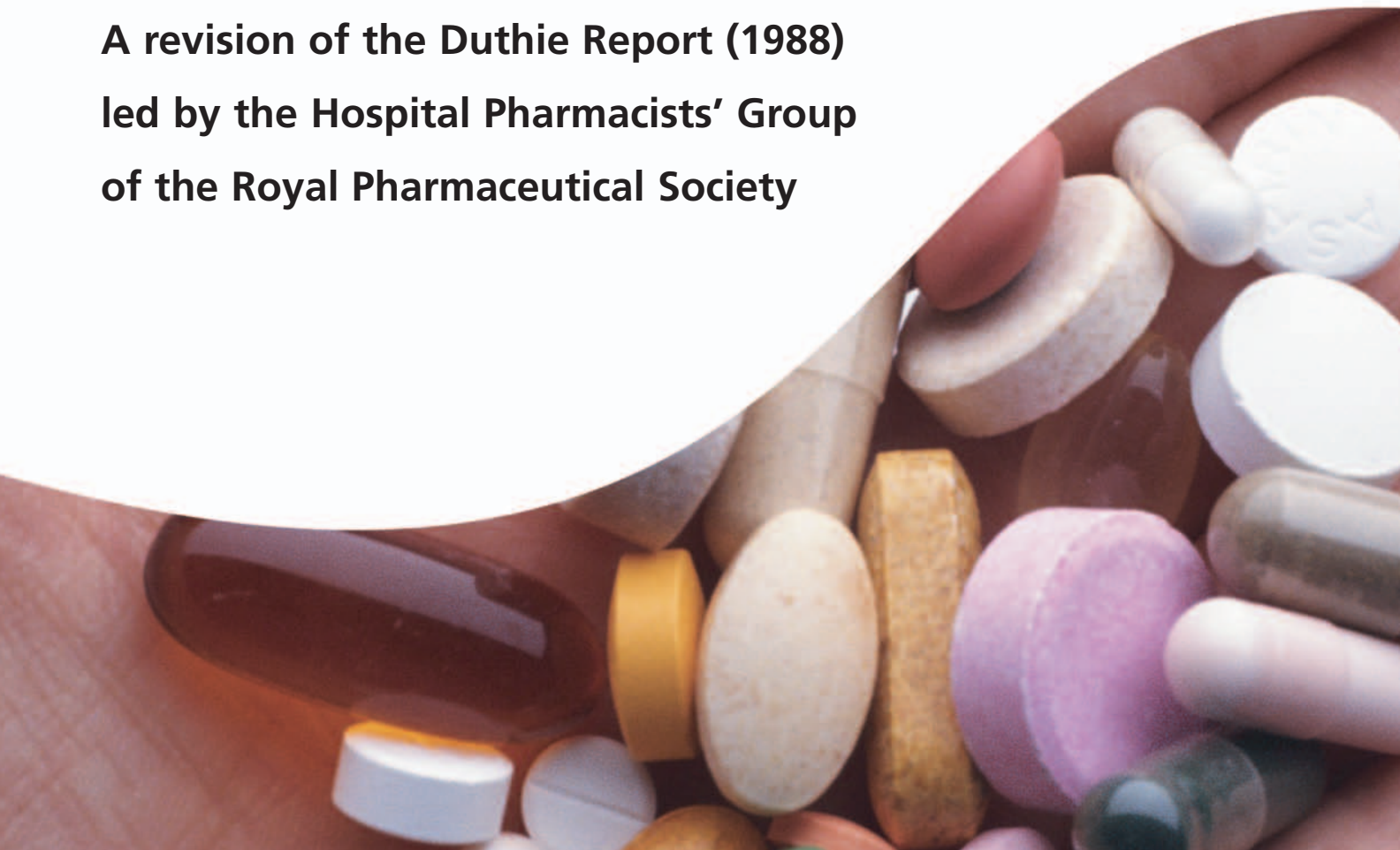
Royal Pharmaceutical Society of Great Britain

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



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.

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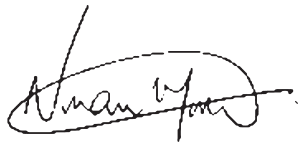

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While the contents of this document have been approved for use in all four countries in the United Kingdom, there are some aspects that are not always appropriate for every country.

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.

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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:

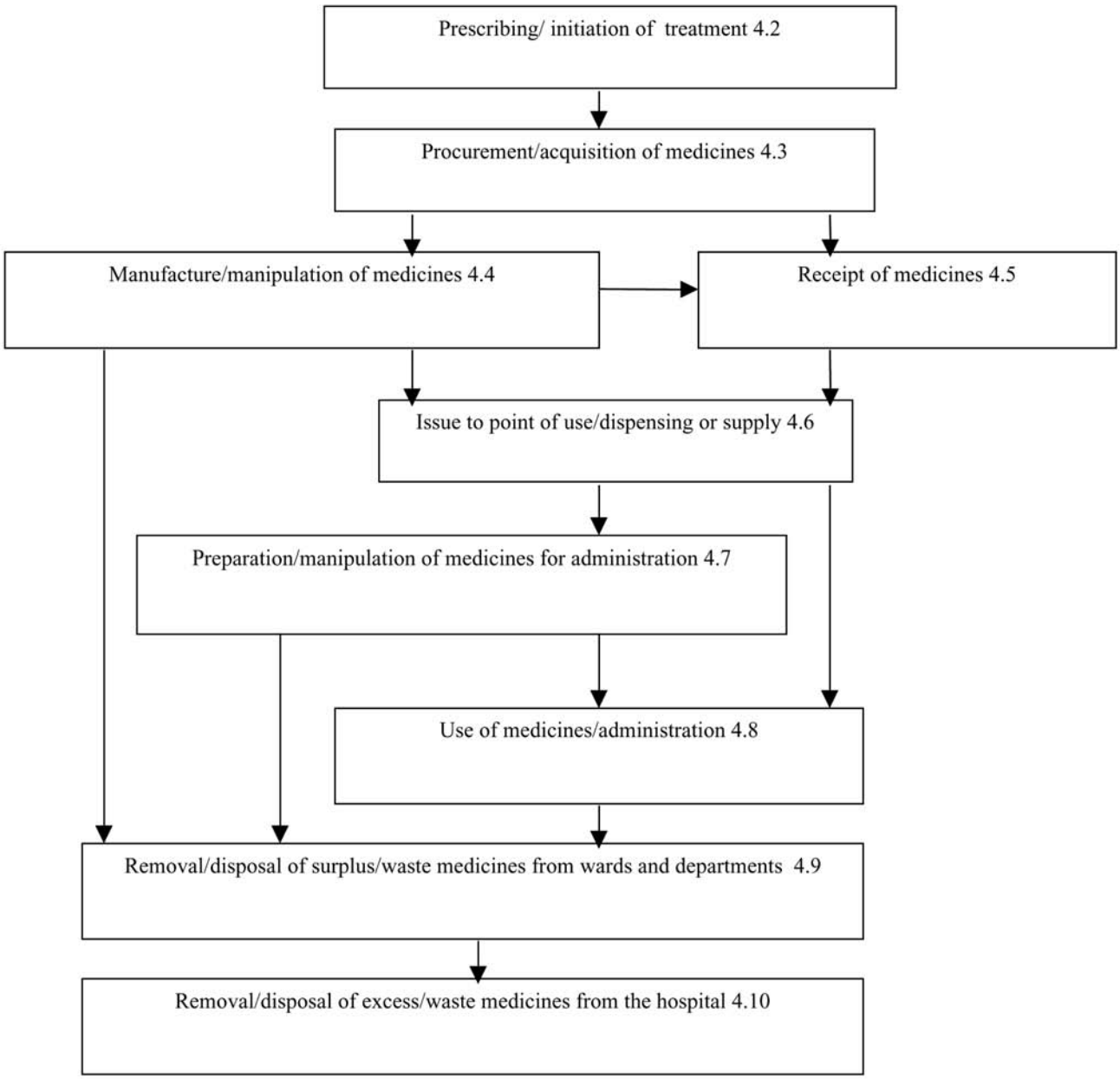
- Patient specific details necessary for dispensing.
- Information about special medicines or formulations - in hospitals where medicines are prepared, either under a "Specials Manufacturing Licence" or using exemption under Section 10 of the Medicines Act, to ensure that a medicine of the correct specification 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 framework. 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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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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