Medicines Management

A Guide for Nurses

Edited by

Philip Jevon
RN, BSc(Hons), PGCE
Resuscitation Officer/Clinical Skills Lead
Manor Hospital
Walsall, UK
Honorary Clinical Lecturer
University of Birmingham, UK

Elizabeth Payne
BSc(Hons) in Pharmacy, MSc in Clinical Pharmacy, MRPharmS
Deputy Director of Pharmacy, Education, Training and Staff Performance
Manor Hospital
Walsall, UK

Dan Higgins
RGN, ENB 100, ENB 998
Senior Charge Nurse Critical Care
University Hospitals Birmingham NHS Foundation Trust
Consultant/Honorary Lecturer Resuscitation Services UK
Visiting Clinical Lecturer
University of Birmingham, UK

Ruth Endacott
RN, DipN(Lond), MA, PhD
Professor of Clinical Nursing
University of Plymouth, UK and La Trobe University, Australia

WILEY-BLACKWELL
A John Wiley & Sons, Ltd., Publication

The *Essential Clinical Skills for Nurses* series focuses on key clinical skills for nurses and other health professionals. These concise, accessible books assume no prior knowledge and focus on core clinical skills, clearly presenting common clinical procedures and their rationale, together with the essential background theory. Their user-friendly format makes them an indispensable guide to clinical practice for all nurses, especially to student nurses and newly qualified staff.

Other titles in the *Essential Clinical Skills for Nurses* series:

Central Venous Access Devices
Lisa Dougherty
ISBN: 9781405119528

Clinical Assessment and Monitoring in Children
Diana Fergusson
ISBN: 9781405133388

Intravenous Therapy
Theresa Finlay
ISBN: 9780632064519

Respiratory Care
Caia Francis
ISBN: 9781405117173

Care of the Neurological Patient
Helen Iggulden
ISBN: 9781405117166

ECGs for Nurses
Philip Jevon
ISBN: 9780632058020

Monitoring the Critically Ill Patient
Second Edition
Philip Jevon and Beverley Ewens
ISBN: 9781405144407

Treating the Critically Ill Patient
Philip Jevon
ISBN: 9781405141727

Pain Management
Eileen Mann and Eloise Carr
ISBN: 9781405130714

Leg Ulcer Management
Christine Moffatt, Ruth Martin and Rachael Smithdale
ISBN: 9781405134767

Practical Resuscitation
Edited by Pam Moule and John Albarran
ISBN: 9781405116688

Pressure Area Care
Edited by Karen Ousey
ISBN: 9781405112253

Infection Prevention and Control
Christine Perry
ISBN: 9781405140386

Stoma Care
Theresa Porrett and Anthony McGrath
ISBN: 9781405114073

Caring for the Perioperative Patient
Paul Wicker and Joy O'Neill
ISBN: 9781405128025

Medicines Management

A Guide for Nurses

Edited by

Philip Jevon
RN, BSc(Hons), PGCE
Resuscitation Officer/Clinical Skills Lead
Manor Hospital
Walsall, UK
Honorary Clinical Lecturer
University of Birmingham, UK

Elizabeth Payne
BSc(Hons) in Pharmacy, MSc in Clinical Pharmacy, MRPharmS
Deputy Director of Pharmacy, Education, Training and Staff Performance
Manor Hospital
Walsall, UK

Dan Higgins
RGN, ENB 100, ENB 998
Senior Charge Nurse Critical Care
University Hospitals Birmingham NHS Foundation Trust
Consultant/Honorary Lecturer Resuscitation Services UK
Visiting Clinical Lecturer
University of Birmingham, UK

Ruth Endacott
RN, DipN(Lond), MA, PhD
Professor of Clinical Nursing
University of Plymouth, UK and La Trobe University, Australia

WILEY-BLACKWELL
A John Wiley & Sons, Ltd., Publication

This edition first published 2010

Blackwell Publishing was acquired by John Wiley & Sons in February 2007. Blackwell's publishing programme has been merged with Wiley's global Scientific, Technical, and Medical business to form Wiley-Blackwell.

Registered office
John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, United Kingdom

Editorial offices
9600 Garsington Road, Oxford, OX4 2DQ, United Kingdom
2121 State Avenue, Ames, Iowa 50014-8300, USA

For details of our global editorial offices, for customer services and for information about how to apply for permission to reuse the copyright material in this book please see our website at www.wiley.com/wiley-blackwell.

Library of Congress Cataloging-in-Publication Data

Medicines management : a guide for nurses / edited by Philip Jevon . . . [et al.].
p. ; cm. – (Essential clinical skills for nurses)
Includes bibliographical references and index.
ISBN 978-1-4051-8163-1 (pbk. : alk. paper) 1. Drugs–Administration–Handbooks, manuals, etc. 2. Nursing–Handbooks, manuals, etc. 3. Therapeutics–Handbooks, manuals, etc. I. Jevon, Philip. II. Series: Essential clinical skills for nurses.
[DNLM: 1. Drug Therapy–nursing–Great Britain. 2. Drug Monitoring–nursing–Great Britain. 3. Medication Errors–prevention & control–Great Britain. 4. Nurse's Role–Great Britain. 5. Prescriptions–nursing–Great Britain. WY 100 M4899 2010]
RM125.M37 2010
615'.1068–dc22
2009037332

A catalogue record for this book is available from the British Library.

Set in 9 on 11 pt Palatino by Toppan Best-set Premedia Limited
Printed in Malaysia

1 2010

Contents

Foreword

Effective and safe medicines management is a key responsibility for all nurses and midwives. The pace of change in this area in recent years has been breathtaking, with the ever-increasing range and complexity of medicines themselves, and the developments in regulation and legislation relating to prescribing and administration. Nurses and midwives have a professional responsibility to keep up-to-date with new developments, guidelines and regulations, and with all aspects of patient safety.

This book details the key components of medicines management from basic pharmacology and principles of safe administration to nurse prescribing. The multi-disciplinary authorship ensures that it is a well balanced, helpful and reliable resource. I congratulate the authors on their achievement.

I would recommend this book for pre-registration and post-registration nurses and midwives. Nurse tutors would also find it helpful and informative and it will be useful for other healthcare professionals concerned with medicines management.

Jane Hare BPharm, MRPharmS
Director of Pharmacy, Walsall Hospitals NHS Trust

Contributors List

Matthew Aldridge RN, RNT, MA(Ed), BSc(Hons), FHEA
Senior Lecturer in Clinical Skills, Faculty of Health, Birmingham City University, UK

Ruth Endacott RN, DipN(Lond), MA, PhD
Professor of Clinical Nursing at the University of Plymouth, UK and La Trobe University, Australia

Brian Gammon BA, MMedSc, RN, PhD
Clinical Trials Practitioner, Sandwell and West Birmingham Hospitals NHS Trust, Birmingham, UK

Richard Griffith LLM, BN, DipN, PgdL, RMN, Cert Ed, RNT
Lecturer in Health Law, School of Health Science, Swansea University, UK

Dan Higgins RGN, ENB 100, ENB 998
Senior Charge Nurse Critical Care, University Hospitals Birmingham NHS Foundation Trust and Consultant/Honorary Lecturer Resuscitation Services UK and Visiting Clinical Lecturer, University of Birmingham, UK

Janet Hunter MA, BSc(Hons)
RN Senior Lecturer in Adult Nursing, School of Community and Health Sciences, West Smithfield, City University London, UK

Elizabeth Payne BSc(Hons) in Pharmacy, MSc in Clinical Pharmacy, MRPharmS
Deputy Director of Pharmacy, Education, Training and Staff Performance, Manor Hospital, Walsall, UK

Kate Roland MPharm, PgD Pharm Prac, MRPharm S
Domiciliary Pharmacist, Devon PCT and Devon County Council, UK

Gareth Walters BSc(Hons), MBChB, MRCP(UK), MRCP(London), AHEA, MInstLM, LCGI
Specialist Registrar in Respiratory and General Medicine, West Midlands Rotation and Honorary Clinical Lecturer, University of Birmingham, UK

Introduction to Medicines Management

1

Ruth Endacott

INTRODUCTION

The term 'medicines management' has become increasingly popular over the last 10 years, but what exactly does it mean? The NHS National Prescribing Centre (NPC) provides the following definition:

> *A system of processes and behaviours that determines how medicines are used by patients and by the NHS.*
>
> (NPC, 2001, p. 5)

This encompasses all activities necessary to select, purchase, deliver, prescribe, administer, store and review medication (Audit Commission, 2001). Pharmacies have provided specific components of medicines management services for many years. However, the responsibility for medicines management services is not only held by pharmacists but also shared with other healthcare professionals and the patients themselves.

So it is true to say that medicines management is not a new concept but an evolving concept, emphasising patient-focused care and services that help deliver that care.

LEARNING OUTCOMES

At the end of this chapter, the reader will be able to:

- ❏ Discuss the importance of medicines management.
- ❏ Discuss the context of medicines management in the UK.
- ❏ List the elements of medicines management.
- ❏ Outline medicines management and health service governance procedures.
- ❏ Discuss the impact of medicines management on patient safety.

- ❑ List the success factors for improving medicines management.

IMPORTANCE OF MEDICINES MANAGEMENT

Medication is by far the most common form of medical intervention, and at least 20% of Primary Care Trust (PCT) funds are spent in this area (NPC, 2001). Most patients are given medication on discharge from hospital, and up to 40% of nurses' time is spent administering medications (Audit Commission, 2001). Four out of five people over 75 years take a prescription medicine, and 36% are taking four or more [Department of Health (DH), 2001].

The prime driver for medicines management is to enhance the overall standard of patient care and to ensure safe and effective use of medicines. Obviously, this is very good news for the patient, but additional improved treatment outcomes can have a knock-on effect in other areas of the health service. The English National Service Framework (NSF) for older people states that medicines are implicated in 5–17% of hospital admissions in this patient group, and whilst in hospital 6–17% of older people experience adverse reactions to medicines (DH, 2001). More recently, a review of patients readmitted to hospital in this age group identified that 38% of readmissions were related to medications (Witherington *et al.*, 2008). Many of these incidents could be avoided if better medicines management systems were in place.

Evidence on medicine taking indicates that 50% of people with chronic conditions may not be taking medicines as intended (DH, 2001). This includes essential medicines for life-threatening conditions such as anti-hypertensive treatment for high blood pressures and anti-rejection treatment post organ transplantation.

Medicines management is also essential to control the NHS drugs bill. New drugs and formulations, changes in demographics and government policies, along with increased patient expectations have caused the drugs bill to rise year on year. If medicines are managed properly, for instance through rational prescribing and effective waste control measures, the NHS can save money, which can then be used more effectively on other treatments. Integrated processes for medicines management also

enable local policies to be developed for the introduction of high-cost drugs, for which there is no National Institute for Clinical Excellence (NICE) guidance. The ongoing cost implications of these medications have an impact across health services, hence policies need to be developed in consultation with a range of stakeholders.

A DH review of adverse events (*An Organisation with a Memory*) identified that around 10 000 NHS hospital patients a year experience adverse effects related to medicines and 20% of all clinical negligence litigation relates to hospital medication errors (DH, 2000). The Audit Commission (2001) identified that medication errors cost the NHS £500m each year and, more importantly, medication errors are responsible for about 20% of the deaths that are due to adverse events in hospital.

THE CONTEXT OF MEDICINES MANAGEMENT IN THE UK

National context

The modernisation programme for the NHS includes an important agenda to improve medicines management. There are a number of key documents (Appendix 1.1) that embrace medicines management and provide broad objectives to improve the use of medicines within the NHS.

The services provided by the NHS are changing to meet national expectations and the expectations of service users and carers. Changes in medicines management is a key part of this process.

Medicines management makes a significant contribution to the Care Quality Commission Annual Health Check and Standards for Better Health (for more information, see www.cqc.org.uk/publications.cfm?fde_id=679, accessed 4 November 2009). It features in several domains but largely within the safety domain to 'keep patients, staff and visitors safe by having systems to ensure that medicines are handled safely and securely'.

Standards for medicines management are also included in the primary care Quality Outcomes Framework (QOF) and form part of the General Medical Services contract (www.bma.org.uk/employmentandcontracts/independent_contractors/quality_outcomes_framework/focusQOF0308.jsp, accessed 22 June 2009).

Indicator points for medicines management, against which funding is provided to GP practices, include the following:

- The practice possesses the equipment and in-date emergency drugs to treat anaphylaxis.
- There is a system for checking the expiry dates of emergency drugs on at least an annual basis.
- The number of hours from requesting a prescription to availability for collection by the patient is 72 hours or less (excluding weekends and bank/local holidays).
- A medication review is recorded in the notes in the preceding 15 months for all patients being prescribed four or more repeat medicines.

National initiatives have been translated into specific benchmarks in many areas, see, for example, the benchmarking policy for medicines management at Eastern and Coastal Kent PCT at www.eastkentcoastalpct.nhs.uk/search/?q=medicines+management+benchmarking+policy).

Local context

The current focus for medicines management within an NHS Trust is the Drug and Therapeutics Committee. This committee meets every month and is chaired by a consultant biochemist who works closely with the Director of Pharmacy to plan the agenda. The committee is accountable to the Clinical Governance Committee and via the Medical Director to the Trust Board. Information and decisions from the committee are communicated via the Medicines Information Bulletin and EnLine.

A Medication Safety Group, made up of doctors, pharmacists and nurses from across the Trust, examines clinical incidents involving medication and makes recommendations to reduce the frequency of these incidents.

The Chief Pharmacist sits on the Clinical Effectiveness Subgroup to ensure that medicines-related aspects of NICE guidance are implemented and on the Executive Board to ensure that medicines and their use are accounted for when Trust-wide decisions are made. The Chief Pharmacist and Chair of the Drug and Therapeutics Committee also represent the Trust on a Countywide Prescribing Group with a wider health community role.

ELEMENTS OF MEDICINES MANAGEMENT

Medicines management includes the selection, procurement, delivery, prescription, dispensing and administration of medicines. The NPC (2008) has developed a flowchart to illustrate how these processes intersect (see Figure 1.1).

Selection and procurement

Decisions about which drugs will be available for clinicians to prescribe and where the drugs will be purchased are taken at Trust level. The medicines management pathway (Figure 1.1) is one tool that is used by commissioners of health services to assess the prescribing and medicines implications of a new clinical pathway (for example, an NSF or a new pathway for managing a particular disease). The potential impact of raising public health awareness (for example, sexual health and smoking cessation campaigns) on prescribing practices is also considered as part of an integrated medicines management system.

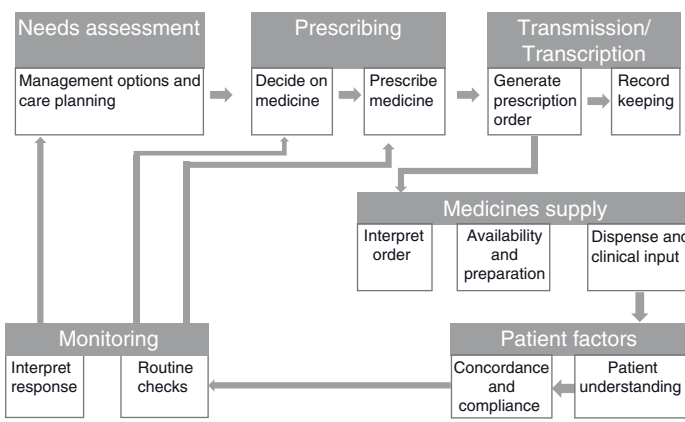

Fig 1.1 Medicines management pathway. From 'Moving towards personalising medicines management: improving outcomes for people through the safe and effective use of medicines' (April 2008). Copyright National Prescribing Centre, reproduced by permission.

Handling

Medicines must be stored according to specific instructions; details for all medications can be found in the electronic Medicines Compendium (see www.emc.medicines.org.uk), including summaries of product characteristics (SPCs) and patient information leaflets. SPCs are written and updated by pharmaceutical companies, in accordance with a mandatory proforma, and are approved by the UK or European medicines licensing agency.

Prescription

Regular review of prescribing practices is recommended as good practice and is rewarded as part of the QOF funding for patients receiving repeat prescriptions. To take an example from mental health, such a repeat prescribing review would include the following questions in discussion with the service user:

- Are the medicines making a positive difference? Is the service user feeling better?
- What side effects are being experienced?
- What are the options for addressing these?
- What healthy living options, such as diet, physical activity, alcohol reduction and smoking cessation, might be appropriate?
- Is the service user having problems remembering to take the medication? If so, what 'concordance' support can be arranged, such as the use of monitored dosage systems in the form of blister packs, medication reminder charts or tablet boxes showing days of the week and times of day?

(NIHME National Workforce Programme, 2008)

Administration

An integrated approach to medicines management provides greater opportunity to identify and manage problems related to medication administration. For example, regular review of drug incidents highlights particular ward environments or times of day when medication administration is more problematic. The development of integrated electronic systems for medication management, including medication administration, is discussed in Chapter 5.

MEDICINES MANAGEMENT AND HEALTH SERVICE GOVERNANCE PROCEDURES

The growing complexity and cost of medicines have led to the recognition that medicines management is a crucial aspect of clinical and financial governance in NHS Trusts, as highlighted in the following documents:

- *Clinical Negligence Scheme for Trusts (CNST)* (NHS Litigation Authority, 2005): Two standards relate directly to medicines management and encompass a variety of areas.
- *Building a Safer NHS for Patients – Improving Medication Safety* (DH, 2004): Medicines management systems are highlighted as the most important facility in assuring patient safety in relation to medicines. The report emphasises the controls necessary to reduce errors in prescribing, dispensing and administering medicines.
- *A Spoonful of Sugar* (Audit Commission, 2001): This report describes medicines management as 'a strategic issue fundamental to the way hospitals work, to the quality of patient care and to the delivery of the NHS Plan'. The central role of pharmacists is recognised, and Trust boards are asked to ensure adequate investment in pharmacy services.
- *An Organisation with a Memory* (DH, 2000): This document emphasises the role of medicines management in reducing risks related to the use of medicines.

THE IMPACT OF MEDICINES MANAGEMENT ON PATIENT SAFETY

As previously identified, medication errors are an important factor in adverse events in health care. There is evidence that this trend is rising (Audit Commission, 2001; NPSA, 2007), with 'severe harm' from medication reported in research studies reaching as high as 9% of hospital inpatients (NPSA, 2007, p12). It is acknowledged that reported medication incidents are the tip of the iceberg; however, in the 18 months between January 2005 and June 2006, just under 60 000 medication incidents were reported to the National Patient Safety Agency, mostly occurring in hospital (NPSA, 2007).

A number of factors have been identified that may contribute to the extent of medication incidents and errors; these are discussed in Chapter 7, along with strategies to reduce medication error.

KEY SUCCESS FACTORS FOR IMPROVING MEDICINES MANAGEMENT

The NPC has identified 10 key success factors for improving medicines management (NIMHE National Workforce Programme, 2008):

1. Involving and listening to patient and carers.
2. Clear leadership.
3. Multidisciplinary approach.
4. Medicines management objectives aligned to organisational priorities.
5. Local medicines management leader.
6. Effective communication.
7. Medicines management champions.
8. Focus on measuring outcomes, not activity.
9. Protected time.
10. Shared learning and networking.

The emphasis in these success factors is firmly on communication between patients, clinicians, pharmacists and Trust boards.

CONCLUSION

This chapter has provided an introduction to medicines management. The importance of medicines management, together with its context in the UK, has been discussed. The elements of medicines management have been listed. Medicines management and health service governance procedures have been outlined, together with their impact on patient safety. Success factors for improving medicines management have been listed.

APPENDIX 1.1 RELEVANT NATIONAL STRATEGIES AND DOCUMENTS

Department of Health (2000) The NHS Plan

Department of Health (2000) Pharmacy in the Future – Implementing the NHS Plan

Department of Health (2000) An Organisation with a Memory – Report of an expert group on learning from adverse events (including the formation of the NPSA)
Audit Commission (2001) 'A Spoonful of Sugar'
Department of Health (2001) National Service Framework for Older People. The Stationery Office, London
Department of Health (2003) Medicines Management Framework in NHS Hospitals. DH, London
Department of Health (2003) A Vision for Pharmacy in the New NHS. DH, London
Department of Health (2004) Building a Safer NHS for Patients – Improving Medication Safety. DH, London
Department of Health (2004i) National Standards, Local Action: Health and social care standards and planning framework 2005/06–2007/08. DH, London
Department of Health and Department for Education and Skills (2004) National Service Framework for Children, Young People and Maternity Services. DH, London
Healthcare Commission Assessment for Improvement. The annual health check
Measuring What Matters (2005)

REFERENCES

Audit Commission (2001) *A Spoonful of Sugar: Medicines Management in NHS Hospitals*. Audit Commission, London.

Department of Health (DH) (2000) *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer*. The Stationery Office, London.

Department of Health (DH) (2001) *Medicines and Older People – Supplement to the National Service Framework for Older People*. The Stationery Office, London.

Department of Health (DH) (2004) *Building a Safer NHS for Patients – Improving Medication Safety*. DH, London.

National Patient Safety Agency (NPSA) (2007) *Safety in Doses: Medication Safety Incidents in the NHS*. The fourth report from the Patient Safety Observatory (PSO/4). NPSA, London.

National Prescribing Centre (NPC) (2001) *Modernising Medicines Management. A Guide to Achieving Benefits for Patients, Professionals and the NHS*. NPC, London.

National Prescribing Centre (NPC) (2008) Moving towards personalising medicines management: improving outcomes for people through the safe and effective use of medicines. Available at www.npc.co.uk/mm/publications.htm?type=:medicines [accessed on 4 November 2009].

NHS Litigation Authority (2005) *CNST General Clinical Risk Management Standards*. NHSLA, London.

NIMHE National Workforce Programme (2008) *Medicines Management: Everybody's Business*. DH, London.

Witherington EMA, Pirzada OM, Avery AJ (2008) Communication gaps and readmissions to hospital for patients aged 75 years and older: observational study. *Qual Safety Health Care* **17**(1): 71–75.

Legal Issues of Medicines Management

2

Richard Griffith

INTRODUCTION

Medicines are used for their therapeutic benefits but they also have great potential to harm those who take them. Drugs such as thalidomide [*S* v *Distillers Co. (Biochemicals)* (1970)] and Opren [*Nash* v *Eli Lilly & Co* (1993)] demonstrate the tragic consequences that may follow poor medication management and administration. The law therefore regulates the arrangements for the supply and administration of medicines to patients.

The Medicines Act 1968, section 58A, requires that medicines that represent a danger to the patient be classified as prescription only and their administration be supervised by an appropriate practitioner. Nurses who meet conditions specified in law can become appropriate practitioners (Medicines Act 1968, section 58(1)). However, unlike doctors, who prescribe from one national formulary, non-medical prescribers have up to seven different roles when prescribing or administering medicines to patients, each with its own requirements and limitations. In order to practise safely and avoid legal and professional liability, nurses must ensure that they manage medicines properly and have the proper authority to prescribe or administer.

For example, a practice nurse was cautioned by the Nursing and Nursery Council's Conduct and Competence Committee when the nurse prescribed drugs to patients without having the authority to do so. The committee stressed that whilst the role of nurses and non-medical prescribers was expanding, public protection demanded that proper medication management be practised [Nursing & Midwifery Council (NMC), 2003].

LEARNING OBJECTIVES

At the end of this chapter, the reader will be able to:

- ❑ Identify the spheres of accountability that regulate nursing practice.
- ❑ Explain the regulation of clinical trials.
- ❑ Discuss the legal regulation of medicines.
- ❑ Discuss the legal regulation of controlled drugs.
- ❑ Outline the civil liability of nurses when managing medicines.
- ❑ Discuss the issues of consent.
- ❑ Describe the elements of good record keeping.

SPHERES OF ACCOUNTABILITY THAT REGULATE NURSING PRACTICE

As registered practitioners, nurses are answerable for their actions to four main legal sources:

- the profession;
- the employer;
- the patient;
- society.

The profession

A nurse who is found guilty of professional misconduct is liable to removal from the professional register. The Nursing and Nursery Council has the authority to hold nurses to account through the Nursing & Midwifery Order 2001. The professional standard required of a nurse by the governing body is given in the Nursing and Nursery Council's code, standards of conduct, performance and ethics for nurses (NMC, 2008a) and in relation to medicines is further elaborated in the standards for medication management (NMC, 2008c).

It is essential that registered nurses abide by the requirements of the code and comply with the standards for medication management. A total of 214 nurses were issued with striking off orders for professional misconduct in 2007–2008. Of the allegations investigated by the Council, about 14% concerned direct contact with patients and 9.87% with maladministration of medication (NMC, 2008b).

The employer

Nurses have legally binding contracts of employment with their employers, which require, among other duties, that they obey the reasonable requests of the employer and work with due care and skill. The contract further requires that nurses are duty bound to account for their actions and to disclose any misdeeds. An employer may therefore hold an employee to account through reasonable disciplinary policies and procedures, which ultimately may lead to dismissal.

For example, a nurse was sacked by her employer and subsequently suspended by the NMC when she admitted stealing medicines from the ward (Nurse struck off for stealing medicines, 2008).

As a result of the control employers exercise over their employees, the law holds them vicariously liable for any tort committed by an employee during the course of their employment, which has the effect of indemnifying the employee against damages for harm caused to another in the course of their employment.

The patient

Patients who feel that they have been harmed by the carelessness of nurses can seek redress though the civil court system. This is a lengthy and costly process and is still a relatively rare occurrence, although the NHS annual compensation bill runs at approximately £500m (NHS Litigation Authority, 2007).

The great majority of patients will usually complain to the nurse's employer or the Nursing & Midwifery Council rather than go to law. However, when a case is successfully brought, an award of significant damages can be made in favour of the patient.

Society

We are all accountable to society through the criminal law. A nurse who breaks the law is as liable to prosecution as any other person. The statutes concerned with the regulation of medicines, such as the Medicines Act 1968 and the Misuse of Drugs Act 1971, carry criminal penalties if breached. It is therefore vital that nurses are within the law when working with medicines.

The four spheres of accountability regulating the practice of the nurse are not mutually exclusive. It is entirely possible that a nurse might be removed from the professional register, be dismissed from post, be sued by a patient and receive a fine, community penalty or imprisonment. It is essential, therefore, that the nurse understands that the notion of accountability is always considered as a whole through all four spheres. This will ensure safe and effective practice, which will benefit the patient and avoid being called to justify one's actions.

REGULATION OF CLINICAL TRIALS

Nurses and their patients need to be confident of the quality and safety of medicines used in practice. In the UK, all medicinal products must be granted a marketing authorisation before they can be sold or prescribed to patients. This authorisation is only granted when the Medicines and Healthcare products Regulatory Agency (MHRA) is satisfied that the drug is safe and effective. Clinical trials are undertaken to allow data on safety and therapeutic effects to be collected and analysed. The trials are conducted with healthy volunteers or patients, depending on the type of medicine and the stage of its development.

The danger to human subjects involved in clinical trials was highlighted by an incident at a trial at Northwick Park Hospital in Hertfordshire in March 2006. Six of the eight participants experienced a life-threatening reaction to the drug being trialled and had to spend several days in intensive care.

To minimise the danger to volunteers, and potentially to the public, from the adverse effects of new untried medicinal compounds, a strict European-wide regulatory framework controls both pre-trial laboratory testing and clinical trial testing on humans to ensure that they are properly designed (Council Directive (EC) 2001/20, 2001).

Since May 2004 all clinical trials are required to meet the standards set by the European Union Clinical Trials Directive (Council Directive (EC) 2001/20, 2001). The directive seeks to harmonise the laws, regulations and administrative provisions of member states in relation to good clinical practice when conducting clinical trials on medicinal products for human use.

Index