started and typically they receive around 25,000 reports per year. In the 5 years prior to June 2013, there have been 2,110 ADR reports reported to MHRA from Northern Ireland. We need to improve our reporting of medicines incidents including ADRs across the HSC and raise public awareness of patient reporting of ADRs.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• All medicines incidents and ADRs are reported via the appropriate mechanisms • All near miss information from pharmacist interventions are captured electronically to enable learning. • A modified risk assessment tool based on the national quality assurance and fit for purpose and medicines error potential tools is used in the procurement process. However, there is a need for other tools to identify medication safety risks.	• The rates of medicines incident reporting and yellow card reporting are low and vary between Trusts, professionals and clinical areas/specialities • The Electronic Pharmacist Intervention Clinical System (EPICS) software to capture pharmacist interventions is not in use in all Trusts. • Although Datix is used to report adverse incidents (AIs) and serious adverse incidents (SAIs), and can be used to help identify medicines safety risks, there are currently no tools, for example, global trigger tool/ medication safety thermometer tool.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• A software system is in place to allow the recording of medicines incidents by GPs in their general practice (e.g. Datix) and to analyse medicines incidents. • All ADRs are reported via the yellow card scheme through the GP IT clinical system. • Tools are available to identify medication safety risks.	• The rates of medicines incident reporting are low. • The rates of yellow card reporting are low. • There are currently no approved tools for example global trigger tool/medication safety thermometer tool.
Community pharmacy	• A software system is in place to allow the recording of medicines incidents by community pharmacists in their pharmacy practice (e.g. Datix) and to analyse medicines incidents. • Community pharmacists actively report ADRs via the yellow card scheme and can do so through their pharmacy IT system.	• The rates of medicines incident reporting are low. • The rates of yellow card reporting are low.
Social Care	• Systems are in place to report ADRs and incident reporting systems for medicines. • Medication incidents are reported from all registered facilities to RQIA.	• The rates of incident and yellow card reporting are low.
Patients	• Systems are in place to allow patients to report medication incidents. • Patients report ADRs via the yellow card scheme.	• Patients are not currently encouraged to report medication incidents. • The rates of yellow card reporting are low.

Actions needed to address the gaps

- An open and fair culture to encourage timely reporting of medicines incidents and ADRs should be established across the HSC.
- A regional programme should be launched to increase yellow card reporting by health care professionals and patients with consideration of introducing contractual requirements to support implementation.
- A regional system should be introduced to allow electronic reporting, monitoring and analysis of medicines incidents by GPs, Community Pharmacies and Social Care Workers.
- A regional system should be introduced to identify and review incident data, identify and develop learning and explore new ways of how to deliver learning and share knowledge. See NICE Guideline NG5 recommendation 1.1
- Formal links should be established with other UK countries with respect to medication incident reporting and learning.
- Process reviews along with engineering and technological solutions should be developed which aim to minimise system failures that underpin medication errors.
- The use of Institute for Healthcare Improvement (IHI) methodology and other improvement science tools should be increased to improve medicines safety.
- A Never Event approach should be introduced as recommended in the Donaldson report for medication errors.

Quality Theme – Effectiveness

Standard 7 – Access to Medicines you Need

Patients have appropriate, equitable and timely access to quality assured, evidence-based and cost-effective medicines.

Why is the standard needed?

Improved access to medicines has contributed to an increase in life expectancy, helping people to stay healthy for longer and many previously debilitating or fatal conditions are now prevented or managed, often on a long term basis, through regular medicines use. The population of Northern Ireland uses a high volume of medicines per head of population. Robust systems are in place to ensure that medicines are prescribed to patients across the region in line with evidence and best practices in a cost effective manner. Furthermore, regional and local procurement practices in Trusts ensure the availability of quality assured medicines in hospitals. Equally, community pharmacies comply with professional standards for the sale and supply of medicines in the community and go to great lengths to ensure that patients have access to the medicines they have been prescribed, whether these are one-off prescriptions or ongoing medicines for long-term conditions. However, Northern Ireland is part of a wider UK and global medicines market and shortages can and do arise within the medicines supply chain which are frequently beyond their control. The consistent delivery of safe, high quality and cost effective prescribing and procurement is essential to facilitate continued access to medicines for the population. For new medicines, a regional managed entry process exists which aims to ensure timely and equitable access for patients to those medicines for which there is an evidence base on efficacy and cost-effectiveness. However, there is a perception that there are differences in access across the region and compared to other UK countries particularly in respect to cancer and specialist medicines.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Hospital pharmacies ensure timely access to safe, quality assured medicines so as to avoid delays in administration. • All Health and Social Care Professionals are aware of the HSCB Regional Managed Entry [72] process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Timely and appropriate access to new medicines for patients for which there is an evidence base on efficacy and cost-effectiveness. • Compliance with regional guidelines for managing medicines shortages in hospitals. • All Individual Funding Request (IFR) applications subject to regionally consistent clinical input and peer review. • Improved support regarding access to unlicensed or off-label medicines in areas of unmet medical need, thus enhancing the landscape for developing, licensing and procuring innovative medicines.	• The funding mechanisms and the process of applying for funding for new, unlicensed and specialist medicines is not well understood. • Unlicensed and off-label medicines are not part of the established regional IFR process. • There is inconsistency across Trusts regarding Non-NICE medicines approval however work is progressing on the implementation of the DHSSPS IFR consultation recommendations.

72 http://niformulary.hscni.net/ManagedEntry/Pages/default.aspx

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• All Health and Social Care Professionals are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness.. • Compliance with regional guidelines for managing medicines shortages in primary care.	• The funding mechanisms for new, unlicensed and specialist medicines is not well understood. • There are no regional guidelines for managing medicines shortages in primary care.
Community pharmacy	• All community pharmacists are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Community pharmacies ensure timely access to safe, quality assured medicines so as to avoid delays in administration However if there are shortages outwith their control, they cannot be held accountable. • Compliance with regional guidelines for managing medicines shortages in primary care. • All patients have their repeat medicines dispensed on time to avoid clinical consequences.	• The funding mechanisms for new, unlicensed and specialist medicines is not well understood. • There are no regional guidelines for managing medicines shortages in primary care.
Patients	• Patients are aware of the HSCB Regional Managed Entry process which supports timely and appropriate access to new medicines for which there is an evidence base on efficacy and cost-effectiveness. • Timely and appropriate access to new medicines for patients for which there is an evidence base on efficacy and cost-effectiveness.	• There is public perception of variance in the managed entry of new, unlicensed and specialist medicines.

Actions needed to address the gaps

- Regional guidance should be developed to improve public and healthcare professional awareness and understanding of the processes for managed entry and access to new, unlicensed and specialist medicines in Northern Ireland. This should include accessible, accurate and up to date information for the public to view and include a schematic that shows how to access medicines in the HSC.

- Regional guidelines on handling medicines shortages in primary care should be developed. This would include the provision of advice by community pharmacists to prescribers of stock shortages and making recommendations for alternative products. If shortages arise within the medicines supply chain which are outwith the control of community pharmacists, they cannot be held to account.

- The recommendations of the DHSSPS IFR consultation should be implemented.

Standard 8 - Clinical and Cost Effective Use of Medicines and Reduced Waste

Within organisations a culture exists promoting a shared responsibility for the appropriate, clinical and cost effective use of medicines supported by systems for avoiding unnecessary waste.

Why is the standard needed?

Within HSC organisations it is important that systems for the procurement, prescribing, ordering and supply of prescribed medicines provide cost effective use of medicines providing optimal health outcomes, safety and avoiding waste.

A regional focus on evidence based and cost effective prescribing has resulted in significant improvements in the quality of prescribing in recent years with evidence of change in terms of drug costs, volumes and levels of compliance with the Northern Ireland Formulary. Advertising campaigns have sought to raise public awareness of the need to reduce medicines waste by only re-ordering repeat medicines that are needed and highlighting actions for community pharmacies, GP practices and care homes. However, evidence shows that around 11% of UK households have one or more medicines that are no longer being used[73] and estimates, based upon a study conducted by the University of York, put the cost of wasted medicines in Northern Ireland at £18m per year[74]. The highest levels of wasted medicines are associated with repeat medicines that are ordered, prescribed, dispensed, collected by the patient/carer but never used and subsequently wasted. Waste in nursing and residential homes is recognised as a particular challenge.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• Prescribing is informed by the Northern Ireland Formulary. • All Trusts have policies promoting the use of patient's own drugs (PODs) where possible on admission to hospital.	• Prescribing data by clinical indication in secondary care is not available. • There are differences between Trusts in how the process of using PODs is adopted.

73 Woolf, M. Residual medicines: a report on OPCS Omnibus Survey data

74 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Prescribing is informed by the Northern Ireland Formulary. • HSC Board medicines management advisors, prescribing support pharmacists and practice-based pharmacists support effective prescribing in GP practices. • Repeat prescribing policies and processes aim to restrict over-ordering and reduce errors in ordering.	• The Northern Ireland Formulary is not linked to GP ICT systems. • Not all GP surgeries have prescribing support. • The current repeat dispensing service is paper based, inefficient and underused. • Unwanted items previously prescribed may be re-ordered in error.
Community pharmacy	• Systems are in place to check that items ordered on repeat prescription are required before supply is made. • Medicines waste returned to pharmacies for disposal is safely handled and levels of waste are monitored. • Pharmacies follow HSC Board guidance relating to ordering and collection of medicines.	• There is no requirement for pharmacies not to dispense prescribed items and unwanted items ordered in error may still be supplied. • The level of waste returned for disposal is not monitored. • Full compliance with the HSC Board guidance relating to ordering and collection of medicines is not assured.
Social Care	• Systems are in place to manage the ordering of prescribed medicines to ensure adequate supplies and prevent wastage. The RQIA encourages and promotes good stock control.	• Stock control is an ongoing problem. • Over ordering and waste returned for disposal from nursing and residential homes is not monitored.
Patients	• Systems are in place to allow patients to order their medicines when needed and prevent inappropriate ordering.	• Inappropriate ordering (over ordering, ordering unwanted items and under ordering) may still occur.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Other	• An ongoing regional medicines waste advertising campaign which seeks to influence patient behaviour and prescription ordering processes in GPs, Community Pharmacies and care homes. This should also encourage patients to bring their medicines into hospital with them to avoid unnecessary waste	

Actions needed to address the gaps

- A regional prescribing database should be available for secondary care with the Dictionary of Medicines and Devices (DM&D) as the dictionary to enable merging with primary care data.
- Prescribers should have access to an electronic Northern Ireland Formulary which is linked to GP ICT systems to inform prescribing.
- Consistent prescribing compliance with the Northern Ireland Formulary should be achieved.
- Levels of waste returned from pharmacies and care homes should be monitored and the impact of interventions on waste reduction measurement.
- Consideration should be given to a role for minimising medicines waste to be included in GP and community pharmacy contracts.
- The repeat dispensing service should be reviewed and re-launched in electronic form.
- To influence patient behaviour regarding medicines waste, the medicines waste advertising campaign should be ongoing.
- New approaches to minimising wasted medicines should be explored including collaboration with the pharmaceutical and technology industry.

Standard 9 – Clinical Medication Review

Clinical medication reviews are carried out with the patient and occur on a regular basis, at least annually.

Why is the standard needed?

The importance of medication reviews is recognised and a number of health policies and service frameworks recommend regular reviews for specific patient groups including: older patients, people with diabetes, respiratory disease and cardiovascular disease.

Medication reviews in this context are clinical reviews conducted with the patient and with full access to patient medication records. They are not medicines reconciliation checks, medicines use reviews (MURs), Manage Your Medicines service reviews or desk top patient medication record checks.

Currently medication reviews may occur at various stages in the patient journey carried out by a range of healthcare professionals with varying levels of clinical autonomy and expertise in medicines. There is a level of inconsistency in approach in terms of what the review involves, the optimal time and frequency for completion and who is best to conduct it.

An increasing challenge for medication reviews is the prevalence of multi-morbidities and polypharmacy as the population ages. Another issue is that patients may have medicines prescribed concomitantly by a number of different doctors and non-medical prescribers involved in their care.

These issues reinforce the need for a robust regional approach to clinical medication reviews.

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• 95% of people admitted to hospital receive a clinical medication review during their stay which is documented. • Clinical medication reviews to optimise medicines use in outpatient clinics for example diabetes, anti-coagulant and rheumatology.	• There is inconsistency in clinical medication reviews carried out in secondary care as the IMM service is currently only available for 50% of beds and there is variance in the quality of delivery of the service between Trusts.

Provider	What best practice should be delivered	Gaps in delivery of best practice
General Practice	• Within the core GMS contract is an expectation that patients on chronic medication have an annual clinical medication review. The appropriate frequency should be tailored to the individual and their care plan and may need to be carried out more frequently than annually • High risk patients are prioritised for 'regular' medication reviews as agreed in patient's care plans.	• Detailed clinical medication reviews are not being undertaken with patients on a consistent basis. • There is no regionally agreed best practice approach to clinical medication reviews resulting in duplication between reviews offered in secondary care, primary care and community pharmacy.
Community pharmacy	• Suitably trained Pharmacist Independent Prescribers (PIPs) with remote access to patient records from general practice have a role in the provision of clinical medication reviews.	• There is no defined role or service for community pharmacy in the provision of clinical medication reviews. • The number of PIPs working in community pharmacy is currently low.
Social Care	• Consultant pharmacist led care in intermediate care, nursing and residential homes supporting appropriate polypharmacy through clinical medication reviews. • GP Local Enhanced Service (LES) 2014/15 PIPs conduct clinical medication reviews of registered patients in nursing and residential homes.	• There is currently no agreed regional service available to provide clinical medication reviews for older people in intermediate care, nursing and residential homes settings.
Patients	• Patients are aware of what a full clinical medication review involves, when it should be carried out and by whom. • Clinical medication reviews should be carried out in a setting and time convenient to the patient where possible.	• Lack of understanding of what a full clinical medication review involves and when it is required.

Actions needed to address the gaps

- A regional model for clinical medication reviews should be developed which describes what should be included in the review, when it should be conducted and by whom. See NICE Guideline NG5 recommendation 1.4, medication review
- In primary care the frequency of clinical medication reviews for patients should be agreed within individual care plans and the requirement for completion of reviews included in GP contracts.
- In Trusts the availability of the IMM service should be increased and the service delivered to a consistent quality involving a clinical medication review conducted by a pharmacist.
- Within multi-disciplinary teams in primary care, secondary care and as outreach from Trusts, pharmacists should conduct clinical medication reviews and a role should be developed for community pharmacists
- The clinical medication review standard should be included as a generic standard in all service frameworks relating to patients with long term conditions, multi-morbidity and polypharmacy.

Standard 10 – Administration

Following an initial check that the direction to administer a medicine is appropriate, patients who have their medicines administered receive them on time and as prescribed.

Why is the standard needed?

A review of all medication incidents reported to the National Reporting and Learning System (NRLS) and England in Wales between 1st January 2005 and 31st December 2010 was undertaken. Incidents involving medicine administration (50%) and prescribing (18%) were the process steps with the largest number of reports. Omitted and delayed medicine (16%) and wrong dose (15%) represented the largest error categories[75]. A Rapid Response Report from the National Patient Safety Agency on 'Reducing harm from omitted and delayed medicines in hospital' highlighted that medicine doses are often omitted or delayed in hospital for a variety of reasons[76]. This can lead to serious harm or death for some critical conditions, for example patients with sepsis or pulmonary embolism where there is a delay/omission of intravenous medicines[77]. Parkinson's UK - Get it On Time campaign[78] outlines the importance of people getting their Parkinson's medication on time, every time in hospitals and care homes. A GAIN audit carried out in 2013 - The Importance of Timing in Parkinsons Medication[79] found that 59% of patients did not receive their medication on time during their hospital stay. A study which investigated the prevalence of medication errors in care homes in the UK found that 22.3% of 256 residents were observed to receive an administration error. The commonest administration errors were omissions because the drug was not available, so omissions need to be monitored and ordering, particularly of "as required" medicines, needs to be improved[80]. In a 2011 study of medicine administration errors in older persons in hospital wards in the UK, the number and severity of medication administration errors was found to be higher than previous studies. During 65 medicine rounds 38.4% of doses were administered incorrectly[81]. In domiciliary care settings nurses and care workers are involved in activities which range from administration to prompting patients to take their medicines. More older people are being cared for in their own homes often with complex and multiple medicines regimens and there is the need for regional best practices that support role clarification, accredited training and support systems for staff.

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75 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct;74(4):597-604

76 National Patient Safety Agency. Patient Safety Observatory Report 4: Safety in doses; 2007.

77 National Patient Safety Agency. Rapid Response Report, 2010.

78 http://www.parkinsons.org.uk/content/get-it-time-campaign

79 http://www.gain-ni.org/images/Uploads/Audit/GAIN_-_FINAL_GIOT_REPORT_-_19_April_2013.pdf

80 Alldred DP, Barber N, Carpenter J, Dean-Franklin B, Dickinson R, Garfield S, Jesson B, Lim R, Raynor DK, Savage I, Standage C Wadsworth P, Woloshynowych M, Zermansky AG. Care homes use of medicines study (CHUMS). Report to the Patient safety {Portfolio, department of Health). 2009.

81 Kelly J and Wright D. Medicine administration errors and their severity in secondary care older persons' ward: a multi-centre observational study J Clin Nursing. 2011

Provider	What best practice should be delivered	Gaps in delivery of best practice
Hospital	• All patients should receive their medicines on time following a check that the direction to administer is appropriate and other related factors taken into consideration for example insulin dose close to meal time and meals are not delayed. • Patients self-administer their own medicines, where the risks have been assessed and the competence of the patient to self-administer is confirmed. • 'One-stop' dispensing[82] and the use of patient bedside medicines lockers to improve access and reduce medicines administration errors. The move from a 'trolley-based' system for administering medicines to a 'one-stop' dispensing system using patient's own drugs and custom-designed patient bedside medicine lockers has resulted in safer and faster medicine administration rounds[83] [84].	• Doses of medication are being omitted and delayed as shown in an audit carried out in the five Trusts in Northern Ireland in 2013.12.7% of doses were omitted and delayed. (NB however work is ongoing to ascertain how many were true omissions/failure to record). • Self-administration occurs to varying degrees in Northern Ireland hospitals. • One-stop dispensing occurs in varying degrees in Northern Ireland hospitals.

82 'One-stop' dispensing refers to the practice of combining inpatient and discharge dispensing into a single supply labelled for discharge. Patients are encouraged to bring their own medicines into hospital on admission and medicines are assessed by pharmacy as suitable for use are used for the patient during their hospital stay. A 28-day supply is given of any medicines deemed unsuitable for us, when the quantity of a particular medicine is depleted and when new medicines are commenced http://www.hospitalpharmacyeurope.com/featured-articles/one-stop-dispensing-and-discharge-prescription-time

83 Anon. Giving medicines from patient lockers reduces errors. Pharmaceut J 2002;268:274

84 Hogg et al. Do patient bedside medicine lockers result in a safer and faster medicine administration round? Eur J Hosp Pharm, July 2012 http://ejhp.bmj.com/content/19/6/525.abstract

Provider	What best practice should be delivered	Gaps in delivery of best practice
Community Pharmacy	• All patients required to take their medicines under supervision are treated in a confidential, non-judgmental manner in a private area within the pharmacy. • Community pharmacists helping to facilitate administration through new systems or additional support provided to care homes. • In domiciliary care community pharmacists supporting self administration of medicines through the provision of a variety of medicines adherence support solutions.	• Patients requiring medicines to be taken under supervision may not always feel that they are treated in a confidential, non-judgemental manner. • There is a limited evidence base for support systems for care homes and domiciliary care and no common regional approach to identifying and assessing non adherence and to the provision of solutions. However Medicines Adherence Support Service (MASS) pilot has been carried out and is currently being evaluated.
Social care	• All residents in care homes who have their medicines administered should receive their medicines on time following a check that the direction to administer is appropriate. • Patients self-administer their own medicines, where the risks have been assessed and the competence of the patient to self-administer is confirmed. • Community nursing core services associated with medicines administration of high risk and specialist medicines as well as other medicines such as vaccines in patients own home. • Domiciliary care workers are appropriately trained and supported to contribute to medicines optimisation.	• Evidence of administration errors in care homes due to omissions. • The roles of nurses and domiciliary care workers in medicines optimisation need to be reviewed and clarified.
Patients	• All patients living at home with predictable conditions are supported to self-administer their medicines and to remain independent for as long as possible.	• There are limited solutions available for supporting independence with medicines taking.

Actions needed to address the gaps

- In secondary care an ePrescribing & Medicines Administration (EPMA) system and the computerisation of records and processes should be introduced, linked to general practice and community pharmacy (see standard 1).
- An increase in the number of wards in hospital providing a 'one-stop' dispensing service should be considered.
- There should be an appropriate skill mix within clinical settings to ensure safe administration of 'critical' medicines.
- Self-administration schemes should be rolled out in secondary care and intermediate care where the risks have been assessed and the competence of the patient to self-administer is confirmed.
- Community pharmacies providing a substitution treatment service should have a private area where supervised administration can be undertaken which serves to normalise the process for patients.
- Consideration should be given as to how community pharmacists could provide additional support in relation to administration to patients living both in their own home and in a care home environment.
- The roles of nurses and care staff in medicines optimisation in domiciliary care settings should be reviewed, clarified and agreed regionally with accredited training and competency based assessments for care staff.
- There should be a regionally agreed process to support community nursing teams and care staff to administer medicines on time.

Integrated Innovation and Change Programme

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SECTION 4

Integrated Innovation and Change Programme

Supporting Continuous Improvement and Innovation in Medicines Use

4.1 The Quality Standards have identified a number of gaps in medicines management systems which impact on the delivery of the Regional Medicines Optimisation Model. Many of the actions needed to address these gaps require regional systems which may involve an element of whole system change with interdependencies across the HSC.

4.2 Traditionally a range of organisations have had active programmes of research and service development relevant to medicines optimisation with funding coming from a variety of sources.

4.3 The ultimate success of these programmes is for their outputs to inform practice throughout the HSC through changes to medicines policy or commissioned services. However, this does not always occur and in many instances outputs are not recognised or valued by commissioners and policy makers or practices are not successfully translated across the HSC leaving fragmented or disjointed services. Outputs need to be demonstrably transferrable across the wider HSC and monitored to ensure the programmes continue to be a success following roll-out.

4.4 A new strategic approach to pharmaceutical innovation is proposed to support and drive continuous improvement through the development and implementation of best practice in medicines optimisation in Northern Ireland exploiting new funding opportunities whilst using existing funding streams and resources efficiently and following the core values and principles of Personal and Public Involvement (PPI).

4.5 This will require a dedicated oversight group to drive the development and implementation of evidence based best practice associated with each medicines quality standard.

4.6 The strategic approach has four components:

- a regional action plan for medicines optimisation;
- a medicines optimisation innovation centre;
- a medicines optimisation network; and
- a regional database to monitor improvement.

Regional Action Plan for Medicines Optimisation

4.7 The Regional Action Plan for medicines optimisation will prioritise activities in a regional change programme of research, service development and translation with clear outputs and timelines for developing, testing and implementing solutions.

4.8 Methodology to develop the plan will include:

- a baseline assessment of all activities underway or in development across the HSC relating to each quality standard;
- stratification of the activities to identify those capable of informing regional versus local best practice;
- agreement with commissioners of the priority and timescales related to the regional activities; and
- analysis of the regional activities to identify the different actions needed, timeframes and costs as follows:

Table 9: Regional Action Plan Analysis of Activities

Type of Activity	Action needed	Timeframe and costs
Activities involving best practices that are or have the potential to be regionally commissioned through existing services or contractual agreements and performance managed thereafter.	• Promote the best practice regionally to all relevant providers and set quality expectations • Amend contractual agreements and/or job descriptions of service providers to include responsibility for delivery • Manage performance	• Immediate to Short term. • No cost.

Type of Activity	Action needed	Timeframe and costs
Activities involving best practices that are available in some but not all areas regionally which need support to scale up and roll out.	• Develop a business case for scale up and roll out • Utilise change management principles to implement consistently across HSC • Amend contractual agreements and/or job descriptions to include responsibility for delivery • Manage performance	• Medium term • Costs associated with regional roll out
Activities addressing gaps in best practice which involve the development, feasibility testing and evaluation of new solutions.	• Agree a prioritised innovation programme of research and service development to develop and test new solutions • Engage the Medicines Optimisation Innovation Centre to manage the programme • Consider the evidence base and type of solution needed • Test and evaluate the solution within the HSC • Develop a business case for scale up and roll out • Utilise change management principles to implement consistently across HSC • Amend contractual agreements and/or job descriptions to include responsibility for delivery • Manage performance	• Longer term • Costs associated with R&D and pilots for service development.

4.9 Methodology to deliver the plan will include:

- an agreement across HSC organisations to adopt regional best practices;
- a system for the timely translation of best practice across the HSC including support for organisations and staff involved in change, utilising evidence based change methodology;
- a prioritised innovation programme of research and service development to develop and test new solutions;
- an agreed process for involving patients in research and service development in medicines optimisation;
- a training and development plan for staff involved in new medicines optimisation roles; and
- a financial plan outlining revenue and capital investment, invest to save approaches and the utilisation of HSC, UK and EU funding streams and resources to deliver the work plan objectives.

Medicines Optimisation and Innovation Centre

4.10 An element of the regional action plan will involve projects seeking new solutions, to address gaps in best practices for the quality standards, which are developed and tested within the HSC prior to commissioning for scale up and implementation regionally. These projects will be undertaken in collaboration with the Medicines Optimisation and Innovation Centre (MOIC).

4.11 The MOIC centre provides a locus for developing a systematic approach to finding and testing solutions for the HSC with the following functions.

- Project manage an innovation programme of research and service development projects.
- Develop, test and evaluate solutions to pre-commissioning stage.
- Support successful translation into HSC service delivery and commissioning.
- Help projects to access and utilise available funding streams.
- Provide a regional centre of expertise for research and service development in medicines optimisation and post-implementation review of service delivery.
- Build local expertise and competence in developing and translating research into practice.
- Facilitate a continuous cycle of improvement within the HSC in the area of medicines optimisation.

4.12 The centre also has wider benefits combining pharmaceutical and R&D skills with technology and business acumen to:

- provide evidence based solutions for medicines optimisation which could be developed commercially, marketed and sold to other countries with the HSC as a beneficiary;
- promote Northern Ireland as a leading area for medicines optimisation research and development and strengthen Northern Ireland's 4 star EU reference status bid;
- attract inward investment into a Northern Ireland Medicines Optimisation Innovation Fund/ Programme; and
- increase collaborative work with other established research networks in UK, Europe and internationally.

Medicines Optimisation Network

4.13 The work of the MOIC will lead to the development of a medicines optimisation network linking the HSC with other health and life science networks and innovation centres in Northern Ireland, UK and internationally. It will also support knowledge sharing both within the HSC and with wider networks and the development of collaborative working partnerships and joint working arrangements between participants that may include the following.

- Commissioning organisations (HSC Board, Trusts, PHA, BSO)
- Policy (DHSSPS)
- Patients and their representative bodies
- Independent contractors (GPs and community pharmacists)
- Independent Domiciliary Care Providers
- Academia (UU and QUB)
- Pharmaceutical and Technology Industries
- Voluntary sector
- Charities
- Expert(s) with research skills
- NIMDTA, NICPLD, NIPEC
- Other Innovation Centres and translational research groups
- Health and Social Care professionals
- Experts from across the UK and international

Regional Database to Monitor Improvement

4.14 To allow commissioners and policy leads to monitor progress and enable comparisons regionally and with other UK countries a new regional database is proposed. This will largely bring together existing data related to medicines use from different sources across the region to monitor trends, enable benchmarking and help drive quality improvements. It will also provide an understanding of how well patients are supported across the region to use their medicines safely and effectively to improve health outcomes. Outcome measurements include:

- patient/client satisfaction;
- medicines safety incident reporting;
- cost effective use of medicines;
- impact on acute health services; and
- achievement of expected therapeutic outcomes.

4.15 Methodology to develop a regional database to monitor improvements will include:

- agreement of core outcome measurements for medicines optimisation in Northern Ireland;
- alignment with a Medicines Optimisation dashboard based on NHS England's dashboard which was developed in collaboration with Clinical Commissioning Groups, Trusts and the pharmaceutical industry; and
- the inclusion of questions relating to patient's experience of medicines in relevant Northern Ireland Health Surveys.

4.16 Implementation of the Medicines Optimisation Quality Framework will be monitored by DHSSPS through existing arrangements for HSC commissioning plans.

4.17 The Medicines Optimisation Quality Framework will be reviewed in 2021.

SECTION 5

Summary of Recommendations

Table 10: Recommendations

1. A Regional Model for Medicines Optimisation should be introduced which outlines what patients can expect when medicines are included in their treatment as they access services in health and social care settings.

2. The model should be delivered by a multi-disciplinary medicines optimisation workforce trained and competent in medicines optimisation, with the involvement of pharmacists in all settings.

3. The medicines optimisation workforce should deliver regional services and roles which are commissioned and coordinated across all HSC organisations and related agencies involved in the prescribing, dispensing and administration of medicines.

4. The services and roles should aim to consistently deliver regional best practices in compliance with new Quality Standards for Medicines Optimisation.

5. Regional best practices should always be co-designed with patients, following the principles of Personal and Public Involvement (PPI).

6. An innovation and change programme should be implemented, linked to HSC commissioning plans, to support the development, testing and scaling up of technology and service solutions to deliver consistent best practices related to the Quality Standards.

7. Regional systems should be implemented supporting HSC connectivity, electronic transmission of prescriptions and access to the Electronic Care Record, prescribing support, Northern Ireland Formulary and enhanced data analysis.

8. Within the HSC a regional organisational infrastructure for medicines optimisation should be maintained that incorporates, the Medicines Governance Team, Pharmacy and Medicines Management Team, Regional Pharmaceutical Procurement Service, Medicines Information Service, Medicines Optimisation Innovation Centre (MOIC).

9. A new regional database for medicines optimisation should be developed to monitor progress and enable comparisons regionally and with other UK countries.

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ANNEX A

History of Medicines Management in Northern Ireland 2000 - 2014

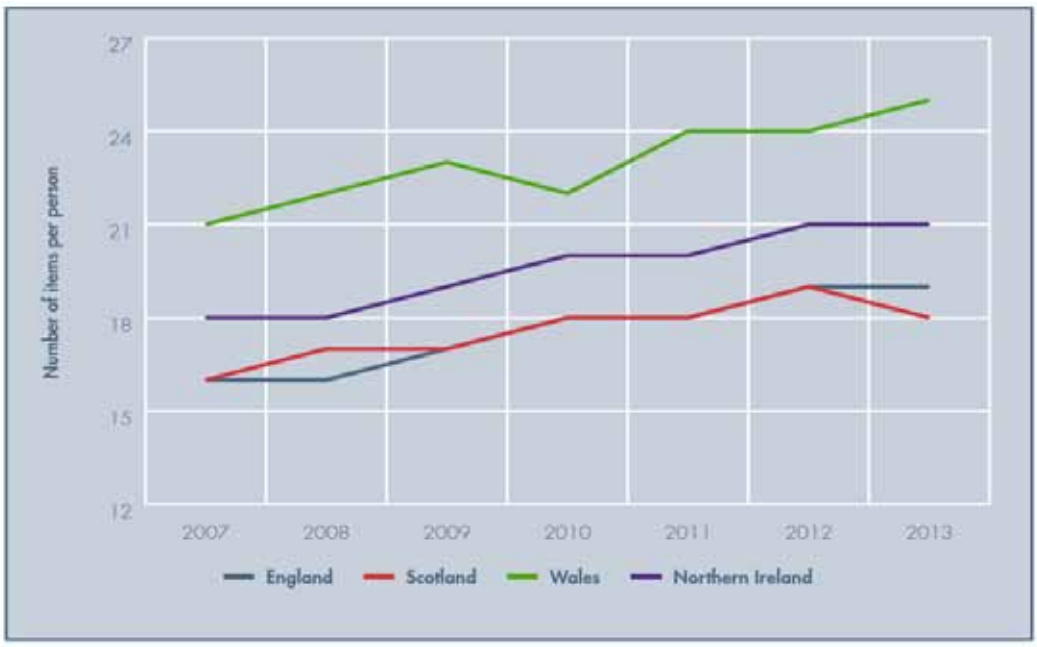
1. Medicines are the most common medical intervention within our population and at any one time 70% of the population[85] is taking prescribed or over the counter medicines to treat or prevent ill-health.

2. From a financial aspect, HSC medicines expenditure equates to £550m/annum in Northern Ireland, representing 14% of the total HSC budget and is the second largest cost after salaries. This does not take into account private transactions.

3. Social deprivation is linked with health and social care needs and levels of need for medicines. In comparison with other UK countries the volume and cost of medicines used per head of population in Northern Ireland is historically high, as detailed in Figures 3 and 4 and Table 11.

Number of items prescribed per head of population in the UK from 2007-2013

Figure 3: Source – NI Audit Office Primary Care Prescribing Report 2014



85 Office of National Statistics Health Statistics 1997.

Prescribing cost per head of population

Figure 4: Source – NI Audit Office Primary Care Prescribing Report 2014

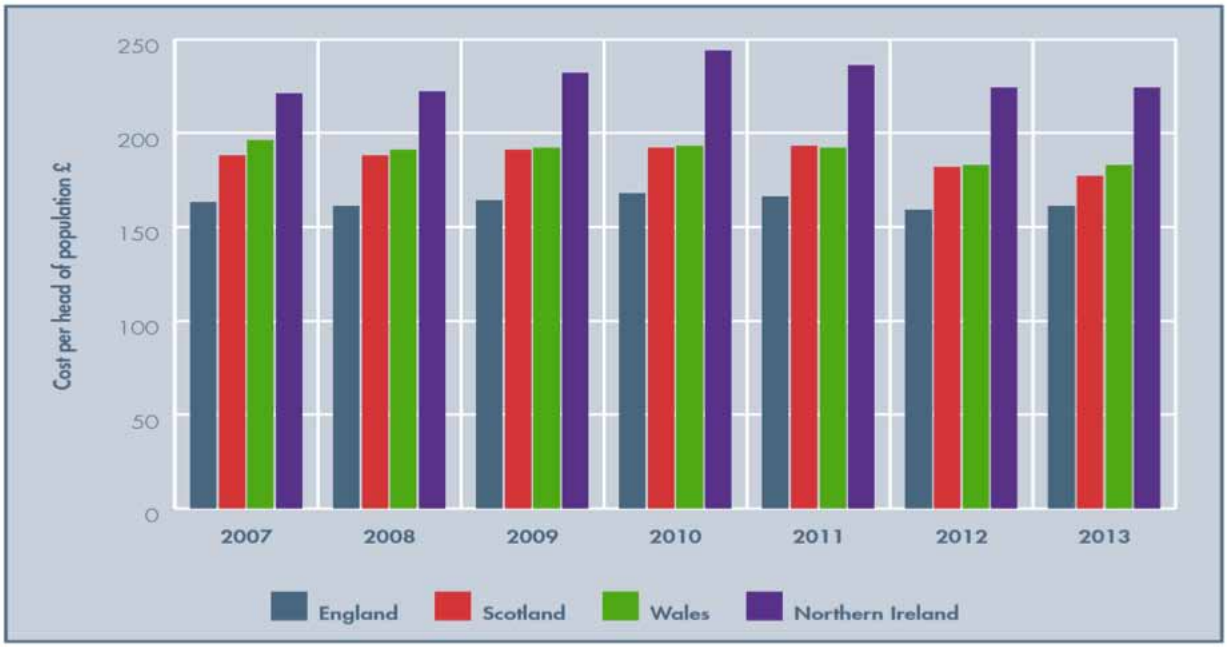


Table 11: Source - Business Services Organisation – Prescription Cost Analysis Reports

		2007	2010	2013
	NI	£221.09	£243.94	£223.54
	England	£162.95	£167.82	£160.12
	Scotland	£187.92	£192.25	£183.73
	Wales	£196.37	£193.05	£182.96

4. The 2014 NI Audit Office Primary Care Prescribing Report[86] highlighted that the volume of items prescribed per head of population per annum has been higher in Northern Ireland than in England and Scotland from 2007 and primary care prescribing costs have been consistently the highest here compared with the other regions in the UK from 2007 to 2013. However, it should be noted that the analysis does not consider the differences in data definitions and prescribing arrangements between the four countries so care is required on interpretation.

86 http://www.niauditoffice.gov.uk/primary_care_prescribing-2.pdf

5. High prescribing costs were first highlighted in 2000 when the limited outcome of the Comprehensive Spending Review required the Department to review spend against all budget areas, including the medicines budget.

6. In response, the Department established a Pharmaceutical Services Improvement Plan (PSIP) which for the first time considered a whole system approach encompassing both primary and secondary care.

7. This work identified and challenged all parts of the medicines journey from procurement through to prescribing, supply and utilisation introducing the concept of "Medicines Management"[87] [88] to HSC practice.

8. Professor John Appleby's Review in 2005 helped inform the next phase of PSIP. The report highlighted the need for new mechanisms to tackle high prescribing costs and to encourage greater use of generic drugs[89].

9. In response the existing PSIP programme was augmented with a new Pharmaceutical Clinical Effectiveness (PCE) Programme comprising a number of initiatives designed to work together to optimise medicines management which delivered savings across the HSC during the period from 2005/06 to 2007/08. Savings of £54m were made against a community drugs budget of approximately £387m. Re-engineering of pharmacy services in secondary care demonstrated savings as described in paragraph 16.

10. The PCE programme was extended into the 2008/09 - 2010/11 period and several new initiatives were added to provide a regional focus to medicines management establishing an infrastructure within the HSC through operational models, systems and policies to deliver:
    a. clinical and cost effective procurement;
    b. clinical and cost effective prescribing;
    c. behavioural change by engaging healthcare professionals in decision making;
    d. Integrated Medicines Management within the HSC; and
    e. extension of the secondary care medicines governance team which was established in 2002 to primary care.

87 Medicines management has been defined as "encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.

88 Audit Commission (2001) A Spoonful of Sugar – Medicines Management in NHS Hospitals.

89 https://www.dhsspsni.gov.uk/publications/appleby-report

11. In the 2014 NI Audit Office Primary Care Prescribing Report it was noted that in the three year period following the introduction of PCE significant efficiencies had been made and the rate of growth in expenditure on drugs was reduced to less than 5 per cent per annum.

12. Responsibility for the prescribing budget was transferred from DHSSPS to the HSC Board in July 2010 and an annual PCE programme was established which continues today[90].

13. In the four year period from 2010/11 to 2013/14 the PCE programme has delivered a total of £132.2m against a target of £122m, an overachievement of approximately £10m.

14. Although the prescribing budget transferred to the HSC Board in 2010 the Department retained a role in pharmaceutical innovation, leading a regional 'Innovation in Medicines Management Programme' based on an 'invest to save' ethos which continues today. The Innovation Programme has overseen a range of medicines optimisation projects within the HSC including the development of the Northern Ireland Medicines Formulary.

15. The PCE and Innovation programmes have resulted in a range of best practices for medicines management as listed in Table 12, many of which are now embedded within HSC systems, services and patient pathways whilst others are suitable for regional roll out.

90 HSC Board's Pharmaceutical Clinical Effectiveness Programme 2014/15 http://www.hscboard.hscni.net/medicinesmanagement/NMP%20-%20Pharmacist%20Prescribing/03%20Pharmaceutical%20Clinical%20Effectiveness%202014-15.pdf

Table 12: Examples of regional best practice in medicines management

Procurement	The rational selection and therapeutic tendering of medicines, in secondary care, in line with NICE guidance and emerging evidence using the Safe and Therapeutic Evaluation of Pharmaceutical Product Selection (STEPSelect)* model[91] [92]
Selection	Northern Ireland Medicines Formulary[93]*
Prescribing	Prescribing Policies • Generic medicines (Generics leaflet)* (Medicines unsuitable for Generic Prescribing)* • Identified therapeutic classes of medicines* (Anticoagulants) (Antipsychotics) (Controlled Drugs) (Diabetes) (Lithium) (Opioid Substance) • Specialist medicines (Interface Pharmacist Network Specialist Medicines, red/amber drugs)* (Trust interface arrangements for patients in the community, eg mental health) • NI Wound Care Formulary* • Prescribing guidance for safe and evidence based prescribing (NICE)[Y] • Antimicrobial guidelines[94] for primary care (Primary Care Management of Infection Guidelines)* and secondary care • Independent Pharmacist, Nurse and other Non-Medical Prescribers (DHSSPS Non-Medical Prescribing)*
Supply	• Extended supplies on hospital discharge (PCE Programme)* • Repeat Dispensing (Repeat Dispensing Guidance)* • Minor Ailments scheme (Minor Ailments)*

* regional initiatives

Y UK-wide guidance

91 Scott MG ,McElnay JC Janknegt R et al Safe Therapeutic Economic Pharmaceutical Selection (STEPSelect) :development .introduction and use in Northern Ireland European Journal of Hospital Pharmacy Practice 2010 ;16:81-3

92 Scott MG Pharmaceutical Clinical Effectiveness Programme (PCEP) –STEPSelect (Safe Therapeutic Economic Pharmaceutical Selection) British Journal of Pharmaceutical Procurement 2012; 3(1):23-6

93 The Formulary provides guidance on first and second line drug choices and covers the majority of prescribing choices and is focused on non-specialist prescribing choices in Northern Ireland. Whilst the Formulary will aim to standardise practice and ensure a level of consistency, it is recognised that individual patients may require medicines which lie outside such guidance.

94 Antimicrobial Guidelines for Primary Care can be accessed in digital format, including through smartphone apps and in secondary care settings, antimicrobial prescribing guidelines are accessible on Trusts' websites, and in some Trusts are also available to download as an app.

Adherence	• NI Single Assessment Tool* (NISAT) • Targeted Medicines Use Reviews (MURs) (Guidance for conducting Medicines Use Reviews)* • Managing Your Medicines Service (Managing Your Medicines)*
Safe transitions of care and Medicines Reconciliation	• The Integrated Medicines Management Service NI clinical pharmacy standards* • Regional Guidelines for the Supply of 'Take Home Medication' from Northern Ireland Emergency Departments* • Regional Guidelines for http://www.gain-ni.org/images/Uploads/Guidelines/Immediate-Discharge-secondary-into-primary.pdf*
Appropriate polypharmacy and optimal outcomes in the elderly	• Pharmaceutical Care Model for Older People within intermediate care, residential and nursing homes[95] [96] [a] • Consultant led Pharmacist clinical medication reviews in nursing homes[97] [a] • Application of PINCER[98] • Application of STOPP/START tool[99]
Governance	• Medicines Governance Networks in Primary and Secondary Care Medicines Governance*
Cost effectiveness	• Pharmaceutical Clinical Effectiveness (PCE) programme (PCE Programme)*
Medicines Information Services	• Regional Medicines and Poisons Information Service* http://www.belfasttrust.hscni.net/Pharmacy.htm

* regional initiatives

a Local Pilot

95 Darcy C, Miller R, Friel A, Scott M. Consultant pharmacist case management of elderly patients in intermediate care. British Geriatrics Society for better health in old age, Book of Abstracts, Spring Meeting 2014; p78 http://www.bgs.org.uk/pdf_cms/admin_archive/2014_spring_abstracts.pdf

96 Miller R, Darcy C, Friel A, Scott M, Toner S. The introduction of a new consultant pharmacist case management service on the care of elderly patients in the intermediate care setting. Int J of Phar Prac, 2014; 22 (Suppl 2): 106-107. Available at: http://onlinelibrary.wiley.com/doi/10.1111/ijpp.12146/pdf

97 McKee H A, Scott M G ,Cuthbertson J and Miller R. Do consultant led pharmacist medication reviews lead to improved prescribing? British Geriatrics Society Autumn Meeting 2014 Page 26 http://www.bgs.org.uk/pdf_cms/admin_archive/2014_autumn_abstracts.pdf

98 Avery et al: A pharmacist-led information technology intervention for medication errors (PINCER): a multicentre, cluster randomised, controlled trial and cost-effectiveness analysis. Lancet 2012

99 Gallagher et al: STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation. Int J Clin Pharmacol Ther. 2008 Feb; 46(2):72-83

Integrated Medicines Management Service (IMM)

16. One example of best practice is the Integrated Medicines Management Service (IMM) which has strategically re-engineered clinical pharmacy services in HSC Trusts. By targeting the work of pharmacists and pharmacy technicians on admission, during the patient's inpatient journey and at discharge, the service has demonstrated significant improvements in patient care validated by two randomised controlled trials. These included reduced length of stay, lower re-admission rates, reduced medication errors and increased medicines appropriateness and revealed that each £1 invested equated to £5-8 in non cash-releasing efficiencies[100] [101]. It was demonstrated that the IMM programme of care was transferable to routine hospital care in two hospital sites in NI supporting the case for roll out of IMM as routine clinical practice in all NI Trusts by 2008[102]. A more recent study which applied risk predictive algorithms to a sample of patients who received IMM throughout their hospital stay has shown a correlation between the number of ward-based clinical pharmacy services with a reduction in risk-adjusted mortality index (RAMI)[103] [104].

17. Many best practices work synergistically to drive whole system improvements in the use of medicines. For example, innovative methodology for medicines selection has resulted in prescribers within the HSC referring to a Northern Ireland Medicines Formulary. This along with a regional generic prescribing policy has helped support the effective utilisation of medicines resources in line with clinical guidance for the benefit of patients. Prescription data analysis relating to the period April-June 2013 shows a high level of prescribing compliance (83%) in primary care with Northern Ireland Formulary recommendations and a 68% generic dispensing rate. Generic prescribing policies are also in place in secondary care with generic supply from pharmacy, where appropriate.

18. In community pharmacy the MUR Service aims to improve patients' knowledge, adherence and use of medicines and vulnerable or at risk patients are further supported through the Managing Your Medicines service.

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100 Scullin et al. An Innovative approach to integrated medicines management. Journal of evaluation in clinical practice. Vol 13, issue 5. Oct 2007: 781-788.

101 Burnett et al. Effects of an integrated medicines management programme on medication appropriateness in hospitalised patients. American journal of health-system pharmacy. May 1 2009 vol 66, no.9: 854-859

102 Scullin C Hogg A Scott MG et al Integrated Medicines Management-can routine implementation improve quality? Journal of Clinical Evaluation 2012 ;18(4) :807-15

103 Feras et al. Enhanced clinical pharmacy service targeting tools: risk-predictive algorithms. Journal of Evaluation in Clinical Practice. Vol 21, issue 2. April 2015: 187-197

104 RAMI is a predictive tool which was developed to calculate the risk of death during inpatient stay based on a range of variables – age, gender, diagnosis-related group, diagnosis and specific co-morbidities within the population being investigated.

19. These are among the initiatives that helped Northern Ireland to be formally identified as a reference site within the European Innovation Partnership in Active and Healthy Aging (EIP-AHA) in April 2013 and awarded three stars for the level of innovation, scalability and outcomes demonstrated in medicines management[105]. This recognises Northern Ireland as one of the leading regions in Europe in addressing the health and social care needs of the older population through innovation in medicines management.

105 European Innovation Programme- https://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/rs_catalogue.pdf

ANNEX B

Moving to Medicines Optimisation – The Challenges and Need for Change

1. It is clear that a significant amount of work has been undertaken to improve how medicines are managed within the HSC Service. However, Northern Ireland has the fastest growing population in the UK, a rising number of older people with increasing multi-morbidities and a health seeking culture in which people use more medicines with higher associated costs per head per annum than other UK countries. The Regulation and Quality Improvement Authority (RQIA) carried out a Review of Medicines Optimisation in Primary Care in 2015 and concluded that more work needs to be done to achieve optimal medicines optimisation processes, leading to better, measurable outcomes for patients. There are potentially significant challenges ahead which require a renewed focus on using medicines to gain the right outcomes for patients at the right cost for the HSC.

Increasing Need

2. Global innovation in medicines development and improved access to medicines with a good evidence base, for example NICE Guidance[106] have contributed to an increase in life expectancy helping people to stay healthy for longer and many previously debilitating or fatal conditions are now prevented or managed, often on a long term basis, through regular medicines use.

3. Medicines use increases with age and 45% of medicines prescribed in the UK are for older people aged over 65 years and 36% of people aged 75 years and over take four or more prescribed medicines[107].

4. Each year community pharmacies in Northern Ireland dispense in excess of 38 million prescription items, for medicines costing £375m. In addition, some £175m of medicines are dispensed in the hospital setting.

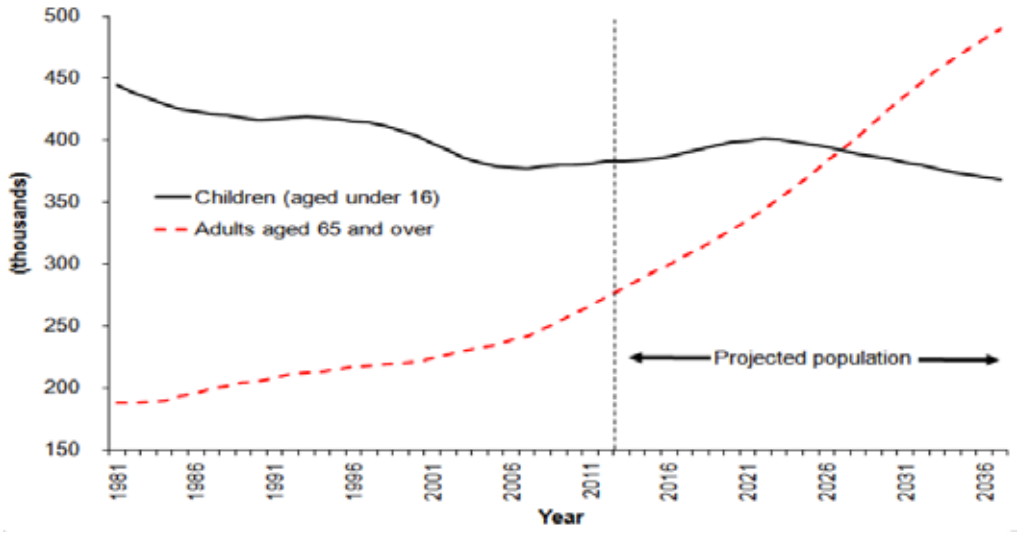
106 https://www.nice.org.uk/guidance

107 Department of Health (2001). Medicines and Older People. Implementing medicines-related aspects of the NSF for Older People. Department of Health. www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4008020

5. Within Northern Ireland the future need for medicines is expected to increase as the population ages and the prevalence of chronic disease increases. Northern Ireland has the fastest growing population in the UK. Currently there are approximately 1.8m people living in Northern Ireland, a figure which is expected to rise to 1.918m by 2022. In 2012, it was estimated that 15% of the population were aged 65 and over. This figure is expected to rise by 26% by 2022 and those aged 85 years and over will increase by 50%[108].

Children aged under 16 and adults aged 65 and over, actual and projected, 1981-2037 (non-zero y-axis)

Figure 5: Source – Northern Ireland Statistics and Research Agency, Statistical Report 2012



6. A report from Public Health Ireland predicts that between 2007 and 2020 the number of adults living with long term health conditions (LTC) in Northern Ireland will rise by 30%[109].

108 Northern Ireland Statistics and Research Agency, Statistical Report 2012 NISRA 2012 Based Population Projections

109 Institute of Public Health in Ireland, 2010 -"Making Chronic Conditions Count"

Table 13: Source – Institute of Public Health - "Making Chronic Conditions Count"

	2007		2015		2020	
	No.	% of population	No.	% of population	No.	% of population
Hypertension	395,529	28.7	448,011	30.3	481,867	31.7
CHD	75,158	5.4	87,848	5.9	97,255	6.4
Stroke	32,941	2.4	38,405	2.6	42,457	2.8
Diabetes (Type 1 & 2)	67,262	5.3	82,970	6.0	94,219	6.6

7. Low health literacy alongside cultural and structural factors have a significant influence on lifestyle decisions. These decisions such as unhealthy diets , smoking and harmful misuse of alcohol also contribute to the overall prevalence of disease in Northern Ireland. Rates of admission to hospital due to alcohol continue to rise year on year and national data indicates that around 70% of weekend emergency department attendances are alcohol-related[110]. From the Northern Ireland health survey 2014/15 - 60% of adults measured were either overweight or obese and 7% of children aged 2-15 years were assessed as being obese. Loss to the local economy as a result of obesity is estimated at £400 m, £100m of these costs being direct healthcare costs[111].

8. As well as the impact on prescribing budgets a rising need for medicines will place increased pressure on primary and secondary care services and community pharmacies. Increased use of medicines by a larger older population will also impact on social care services.

110 http://www.publichealth.hscni.net/sites/default/files/Drug%20and%20Alcohol%20Commissioning%20Framework%20Consultation%20Document.pdf

111 The Cost of Overweight and Obesity on the Island of Ireland – Safefood, November 2011)

Patient Engagement

9. In NI, the involvement of users and carers is a statutory duty for all those employed in statutory HSC organisations[112]. Donaldson highlighted that we are trailing behind with patients and families having a much weaker voice in shaping the delivery and improvement of care than is the case in the best healthcare systems of the world. It is crucial that Personal and Public Involvement (PPI) is supported by all involved in decisions at all levels of care; including at a strategic level and that the values that underpin all PPI work which include dignity and respect, inclusivity, equality and diversity, collaboration and partnership, transparency and openness are promoted. The value and importance of involving individuals in decisions about their care is recognised in the King's Fund paper[113] and in national guidance from NICE [NICE Clinical Guideline 76 which now overlaps with NICE Guideline NG5 Medicines optimisation] although full implementation of its recommendations will require change in existing service models. For example, consultations with patients may need to be longer to provide time to prescribers to listen to any concerns patients may have, provide better information about newly prescribed medicines empowering patients to make informed decisions, anticipated treatment outcomes and to consider patient choice, benefits and acceptability. Furthermore, sufficient time will be needed for regular medication and adherence reviews and patients taking multiple or high risk medicines will require regular scheduled specialist clinical reviews. Patients living with their health condition(s) are often 'experts by experience' and communication with patients about their experience helps inform decisions regarding their medication at review.

Non Adherence

10. The volume and costs of prescribed medicines are increasing but there is evidence that between a half and a third of medicines prescribed for long term conditions are not taken as recommended[114].

11. This is known as non-adherence and can involve people taking either more or less medicines than prescribed or not taking them at all. The factors which contribute to non-adherence fall into two overlapping categories.

    - **Intentional** where the individual decides not to follow the treatment recommendations perhaps because of concerns about the value or effectiveness of medicines, their side-effects, and the inconvenience of taking the drugs at the prescribed times and frequency. Also, patients with a mental health illness for example, schizophrenia, may have altered thinking and beliefs about medicines and their illness which may affect adherence.

112 www.publichealth.hscni.net/sites/default/files/PPI%20Strategy%20-%20March%202012_0.pdf

113 http://www.kingsfund.org.uk/sites/files/kf/Making-shared-decision-making-a-reality-paper-Angela-Coulter-Alf-Collins-July-2011_0.pdf

114 Horne R, Weinman J, Barber N, Elliott R, Morgan M. Concordance, adherence and compliance in medicine-taking. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D. 2005.

- **Unintentional** where the individual wants to follow the treatment recommendations but is prevented from doing so by practical barriers which include cognitive problems, poor organisational skills, polypharmacy and difficulty accessing medicines[115].

12. There are many layers to non-adherence and whatever the cause(s), non-adherence represents a health loss for the individual and an economic loss for society. Consequences include; reduced quality of life; deterioration of health; and unplanned admissions to hospital as people fail to gain the optimal outcomes from their medicines.

Generic Medicines

13. Government policy promotes the use of generic medicines, where appropriate. However, patients concerns regarding inconsistency in the medicines they are supplied with has been highlighted in the Patient Client Council Report 2011[116]. For example, variations in size, colour and shape of their medicines which are made by a range of manufacturers. This is particularly confusing for the elderly who may be on multiple medications leading to an inability to manage their medicines appropriately, risking their independence and impacting on the help they need from carers and families. Lack of support and unexplained changes to how a medication looks can result in patients not taking their medicines. Community pharmacists are well placed to provide advice if the presentation changes but all health and social care professionals and patients should be aware that the presentation of medicines can change and that there is a system to support patients when this occurs.

Medicines Related Harm

14. All medicines are associated with a level of risk and each year millions of people worldwide are hospitalised due to potentially avoidable, medicine-related factors. Medicines used in combination and patients with multiple co-morbidities who are taking multiple medicines are at increased risk. The constant repeating of medicines without regular medication reviews leaves patients susceptible to harm from medicines which they may not need to be taking. Additionally an individual's social circumstances can significantly affect the level of harm related to medicines use. On average, around 3-6% of hospital admissions are due to the adverse effects of medicines[117] [118] [119] and this can increase up to almost 30% in elderly

115 Steinman MA and Hanlon JT. Managing Medications in Clinically Complex Elders "There's Got to Be a Happy Medium". Journal of the American Medical Association. 2010; 304(14):1592-1601. doi: 10.1001/jama.2010.1482

116 http://www.patientclientcouncil.hscni.net/uploads/research/People%E2%80%99s_views_about_prescription_charging_and_products_available_on_prescription_-_June_2011.pdf

117 Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998; 279:1200-5.

118 Pirmohamed et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329:15-9

119 Roughead EE. The nature and extent of drug-related hospitalisations in Australia. J Qual Clin Pract 1999;19:19-22

people who are taking more medicines and are more susceptible to their adverse effects[120]. In Northern Ireland, positive steps taken to reduce harm related to medicines include the work of multidisciplinary medicines governance committees in HSC Trusts, the implementation of National Patient Safety Agency (NPSA) alerts and the HSCB/PHA management of serious adverse incidents (SAIs) through the Quality, Safety and Experience (QSE) multidisciplinary group and the Safety, Quality and Alert Team (SQAT). More recently to improve safety, there has been a standardisation of adult medicines kardexes (process for prescribing and recording administration of medicines to patients in hospital).

15. UK evidence shows that one in 15 hospital admissions are medication related, with two-thirds of these being preventable[121]. Evidence also shows that some medicines are associated with a higher risk of harm than others with four groups of drugs accounting for 50% of preventable drug related admissions to hospital[122]. A review carried out of medication incidents reported to the National Reporting and Learning System in England and Wales over a 6 year period showed that the top 5 medicines where the clinical outcome was death or severe harm were opioids, antibiotics, warfarin, low molecular weight heparins and insulin[123]. In Northern Ireland, examples of high risk medicines are available on a poster for GPs and community pharmacies however there is no agreed system for highlighting high risk and specialist medicines on patient records and ECR.

16. Another cause of harm is medication errors which can occur at any stage of the medicines process from prescription, to dispensing to the patient taking the medication. A report for the General Medical Council in 2012 investigating the prevalence of prescribing errors in general practice found that one in 20 prescriptions contained an error with a higher prevalence associated with prescriptions for the elderly and those taking 10 or more medications[124]. Prescribing errors in hospital in-patients are a common occurrence affecting 7% of medication orders, 2% of patient days and 50% of hospital admissions[125]. The NPSA estimated that medication errors in 2007 cost £770m due to the cost of admissions for adverse drug reactions and the cost of harm due to medicines during inpatient stay[126].

120 Chan M, Nicklason F, Vial JH. Adverse drug events as a cause of hospital admission in the elderly.Intern Med J 200; May-Jun;31(4):199-205

121 Garfield S, Barber N, Walley P, Willson A, Eliasson L. Quality of medication use in primary care--mapping the problem, working to a solution: a systematic review of the literature. BMC Medicine 2009; 7:50.

122 Which drugs cause preventable admissions to hospital? A systematic review. www.ncbi.nlm.nih.gov/pubmed/16803468

123 Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years. Br J Clin Pharmacol; 2012 Oct;74(4):597-604

124 http://www.gmc-uk.org/Investigating_the_prevalence_and_causes_of_prescribing_errors_in_general_practice___The_PRACtICe_study_Reoprt_May_2012_48605085.pdf

125 Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf 2009; 32(5):379-389.

126 NPSA safety in doses:medication safety incidents in the NHS 2007

17. When patients transfer between HSC settings there is a greater risk of medication error and evidence shows that 30% to 70% of patients have an error or unintentional change to their medicines when their care is transferred[127]. In a study carried out in Northern Ireland, it was shown that 33% of patients post discharge had medication related problems[128].

Polypharmacy

18. Polypharmacy, the concurrent use of multiple medications by one individual, is becoming increasingly common. UK data highlight that of those patients with two clinical conditions, 20.8% were receiving four to nine medicines, and 10.1% receiving ten or more medicines; in those patients with six or more co-morbidities, these values were 47.7% and 41.7 %, respectively, and increasing with age[129].

19. The 2013 Kings Fund report on Polypharmacy and Medicines Optimisation[130] proposes that polypharmacy can be classified as appropriate or problematic recognising that it has the potential to be beneficial for some patients, but also harmful if poorly managed. The value of a co-ordinated, multidisciplinary approach to managing polypharmacy has been recognised by other UK countries and the Scottish Government has issued specific guidance on polypharmacy in the elderly.[131]

20. Patients are finding it increasingly difficult to manage the volume of medicines they are prescribed. In particular, older people are most likely to be prescribed multiple medications for multi morbidities (different diseases) and polypharmacy is a growing challenge for individuals, carers and social care workers trying to manage complicated medicines regimens at home. Multi-compartment compliance aids/Monitored dosage systems (MDS) are often used to support patients to manage their medicines and are currently perceived as the only solution for the elderly and those with dementia in particular. However, there are many other ways in which patients can be helped to take their medicines safely, or carers supported to administer medicines correctly, and alternative interventions should be considered as outlined in the Royal Pharmaceutical Society guidance, The Better Use of Multi-compartment Compliance Aids[132].

21. Polypharmacy is also a challenge for prescribers. Prescribing is largely based on single disease evidence-based guidance which does not generally take account of multi-morbidity, now the

127 Campbell et al. A systematic review of the effectiveness and cost-effectiveness of interventions aimed at preventing medication error (medicines reconciliation) at hospital admission. The University of Sheffield, School of Health and Related Research (ScHARR), Sep 2007

128 Brookes K Scott MG McConnell JB The benefits of a hospital based community liaison pharmacist. Pharmacy World and Science 2000; 22(2): 33-8

129 Payne RA, et al. Prevalence of polypharmacy in a Scottish primary care population. Eur J Clin Pharm 2014; in press.

130 The Kings Fund 2013 Polypharmacy and Medicines Optimisation - Making it Safe and Sound

131 Scottish Government 'Polypharmacy Guidance' October 2012

132 http://www.rpharms.com/support-pdfs/rps-mca-july-2013.pdf

norm in those over 65 years[133]. Also, prescribing decisions may be made by different medical and non-medical prescribers involved in the individual's care resulting in combinations of medicines which may not work effectively together and increase the risks of medicines related harm. Deprescribing i.e. the process of tapering, reducing or stopping medication which may be causing harm, may no longer be providing benefit or may be considered inappropriate should be a planned process for patients on multiple medications. There are barriers to deprescribing so guidance and the use of tools such as STOPP/START could help facilitate the process.

Specific Patient Groups

22. Difficulties arise across interfaces when specific patients for example mental health patients who live in the community require secondary care services. The primary/secondary care interface and responsibilities of the various professionals can make it difficult for patients to receive the medication they require. For patients with Parkinson's disease where it is crucial that they get the right medication at the right time, there is a clear need for a consistent service when they move across interfaces and between different healthcare professionals. Those with life-long conditions for example Inflammatory Bowel Disease which most commonly presents in patient's teenage years/early twenties need access to multidisciplinary teams working collaboratively with them and each other and is key to ensuring optimisation of their medicines.

23. Better knowledge and understanding of rare diseases among healthcare professionals is essential to ensure that patients receive a timely and accurate diagnosis. Delays in diagnosis of rare diseases can lead to patients not receiving timely and appropriate medication for their condition. Additionally, misdiagnoses can mean that patients may receive inappropriate treatment and lack of support. A multidisciplinary approach to accurate and safe care plans and shared decision making regarding treatment choices is necessary to delivering effective care to these patients.

133 Barnett K, Mercer SW, Norbury M et al. Epidemiology of multimorbidity and implications for healthcare, research, and medical education: a cross sectional study. The Lancet 2012:380:37-43

Access to Information

24. Access to good quality information about medicines is essential to enable optimal management of clinical conditions. However, there is a vast amount of information on the internet regarding medicines, some of which is reliable and relevant in the UK and some is not. There are some credible websites and proposed plans for the development of a patient portal on the NIDirect website to help direct patients to appropriate information about medicines and how to use this information are welcomed.

Over Use and Misuse of Medicines

25. Increased access to medicines via prescription, internet and over the counter sale introduces new risks. The New Strategic Direction for Alcohol and Drugs Phase 2 highlighted the emerging issue of the misuse of prescription drugs and over-the-counter drugs with benzodiazepines reported as one of the main drugs of misuse[134] in Northern Ireland. Although there has been some success in tackling benzodiazepine use, other challenges with regards to potential for abuse remain with commonly prescribed medicines including opiate painkillers and pregabalin.

26. A Scottish literature review explored the links between poverty, social exclusion and problematic drug use. It supported the view that the extent of drug problems is strongly associated with a range of social and economic inequalities and is complex[135]. A study which looked at the influence of socioeconomic deprivation on multimorbidity at different ages found that higher rates of drug misuse correlated with deprivation across all age groups, but particularly in those under 45 years of age[136].

27. Inappropriate and overuse of antimicrobial medicines is a particular concern and the consequences are that common infections will be harder to treat as the incidence of antimicrobial resistance and healthcare acquired infections increases presenting a major public health challenge[137]. Increasing healthcare professional, patient and public awareness and changing behaviour by applying behavioural science may help address this issue. A recent literature review and behavioural analysis carried out by the Department of Health and Public Health England proposes a range of behavioural science interventions that could be tested in practice[138].

134 DHSSPS (2011) New Strategic Direction for Alcohol and Drugs, Phase 2 2011-2016

135 Drugs and poverty:A literature review. Scottish drugs forum report, March 2007

136 McLean G et al. The influence of socioeconomic deprivation on multimorbidity at different ages: a cross-sectional study. Br J Gen Pract. Jul 2014; 64(624): e440-e447

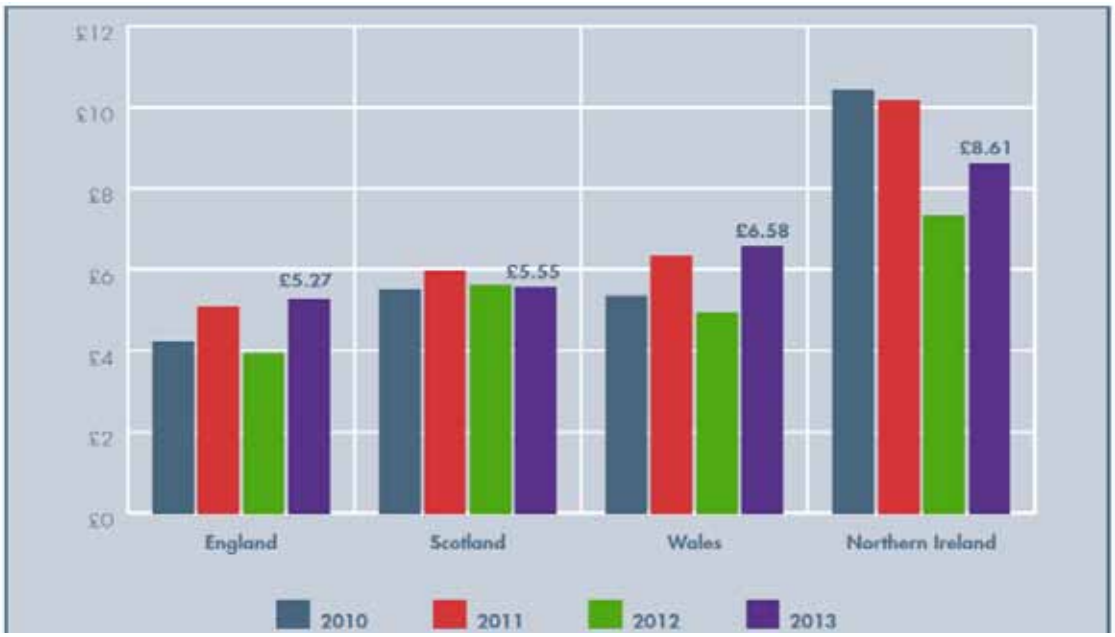
137 DHSSPS Strategy for tackling antimicrobial resistance (STAR) 2012-2017

138 Behaviour change and antibiotic prescribing in healthcare settings, literature review and behavioural analysis. February 2015 https://www.gov.uk/government/publications/antibiotic-prescribing-and-behaviour-change-in-healthcare-settings

28. Antidepressant use in Northern Ireland is high compared to other countries in Western Europe. In comparison to other countries in the UK, Northern Ireland had higher antidepressant costs per head of population from 2010 to 2013.

The cost of anti-depressant prescribing per head of population in the UK over the 4 year period to 2013

Figure 6: NI Audit Office Primary Care Prescribing Report 2014



29. Better access to services, for example counselling, stress and anxiety management is crucial if we are to see a reduction in the use of medicines to manage some mental health conditions. Choice and Medication[139] is a good example of where people can access information regarding alternatives to medicines and when necessary and appropriate, information regarding their medicines to manage their condition.

Waste

30. Wasted medicines are a significant problem in Northern Ireland with large quantities of unused medicines regularly returned to community pharmacies for safe disposal. These medicines are either ordered but no longer required or no longer prescribed for a particular condition. Returned medicines to community pharmacies cannot be re-used and are destroyed because their safety and effectiveness cannot be guaranteed. Not all unused medicines are returned

139 www.choiceandmedication.org/hscni/

to pharmacies and many are kept in patients' homes, sometimes well past their expiry date, or are incorrectly added to household waste. In hospital, medicines that are no longer required are returned to the hospital pharmacy for safe disposal or, where appropriate, recycled and reused to minimise waste. It is difficult to measure the exact value of medicines wasted. Based on research findings elsewhere in the UK the value of medicines wasted in Northern Ireland is estimated to be around £18m per annum[140] although as yet there is no way of accurately validating this figure.

Reform of Health and Social Care Services

31. Ongoing HSC reform supporting care closer to home will mean that in future more people will receive care at home rather than in residential care or hospital. For many people care at home will require support with managing and taking multiple medicines. This will require changing roles for social care workers and an increasing demand for pharmaceutical care in the community and primary care to support safe and effective medicines use[141].

32. As new services develop creating new interfaces for example acute care at home and rapid response respiratory services, issues of prescribing and supply need to be addressed. Drug specific shared care agreements are available already for specialist medicines through the 'Interface Pharmacist Network Specialist Medicines' but are not yet available for non specific prescribing and supply in such new settings.

33. Another issue is the increasing use of third party homecare services. A homecare service in this context is defined as the delivery of medicines and where necessary, associated care, which is initiated by the hospital prescriber, direct to the patient's home with their consent. This is a growing market and the volume and costs of medicines supplied through homecare services in Northern Ireland has increased from £6m in 2008 to almost £22m in 2014. Homecare services bring both benefits and risks for patients and new challenges for the provision of pharmaceutical care by HSC Trusts. A review of homecare medicines supply in England in 2011[142] included having stable contractual arrangements which would enable Trusts to adapt easily and safely to changes in homecare providers and through a quality framework have clear lines of responsibility for dispensing, delivery to patients and nursing care provision when required. Better use of technology could track expenditure and interface with electronic care

140 Evaluation of the Scale, Causes and Costs of Waste Medicines, University of London and York 2010

141 Pharmaceutical Care is defined as "A patient-centred practice in which the practitioner assumes responsibility for a patient's medicines-related needs and is held accountable for this commitment". Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice: the clinicians guide. 2nd ed. New York:McGraw-Hill; 2004.

142 Homecare medicines – towards a vision for the future, DH 2011

records would allow information to be available in real time. Communication of the service to all healthcare professionals involved in a patient's care is essential. A regional assessment of the optimal approach to homecare medicines is needed to ensure quality, good governance, accountability and effective use of resources.

34. HSC reform will also support new integrated models of care as exemplified by Integrated Care Partnerships (ICPs). ICPs are collaborative networks of care providers, bringing together doctors, nurses, pharmacists, social workers, hospital specialists, other healthcare professionals and the voluntary and community sectors, as well as service users and carers to design and coordinate local HSC services. These collaborative networks present new opportunities for the integration and co-ordination of care for frail older people and those with long term conditions. ICPs are tasked with focussing on four key aspects for delivery of integrated care; Risk Stratification, Information Sharing, Care Planning and Evaluation (RICE). All 17 ICPs in Northern Ireland are currently delivering person centred proactive care management for a risk stratified cohort of patients through collaborative multidisciplinary working. A more co-ordinated and person centred approach to medicines management has been an important aspect of this work. There are also a number of local ICP service improvements which involve improved integration of community pharmacy services as part of the care pathway. The structure of ICPs which has community pharmacists embedded at a local level to promote the development of collaborative relationships is an effective platform for the delivery of improved medicines management and associated patient outcomes.

35. More recently the Northern Ireland General Practice Committee (NIGPC) has developed a network of GP Federations with the vision of supporting primary care and working at the scale needed to realise the ambitions of Transforming Your Care.

36. In future, patients are likely to have a number of health and social care professionals involved in their overall care at the same time. This will include an increasing number of non-medical prescribers (DHSSPS non-medical prescribing) using existing skills and knowledge to ensure better patient access to advice about medicines, assessment of their condition and help patients receive appropriate medication without delay alongside helping reduce demand on GPs and medical staff in hospitals.

37. The Donaldson Report, Transforming Your Care, Living with Long Term Conditions Framework[143] and the RQIA Review of Medicines Optimisation in Primary Care all recognise the increased role that pharmacists (in particular community pharmacists) have to play in raising a patient's quality of care and improving their health outcomes. The Community Pharmacy Future Project[144] shows that patients derive considerable benefits in terms of health outcomes and quality of life when they receive additional support and advice from community pharmacists alongside the supply of their normal medication. The profession could be further utilised in this setting by using their clinical skills, working in partnership with patients and other health and social care professionals to contribute significantly to medicines optimisation.

38. A recent Royal Pharmaceutical Society (RPS) and Royal College of General Practitioners (RCGP)[145] Joint Statement supports the inclusion of practice based pharmacists within primary care teams to improve patient care. They state that there is considerable evidence to support the benefit of this role and the RPS and RCGP will work together to promote the uptake of practice based pharmacists.

39. As new models of care develop it will be necessary to establish a clear understanding of roles and responsibilities for medicines optimisation for health and social care professionals within the patient's care. This will require clarification of existing roles and the development of new roles within integrated secondary care, general practice and community pharmacy linking to social care supporting safe, appropriate and effective medicines use throughout the patient journey. This is a patient centred model in which multidisciplinary professionals will work collaboratively and share information to meet the needs of patients.

Variance

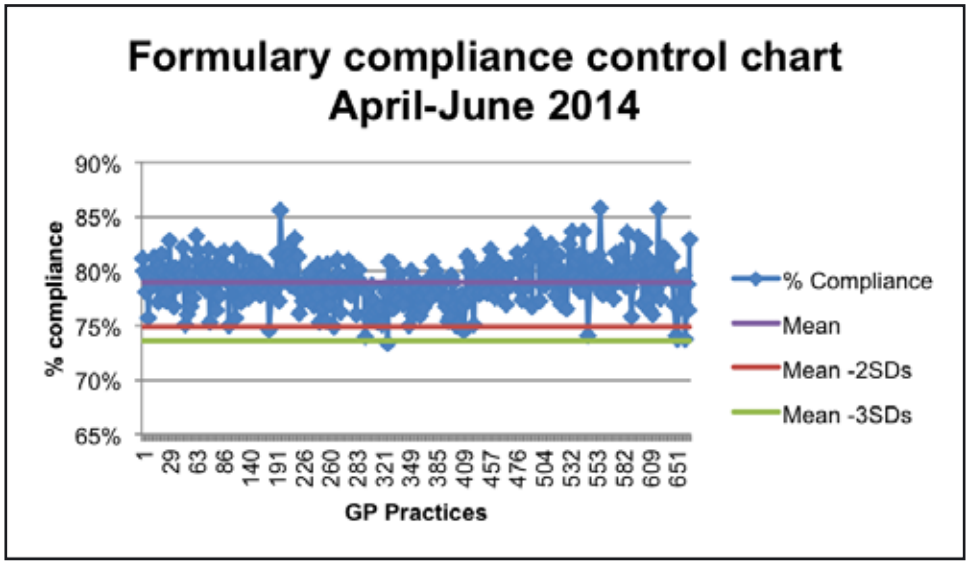
40. There is variation in how medicines are used and managed across the HSC. For example there are differences in; the uptake of NICE approved medicines and implementation of NICE guidance; delivery of the IMM Service and service provision across seven day working within HSC Trusts. The introduction of the Northern Ireland Formulary is supporting a reduction in variance in prescribing in general practice as demonstrated in Figure 7.

143 https://www.dhsspsni.gov.uk/publications/living-long-term-conditions-policy-framework

144 http://www.communitypharmacyfuture.org.uk/pages/sitesearch.cfm

145 http://www.rpharms.com/promoting-pharmacy-pdfs/rcgp-joint-statement-for-pharmacists-in-gp-surgeries-version-2.pdf

Figure 7: % compliance with the Northern Ireland Formulary, quarter 2, 2014



41. A King's Fund report in 2011 concluded that there are wide variations in the quality of care in general practice stating that the delivery of high-quality care requires effective team working for which the skill-mix needs to evolve, so that the GP should no longer be expected to operate as the sole reactive care giver, but should be empowered to take on a more expert advisory role, working closely with other professionals[146].

42. There is a growing awareness of the risks of variance in the quality of service delivery within the health service as exemplified by the Francis Report 2013 which emphasised the need to put patients first at all times and that they must be protected from avoidable harm and the Berwick Report 2013 which recommends 4 guiding principles for improving patient safety including:

- place the quality and safety of patient care above all other aims for the NHS;
- engage, empower and hear patients and carers throughout the entire system and at all times;
- foster wholeheartedly the growth and development of all staff, especially with regard to their ability and opportunity to improve the processes within which they work; and
- insist upon, and model in your own work, thorough and unequivocal transparency, in the service of accountability, trust, and the growth of knowledge.

146 Improving the quality of care in general practice. Report of an independent inquiry commissioned by the King's Fund, 2011. http://www.kingsfund.org.uk/publications/improving-quality-care-general-practice

43. Whilst it is important that variance in practice is reduced where appropriate across the HSC advances in personalised or precision medicines will introduce an approach which is used for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. As we move towards an era of personalised or precision medicine it is clear that more choice and variability will be required to select the most appropriate medicine for a specific patient.

Evidence Based Decision Making

44. Evidence-based medicine (EBM) is the cornerstone of modern medical practice. Defined as the conscientious, explicit, and judicious use of current best evidence, in combination with the physician's clinical expertise and the preferences of the patient in making decisions about the care of individual patients[147], EBM relates to all aspects of medical practice including the prescribing of medicines.

45. With over 13,000 medicines with Marketing Authorisations in the UK[148], prescribers need to be able to keep up to date with the evidence base in order to select the most appropriate, safe, clinically effective and cost effective medicines for their patients.

46. Scientific advances in drug development mean that the clinical use of medicines is becoming more complex and increasing sophistication inevitably leads to higher costs both for the medications themselves and for the clinical management process (e.g. increased monitoring).

47. Not only does this pose challenges in terms of resource implications but it requires increasing diligence as to the appropriateness of the introduction of new medicines. In Northern Ireland, systems exist through NICE (DHSSPS NICE guidance)[149] and the Scottish Medicines Consortium to adjudicate the utility of new medications allied to their provision within the NHS through managed entry arrangements (HSC Board Managed Entry).

48. There is already clear evidence of where the pressures are, for example in the areas of cancer, biologics and mental health and these will continue to be significantly resource intense areas. Similarly, the growth in long term preventative medicine e.g. use of statins and an escalating trend in treatments for lifestyle related disease such as anti-obesity medicines has major cost implications for the pharmacy elements of the health and care system.

147 Dawes M, Summerskill W, Glasziou P, et al. Second International Conference of Evidence-Based Health Care Teachers and Developers. Sicily statement on evidence-based practice. BMC Med Educ. 2005;5(1):1.

148 This figure includes different strengths of the same medicine and generics. Source – Medicines and Healthcare Products Regulatory Agency

149 https://www.dhsspsni.gov.uk/articles/nice-clinical-guidelines

49. In addition, the evidence base for medicines management practices will continue to expand in the coming years. For example, the NICE Guideline NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes was published in March 2015 and other NICE clinical guidelines and quality standards are under development relating to medicines optimisation, domiciliary care, managing medicines in care homes, older people with long term conditions and multi-morbidities.

50. These guidelines and standards are useful and will inform best practice in Northern Ireland but their timely implementation and consistent incorporation into existing services and roles will have to be monitored and managed.

Improvements in Communication, Technology, Data Management

51. The ECR and ongoing ICT development programme will facilitate better sharing of information between healthcare professionals and enable advances such as electronic prescribing. There needs to be 'one source of truth' regarding documentation of patient's medications which can be accessed by the patient and shared by all healthcare professionals. Patients' views need to be taken into consideration when decisions are being made regarding the level of clinical data being shared. The growing use of health analytics (which analyses large, complex data sets with sophisticated software) will help clinicians and managers to utilise various information sources to identify and target interactions of patients with the highest risk. This will further necessitate role clarification among health and social care professionals and standardised approaches to medicines management.

52. However, tracking activities in secondary care requires improvements in informatics and data management systems to provide the level of whole system monitoring of medicines use and service delivery needed to support improved quality and governance across the HSC and allow comparison with other UK countries.

53. Further advances in technology, robotics and tele-health will enable the automation of routine processes and self-monitoring by patients and allow health and social care professionals more time to focus on clinical care and optimising health outcomes. To maximise the benefit of these advances for patient outcomes their integration into patient care plans needs to be planned and managed.

Prevention and Alternatives to Medicines

54. This Framework deliberately focuses on improving the use of medicines. However, it is recognised that over time the aim of health policy is to reduce the population's need for medicines. Current Government strategies like Making Life Better[150] and Making it Better through Pharmacy in the Community[151] support this, encouraging people to be more aware of healthier lifestyle choices and supporting prevention through initiatives to help address the underlying causes of disease. In modern healthcare there is a heavy reliance on medicines and the system needs to change to adopt a more holistic approach where medicines are not seen as the only solution available. This issue is highlighted in the Patient and Client Council's Pain Report[152].

Summary

55. In summary, the future will bring new challenges as the number of older people rises, demand for medicines grows, advances in medicine, therapeutics and technology accelerate and the evidence base for decision making expands.

56. In this era of economic, demographic and technological challenge, optimal use of medicines will help secure better quality, patient outcomes and value from medicines.

150 Making Life Better 2013-2023 https://www.dhsspsni.gov.uk/articles/making-life-better-strategic-framework-public-health

151 Making it Better through Pharmacy in the Community 2015-2019 https://www.dhsspsni.gov.uk/publications/making-it-better-through-pharmacy-community

152 http://www.patientclientcouncil.hscni.net/uploads/research/Pain_Report_-_Final_HARDCOPY_VERSION.pdf