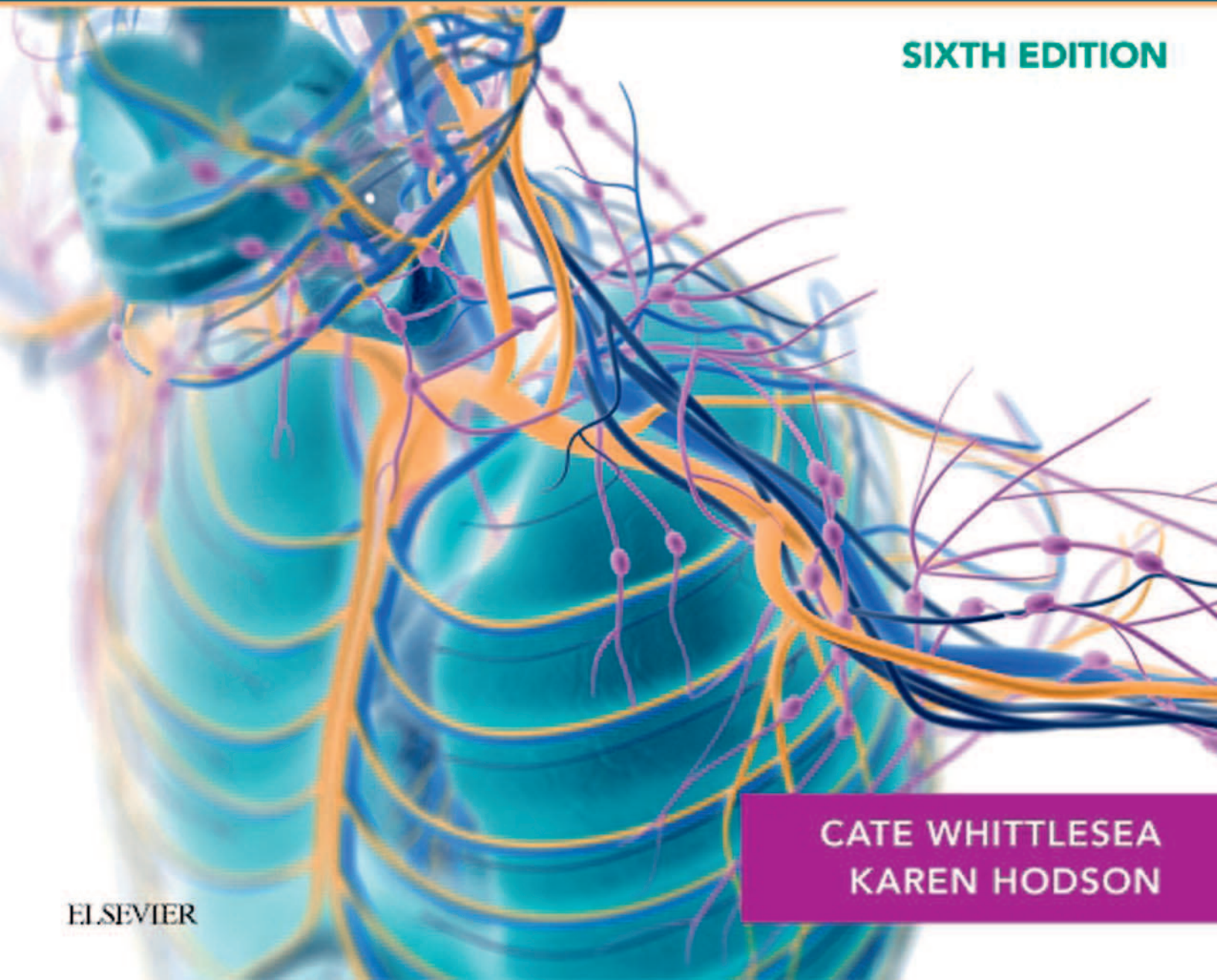
CLINICAL PHARMACY AND THERAPEUTICS

SIXTH EDITION



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KAREN HODSON

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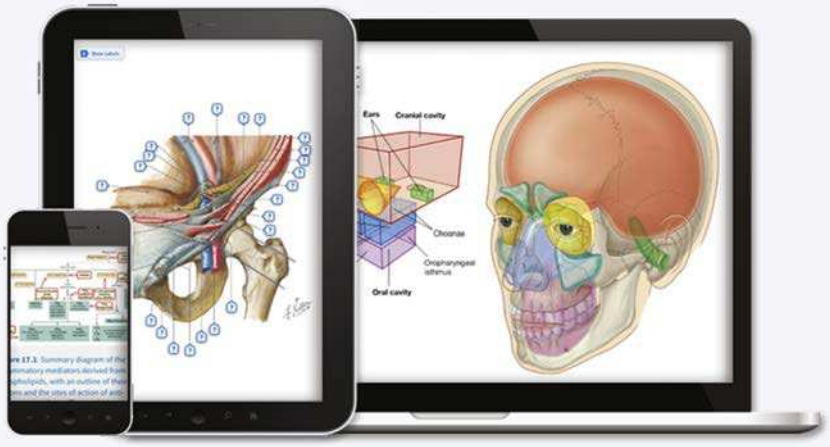

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SIXTH EDITION

EDITED BY

CATE WHITTLESEA, BSc, MSc, PhD, MRPharmS
Professor of Pharmacy Practice and Associate Director of Clinical Education
UCL School of Pharmacy
University College London
London, UK

and

KAREN HODSON, BSc(Pharm), MSc, PhD, FRPharmS, FFRPS
Director MSc in Clinical Pharmacy and Pharmacist Independent Prescribing Programmes
School of Pharmacy and Pharmaceutical Sciences, Cardiff University
Cardiff, UK

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Senior Content Strategist: Pauline Graham
Content Development Specialist: Carole McMurray
Project Manager: Beula Christopher
Design: Paula Catalano
Illustration Manager: Amy Faith Heyden
Illustrator: MPS LLC
Marketing Manager: Deborah Watkins

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Preface

In both primary and secondary health care, the use of medicines is the most common intervention. However, the use of medicines is not without risk. Selecting and prescribing drugs is increasingly complex and demanding, and it is undertaken as part of a multi-disciplinary process that involves pharmacists, some of whom are now prescribers in their own right, along with doctors, nurses and other members of the healthcare team. All must strive to promote safe, appropriate and cost-effective prescribing that respects patient choice and promotes adherence. This book was written to help the reader understand and address many of these issues. It is unashamedly written from a pharmacy perspective, although we do hope those from other disciplines will also find it of use.

We have made considerable effort to update each chapter and ensure the content is relevant to current practice. Selected website addresses have been included to assist those who want to obtain further information, and many references are now available electronically. However, knowledge in therapeutics progresses rapidly, changes to dose regimens and licensed indications are frequent, safety issues emerge with established drugs and new medicines appear at regular intervals. Yesterday another landmark study may have been published that added to, or perhaps altered, the evidence base for a specific treatment. Together with the ongoing publication of national and international guidelines and frameworks, the face of therapeutics is ever changing. It is therefore inevitable that some sections of this book will date more quickly than others.

In practice, many licensed drugs are used 'off label' or 'near label' when prescribed for a certain indication or used in a specific patient group, such as children. To omit reference to these agents in the relevant chapter would leave an apparent gap in therapeutic management. As a consequence, we have encouraged our authors to present details of all key drugs used, along with details of the prescribed regimens, even if not licensed for that specific indication. There is, however, a downside to this approach. The reader must always use this text critically and with caution. If this is done, the book will serve as a valuable learning resource and help the reader understand some of the principles of therapeutics. We hope that, in some small way, this will also assist in achieving positive patient outcomes.

Cate Whittlesea
Karen Hodson

Acknowledgements

The first edition of this book was published in 1994 by Roger Walker and Clive Edwards. We very much hope that this edition lives up to the high standards of both past editors. We acknowledge the enormous contribution Roger Walker made to all previous editions and very much hope he will look in pride at this, our first edition, without him at the helm. Like Roger, undergraduate and postgraduate students have sustained our enthusiasm and commitment while continuing to be the inspiration and the *raison d'etre* for this book. To all those who have provided feedback in the past, thank you. For those who would like to comment on this edition, we welcome your feedback; please contact us at c.whittlesea@ucl.ac.uk or hodsonkl@cardiff.ac.uk.

We remain indebted to all authors who, through their hard work, patience and tolerance, have contributed to the sixth edition of this book. We are particularly grateful to those who have again contributed to another edition of this textbook and who strive, along with us, to produce an ever-better book. To our first-time authors, we are very grateful for your contribution, that you accepted our cryptic editorial comments in good faith and still managed to submit on time. We hope that you will continue to work with us on future editions.

A textbook of this size cannot, of course, be produced without the invaluable help, support and occasional comments of numerous colleagues, particularly from the Department of Pharmacy, Durham University, UCL School of Pharmacy and the Associate Course Directors of the MSc in Clinical Pharmacy within the School of Pharmacy and Pharmaceutical Sciences, Cardiff University. It would be invidious to name individuals who have helped us, in part for fear of offending anyone we might miss. We do, however, continue to make one exception to this rule. The administrative support from Dean Routledge has been invaluable.

Finally, and on a personal note, we would like thank our close families for their support and tolerance with our indulgence in editing this text. At times it may have appeared that everything in our lives took second place to 'the book'. We are eternally grateful for their understanding, particularly when we got our priorities in life wrong. Without the unfailing support of Rob and Phil, Maddy and Logan, this book would never have materialised.

Cate Whittlesea
Karen Hodson

List of Contributors

The editors would like to acknowledge and offer grateful thanks for the input of all previous editions' contributors, without whom this new edition would not have been possible.

Tamara Ahmed Ali
Directorate Lead Pharmacist-Ophthalmology, City Hospitals Sunderland NHS Trust, Sunderland, UK
56. Glaucoma

Sotiris Antoniou
Consultant Pharmacist, Cardiovascular Medicine, Barts Health NHS Trust, St Bartholomew's Hospital, London, UK
22. Arrhythmias

Kelly Atack
Advanced Clinical Pharmacist, Medicines Management and Pharmacy, St James's University Hospital, Leeds Teaching Hospital NHS Trust, Leeds, UK
25. Asthma

Deborah Baidoo
Chief Pharmacist (Interim), West London Trust, St Bernard's Hospital, Middlesex, London, UK
27. Insomnia

David S. Baldwin
Professor of Psychiatry, Clinical and Experimental Sciences Academic Unit, Faculty of Medicine, University of Southampton, Southampton, UK
28. Anxiety disorders

Catrin Barker
Chief Pharmacist, Pharmacy Department, Alder Hey Children's NHS Foundation Trust, Liverpool, UK
10. Paediatrics

Roger Barker
Professor of Clinical Neuroscience, Honorary Consultant in Neurology, University of Cambridge and Addenbrooke's Hospital, Cambridge, UK
32. Parkinson's disease

Lee Beale
Anaesthetic Registrar ST7, University Hospital of Wales, Cardiff, UK
6. Laboratory data

Jonathan Berry
Academic Clinical Educator, School of Pharmacy, Keele University, Staffordshire, UK
14. Constipation and diarrhoea

Stephen Bleakley
Chief Pharmacist, Salisbury NHS Foundation Trust, Salisbury, UK
28. Anxiety disorders

Gonçalo Cação
UCL Institute of Neurology, London, UK
31. Epilepsy

Anthony Cadogan
Macmillan Advanced Pharmacist, Haematology and Oncology, Prince Charles Hospital (Merthyr Tydfil) and Royal Glamorgan Hospital (Llantrisant), Cwm Taf University Health Board, Wales, UK
50. Anaemia

Laura Cameron
Principal Pharmacist - Cancer Services Operational Lead, Guy's and St Thomas' NHS Foundation Trust, London, UK
52. Lymphomas

Toby Capstick
Lead Respiratory Pharmacist, Pharmacy Department, Leeds Teaching Hospitals NHS Trust, Leeds, UK
41. Tuberculosis

Neil J. B. Carbarns
Consultant Medical Microbiologist, Aneurin Bevan University Health Board, Abergavenny, Monmouthshire, UK
37. Urinary tract infections

Sheena Castelino
Principal Pharmacist, HIV and Sexual Health, Guy's and St Thomas' NHS Foundation Trust, Pharmacy Department, St Thomas' Hospital, London, UK
42. HIV infection

Ben Challocombe
Consultant Urologist, Guy's and St Thomas' NHS Foundation Trust, London, UK
49. Prostate disease

Ian Clifton
Consultant Respiratory Physician and Honorary Senior Lecturer, Department of Respiratory Medicine, St James's University Hospital, Leeds Teaching Hospital NHS Trust, Leeds, UK
25. Asthma

Paul Cockwell
Consultant Nephrologist, University Hospital Birmingham and Professor of Nephrology, University of Birmingham, Birmingham, UK
17. Acute kidney injury
18. Chronic kidney disease and end-stage renal disease

Katie Conway
Consultant Physician in GU/HIV Medicine, Guy's and St Thomas' NHS Foundation Trust, Pharmacy Department, St Thomas' Hospital, London, UK
42. HIV infection

Jonathan Cooke
Honorary Professor, Manchester Pharmacy School, Faculty of Biology, Medicine and Health, University of Manchester, Manchester; Visiting Professor in the Infectious Diseases and Immunity Section, Division of Infectious Diseases, Department of Medicine, Imperial College London, London, UK
8. Pharmacoeconomics

Alan G. Cosslett
Lecturer, School of Pharmacy and Pharmaceutical Sciences, Cardiff University, Cardiff, UK
7. Parenteral nutrition

Anthony R. Cox
Senior Lecturer in Clinical Pharmacy and Drug Safety, School of Pharmacy, University of Birmingham, Birmingham, UK
5. Adverse drug reactions

Netty (Annette) Cracknell
Specialist Oncology Pharmacist, Netty Cracknell Consultancy; Pharmacy Manager, Springfield Hospital, Chelmsford, UK; Executive Committee Member, British Oncology Pharmacy Association (BOPA), UK
53. Solid tumours

Daniel Creamer
Consultant Dermatologist, Department of Dermatology, King's College Hospital NHS Foundation Trust, London, UK
57. Drug-induced skin disorders

Sarah Cripps
Consultant Pharmacist - Gastroenterology/Hepatology, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
13. Inflammatory bowel disease

Emma Crosbie
NIHR Clinician Scientist, Senior Lecturer and Honorary Consultant in Gynaecological Oncology, Division of Molecular and Clinical Cancer Sciences, University of Manchester, St Mary's Hospital, Manchester, UK
46. Menstrual cycle disorders
47. Menopause

Octavio Aragon Cuevas
Lead Rheumatology Pharmacist, Pharmacy Department, Alder Hey Children's NHS Foundation Trust, Liverpool, UK
10. Paediatrics

J. Graham Davies
Professor of Clinical Pharmacy and Therapeutics, King's College London, London, UK
1. Clinical pharmacy practice

Nemesha Desai
Consultant Dermatologist, St John's Institute of Dermatology, Guy's and St Thomas' NHS Foundation Trust, London, UK
58. Eczema and psoriasis

Mark D. Doherty
Consultant Ophthalmologist, Sunderland Eye Infirmary, Sunderland, UK
56. Glaucoma

Tobias Dreischulte
Research Pharmacist, NHS Tayside, Community Health Sciences Division, Dundee, UK
21. Chronic heart failure

Jackie Elliott
Senior Clinical Lecturer in Diabetes and Honorary Consultant, Diabetes and Endocrine Centre, Northern General Hospital, Sheffield, UK
45. Diabetes mellitus

Sarah Fenner
Director, West Midlands Medicines Information Service and UK Drugs in Lactation Advisory Service, Good Hope Hospital, Sutton Coldfield, UK
48. Drugs in pregnancy and lactation

Ray W. Fitzpatrick
Clinical Director of Pharmacy, New Cross Hospital, Wolverhampton, UK
3. Practical pharmacokinetics

Peter Golightly
Senior Medicines Information Pharmacist, West Midlands and Trent Regional Medicines Information Services and UK Drugs in Lactation Advisory Service, Good Hope Hospital NHS Trust, Sutton Coldfield, UK
48. Drugs in pregnancy and lactation

Alison Grant
Highly Specialist Pharmacist in HIV and Sexual Health, Guy's and St Thomas' NHS Foundation Trust, St Thomas' Hospital, London, UK
42. HIV infection

Jim Gray
Consultant Microbiologist, Department of Microbiology, Birmingham Women's and Children's NHS Foundation Trust, Birmingham Children's Hospital, Birmingham, UK
38. Gastro-intestinal infections
39. Infective meningitis

Dan Greer
Pharmacist Lecturer/Practitioner, Programme Manager, Postgraduate Programme in Pharmacy Practice, University of Leeds, Leeds, UK
12. Dyspepsia, peptic ulcer disease and gastro-oesophageal reflux disease

Imran Hafiz
Principal Cardiovascular Pharmacist, Guy's and St Thomas' NHS Foundation Trust; Clinical Lecturer, King's College London, UK
20. Coronary heart disease

Keith Harding
Dean of Clinical Innovation, Professor of Wound Healing Research, Clinical Innovation Cardiff (CIIC), College of Biomedical and Life Sciences, Cardiff University School of Medicine, Cardiff, UK
59. Wounds

Susanna J. Harwood
Pharmacist, Aseptic Services, University Hospital of Wales, Cardiff, UK
7. Parenteral nutrition

Tina Hawkins
Retired Specialist Pharmacist in Rheumatology, Leeds, UK
54. Rheumatoid arthritis and osteoarthritis
55. Gout and hyperuricaemia

Gregory J. Hobbs
Consultant in Pain Medicine, Primary Integrated Community Solutions, Nottingham, UK
34. Pain

Samantha Holloway
Senior Lecturer/Programme Director, Centre for Medical Education, School of Medicine, Cardiff University, Cardiff, UK
59. Wounds

Philip Howard
NHS-Improvement AMR Project Lead, Leeds Teaching Hospitals, Leeds, UK
40. Surgical site infection and antimicrobial prophylaxis

Gail Jones
Consultant Haematologist, Northern Centre for Cancer Care, Freeman Hospital, Newcastle upon Tyne, UK
51. Leukaemia

Atul Kalhan
Endocrinology, Department of Diabetes and Endocrinology, Royal Glamorgan Hospital, Ynysmaerdy, Llantrisant, UK
44. Thyroid and parathyroid disorders

Sallianne Kavanagh
Lead Pharmacist – Diabetes and Endocrinology, Sheffield Teaching Hospital NHS Foundation Trust, Pharmacy Department, Sheffield, UK
45. Diabetes mellitus

Patrick Kennedy
Reader in Hepatology, Blizard Institute, Barts and The London School of Medicine and Dentristy, Queen Mary University of London, London, UK
16. Liver disease

Roger David Knaggs
Associate Professor in Clinical Pharmacy Practice, School of Pharmacy, University of Nottingham; Specialist Pharmacist in Pain Management, Primary Integrated Community Solutions, Nottingham, UK
34. Pain

Apostolos Koffas
ST4 in Gastroenterolgy and Hepatology, University Hospital of Larisa, Larisa, Greece
16. Liver disease

Janet Krska
Professor of Clinical and Professional Practice, Medway School of Pharmacy, Chatham, Kent, UK
5. Adverse drug reactions

Alan Lamont
Clinical Oncologist (Retired), Colchester Hospital University Foundation Trust, Colchester, UK; Chair, Cambridge East Research Ethics Committee, Health Research Authority, London, UK
53. Solid tumours

Emma Lane
Senior Lecturer in Pharmacology, School of Pharmacy and Pharmaceutical Sciences, Cardiff University, Cardiff, UK
32. Parkinson's disease

Michelle Lannon
Post CCT Fellow, Haematology, Northern Centre for Cancer Care, Freeman Hospital, Newcastle Upon Tyne, UK
51. Leukaemia

Catherine Loughran
Lead Pharmacist, Haematology, Pharmacy Department, Leicester Royal Infirmary, Leicester, UK
52. Lymphomas

Katie Maddock
Director of Master of Pharmacy Learning and Teaching, School of Pharmacy, Keele University, Keele, UK
3. Practical pharmacokinetics

Helen Marlow
Lead Pharmacist, Surrey Down CCG, Leatherhead, UK
2. Prescribing

John Marriott
School of Clinical and Experimental Medicine, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK
17. Acute kidney injury
18. Chronic kidney disease and end-stage renal disease

Kay Marshall
Head of the School of Health Sciences, University of Manchester, Manchester, UK
46. Menstrual cycle disorders
47. Menopause

Emma Mason
Department of Acute Medicine, Royal Gwent Hospital, Newport, Wales, UK
35. Nausea and vomiting

John McAnaw
Head of Pharmacy, NHS 24, South Queensferry, UK
21. Chronic heart failure

Niamh McGarry
Lead Pharmacist for Care of the Elderly/Older People Services, Belfast Health and Social Care Trust, Belfast City Hospital, Belfast, UK
50. Anaemia

Duncan McRobbie
Associate Chief Pharmacist – Clinical Services, Guy's and St Thomas' NHS Foundation Trust; Clinical Reader, Kings College London; Visiting Professor UCL School of Pharmacy, Pharmacy Department, St. Thomas' Hospital, London, UK
1. Clinical pharmacy practice
20. Coronary heart disease

Helen Meynell
Consultant Pharmacist/Clinical Governance Lead, Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust, Doncaster, UK
26. Chronic obstructive pulmonary disease

Catherine Molyneux
Consultant Microbiologist, County Durham and Darlington NHS Foundation Trust, Durham, UK
36. Respiratory infections

Manjusha Narayanan
Consultant Microbiologist, Department of Microbiology, Royal Victoria Infirmary, Newcastle upon Tyne, UK
43. Fungal infections

Mike D. Page
Consultant Diabetes and Endocrinology (Retired), Royal Glamorgan Hospital, Ynysmaerdy, Llantrisant, UK
44. Thyroid and parathyroid disorders

Caroline Parker
Consultant Pharmacist Adult Mental Health, St Charles' Hospital for Central and North West London NHS Foundation Trust, London, UK
30. Schizophrenia

Alan Pollard
Independent Mental Health Pharmacy Consultant, Associate Lecturer Worcester University, Worcester, UK
29. Affective disorders

Sophie Rintoul-Hoad
Specialist Registrar in Urology, Guy's and St. Thomas' hospital, London, UK
49. Prostate disease

Ali Robb
Consultant Microbiologist, Royal Victoria Infirmary, Newcastle upon Tyne, UK
36. Respiratory infections

Trevor Rogers
Consultant Respiratory Physician and Director of R&D, Chest Clinic, Doncaster Royal Infirmary, Doncaster, UK
26. Chronic obstructive pulmonary disease

Linda Ross
Highly Specialist Renal Transplant and Urology Pharmacist, Department of Renal Transplant and Urology, Guy's and St Thomas' NHS Foundation Trust, Guy's Hospital, London, UK
49. Prostate disease

Philip A. Routledge
Professor Emeritus of Clinical Pharmacology, Cardiff University; Clinical Director of the All Wales Therapeutics and Toxicology Centre, Cardiff, UK
23. Thrombosis
35. Nausea and vomiting

Paula Russell
Principal Pharmacist (Medicines Information and NHSD Support), Newcastle Drug and Therapeutics Centre, Newcastle upon Tyne, UK
48. Drugs in pregnancy and lactation

Josemir W. Sander
Professor of Neurology, University College London, London, UK
31. Epilepsy

Jonathan Sandoe
Consultant Microbiologist, St James University Hospital, Leeds, UK
40. Surgical site infection and antimicrobial prophylaxis

Sara Sawieres
Senior Clinical Pharmacist, Liver and Private Patient Services, King's College Hospital, London, UK
15. Adverse effects of drugs on the liver

Hamsaraj Shetty
Consultant Physician and Honorary Senior Lecturer, University Hospital of Wales and Cardiff University, Cardiff, UK
11. Geriatrics
23. Thrombosis

Michele Sie
Chief Pharmacist, Pharmacy Department, South West London and St George's Mental Health NHS Trust, Springfield University Hospital, London, UK
27. Insomnia

Ian Smith
Teaching Fellow, School of Pharmacy, Keele University, Staffordshire, UK
14. Constipation and diarrhoea

Simon Sporton
Consultant Cardiologist, Barts and the London NHS Trust, St Bartholomew's Hospital, London, UK
22. Arrhythmias

Stephanie Stringer
Consultant Nephrologist, Queen Elizabeth Hospital Birmingham, Birmingham, UK
17. Acute kidney injury
18. Chronic kidney disease and end-stage renal disease

Denise Taylor
Senior Lecturer, Graduate School of Nursing, Midwifery and Health, Victoria University of Wellington, New Zealand
33. Dementia

Ruben Thanacoody
Consultant Physician and Clinical Pharmacologist, Newcastle upon Tyne Hospitals NHS Foundation Trust; Honorary Clinical Senior Lecturer, Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK
4. Drug interactions

Sarah Walsh
Consultant Dermatologist, Department of Dermatology, Kings College Hospital NHS Foundation Trust, London, UK
57. Drug-induced skin disorders

John Warburton
Critical Care Pharmacist, Bristol Royal Infirmary, University Hospitals Bristol NHS Foundation Trust, Bristol, UK
6. Laboratory data

Martin P. Ward-Platt
Consultant Paediatrician and Honorary Clinical Reader in Neonatal and Paediatric Medicine, Newcastle Neonatal Service, Royal Victoria Infirmary, Newcastle upon Tyne, UK
9. Neonates

David Webb
Chief Pharmacist, Guy's and St Thomas' NHS Foundation Trust, London, UK
1. Clinical pharmacy practice

Paul Whitaker
Consultant in Respiratory Medicine, Department of Respiratory Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, UK
41. Tuberculosis

Cate Whittlesea
Professor of Pharmacy Practice and Associate Director of Clinical Education, UCL School of Pharmacy, University College London, London, UK
2. Prescribing

Simon J. Wilkins
Senior Lecturer and Programme Director, Cardiff University School of Medicine, Cardiff, UK
23. Thrombosis

Helen Williams
Consultant Pharmacist for Cardiovascular Disease, South London; Clinical Director for Atrial Fibrillation, Health Innovation Network; Clinical Associate for CV Disease, Southwark CCG; Clinical Network Lead for CV Disease, Lambeth CCG, Hosted by Southwark CCG, Medicines Optimisation Team, Southwark CCG, London, UK
19. Hypertension
24. Dyslipidaemia

Ken Woodhouse
Professor Emeritus of Geriatric Medicine, Cardiff University, Cardiff, UK
11. Geriatrics

Richard Woolf
Academic Clinical Lecturer and Specialist Registrar in Dermatology, St John's Institute of Dermatology, King's College London, Guy's Hospital, London, UK
58. Eczema and psoriasis

Laura Yates
Head of Teratology, UK Teratology Information Service, Newcastle Drug and Therapeutics Centre, Newcastle upon Tyne, UK
48. Drugs in pregnancy and lactation

Contents

SECTION 1

GENERAL

1 Clinical Pharmacy Practice

Duncan McRobbie, David Webb and J. Graham Davies

Key points

- Clinical pharmacy comprises a set of skills that promote the optimal use of medicines for individual patients. Optimising the use of medicines requires a patient-centred approach that is grounded in principles of safety, evidence-based and consistent practice, and an understanding of the patient's experience.
- Clinical pharmacy has enabled pharmacists to shift from a product-oriented role towards direct engagement with patients and the value they derive from, or the problems they encounter with, their medicines.
- Achieving specific and positive patient outcomes from the optimal use of medicines is a characteristic of the pharmaceutical care process. The practice of clinical pharmacy is an essential component of pharmaceutical care.
- The three main elements of the care process are assessing the patient, determining the care plan and evaluating the outcome.
- An ability to consult with patients is a key step in the delivery of pharmaceutical care and the optimal use of medicines. Consultation skills require regular review and practice, regardless of the practitioner's experience.

Clinical pharmacy encourages pharmacists and pharmacy support staff to shift their focus from product orientation to more direct engagement with patients, to maximise the benefits that individuals obtain from the medicines they take. Since the late 1980s the practice of clinical pharmacy has grown from a collection of patient-related functions to a process in which all actions are undertaken with the intention of achieving explicit outcomes for the patient. In doing so clinical pharmacy has moved forward to embrace the philosophy of pharmaceutical care (Hepler and Strand, 1990) and, more recently, the principles of medicines optimisation (Royal Pharmaceutical Society, 2013).

The aim of this chapter is to provide a practical framework within which knowledge of therapeutics and an understanding of clinical practice can best be utilised. This chapter describes a pragmatic approach to applying aspects of the pharmaceutical care process and the specific skills of clinical pharmacy to support the optimal use of medicines in a manner that does not depend on the setting of the practitioner or patient.

Development of clinical practice in pharmacy

The emergence of clinical pharmacy as a form of professional practice has been attributed to the poor medicines control systems that existed in hospitals during the early 1960s (Cousins and Luscombe, 1995). Although provoked by similar hospital-associated problems, the nature of the professional response differed between the USA and the UK.

In the USA the approach was to adopt unit dose dispensing and pursue decentralisation of pharmacy services. In the UK the unification of the prescription and the administration record meant this document needed to remain on the hospital ward and required the pharmacist to visit the ward to order medicines. Clinical pharmacy developed from the presence of pharmacists in these patient areas and their interest in promoting safer medicines use. This was initially termed 'ward pharmacy', but participation in medical ward rounds in the late 1970s signalled the transition to clinical pharmacy.

Medication safety may have been the spur, but clinical pharmacy in the 1980s grew because of its ability to promote the cost-effective use of medicines in hospitals. This role was recognised by the government, which in 1988 endorsed the implementation of clinical pharmacy services to secure value for money from medicines. Awareness that support depended to an extent on the quantification of actions and cost savings led several groups to develop ways of measuring pharmacists' clinical interventions. Coding systems were necessary to aggregate large amounts of data in a reliable manner, and many of these drew upon the eight steps (Table 1.1) of the drug use process (DUP) indicators (Hutchinson et al., 1986).

Data collected from these early studies revealed that interventions had very high physician acceptance rates, were made most commonly at the 'select regimen' and 'need for drug' stages of the DUP, and were influenced by hospital ward type (intensive care and paediatrics having the highest rates), pharmacist seniority (rates increasing with seniority) and time spent on wards (Barber et al., 1997).

Despite the level of activity that intervention monitoring revealed, coupled with evidence of cost containment and a broadly supportive healthcare system, frustrations began to

Table 1.1 Drug use process indicators

DUP stage	Action
Establish need for a drug	Ensure there is an appropriate indication for each medicine and that all medical problems are addressed therapeutically. Consider deprescribing medicines that are no longer appropriate.
Select drug	Select and recommend the most appropriate medicine based upon the ability to reach therapeutic goals, with consideration of patient variables, formulary status and cost of therapy.
Select regimen	Select the most appropriate medicines for accomplishing the desired therapeutic goals at the least cost without diminishing effectiveness or causing toxicity.
Provide drug	Facilitate the dispensing and supply process so that medicines are accurately prepared, dispensed in ready-to-administer form and delivered to the patient on a timely basis.
Administer drug	Ensure that appropriate devices and techniques are used for medicines administration.
Monitor drug therapy	Monitor medicines for effectiveness or adverse effects to determine whether to maintain, modify or discontinue.
Counsel patient	Counsel and educate the patient or caregiver about the patient's therapy to ensure proper use of medicines.
Evaluate effectiveness	Evaluate the effectiveness of the patient's medicines by reviewing all the previous steps of the DUP and taking appropriate steps to ensure that the therapeutic goals are achieved.

DUP, Drug use process.

appear. These in part stemmed from a lack of certainty about the fundamental purpose of clinical pharmacy and also from tensions between the desire for clinical specialisation and organisational goals of improving services more generally in hospitals and other care settings.

Pharmaceutical care

A need to focus on outcomes of medicines use, as opposed to the functions of clinical pharmacy, became apparent (Hepler and Strand, 1990). The launch of pharmaceutical care as the 'responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life' (Hepler and Strand, 1990, p. 539) was a landmark in the topography of pharmacy practice. In reality, this was a step forward rather than a revolutionary leap, as expansion of the traditional dispensing role and the acquisition of new responsibilities, in particular

Table 1.2 Definitions of clinical pharmacy, pharmaceutical care and medicines optimisation

Term	Definition
Clinical pharmacy	Clinical pharmacy comprises a set of functions that promote the safe, effective and economic use of medicines for individual patients. Clinical pharmacy process requires the application of specific knowledge of pharmacology, pharmacokinetics, pharmaceutics and therapeutics to patient care.
Pharmaceutical care	Pharmaceutical care is a cooperative, patient-centred system for achieving specific and positive patient outcomes from the responsible provision of medicines. The practice of clinical pharmacy is an essential component in the delivery of pharmaceutical care.
Medicines optimisation	Medicines optimisation aims to ensure that the right patients get the right choice of medicine at the right time. The purpose is to help patients take their medicines appropriately and, by doing so, avoid unnecessary treatment, improve safety and outcomes, and reduce wastage. Ultimately it can support patients to take greater ownership of their treatment.

the ability to be able to handle the interpersonal relationships required at the interface of the pharmacy system and the patient, had been debated for some time (Brodie, 1981).

The delivery of pharmaceutical care is dependent on the practice of clinical pharmacy, but the key feature of care is that the practitioner takes responsibility for a patient's medicines-related needs and is held accountable for that commitment. None of the definitions of pharmaceutical care is limited by reference to a specific professional group. Although pharmacists and pharmacy support staff would expect to play a central role in pharmaceutical care, it is essentially a cooperative system that embraces the contribution of other professionals and patients (Table 1.2). The philosophy of pharmaceutical care anticipated healthcare policy in which certain functions, such as the prescribing of medicines, have extended beyond their traditional professional origins to be undertaken by those trained and identified to be competent to do so.

Medication-related problems

When the outcome of medicines use is not optimal, the underlying medication-related problem (MRP) can be classified according to the criteria set out in Box 1.1 (Hepler and Strand, 1990). Some MRPs are associated with significant morbidity and mortality. Preventable medication-related hospital admissions in the UK and USA have been estimated to have a prevalence rate of 4% to 5%, indicating that gains in public health from improving prescribing, monitoring and adherence to medicines would be sizeable (Howard et al., 2003; Winterstein et al., 2002).

In prospective studies, up to 28% of accident and emergency department visits have been identified as medication related, of

Box 1.1 Categories of medication-related problems

- Untreated indication
- Treatment without indication
- Improper drug selection
- Too little drug
- Too much drug
- Non-adherence
- Adverse drug reaction
- Drug interaction

which 70% were deemed preventable (Zed, 2005). Again the most frequently cited causes were non-adherence and inappropriate prescribing and monitoring. In England adverse drug reactions (ADRs) have been identified as the cause of 6.5% of hospital admissions for patients older than 16 years. The median bed stay for patients admitted with an ADR was 8 days, representing 4% of bed capacity. The projected annual cost to the National Health Service (NHS) was £466 million, the equivalent of seven 800-bed hospitals occupied by patients admitted with an ADR. More than 70% of the ADRs were determined to have been avoidable (Pirmohamed et al., 2004).

Between 2005 and 2010 more than half a million medication incidents were reported to the National Patient Safety Agency, and 16% of these reports involved actual patient harm (Cousins et al., 2012). In 2004 the direct cost of medication errors in NHS hospitals, defined as preventable events that may cause or lead to inappropriate medicines use or harm, was estimated to lie between £200 and £400 million per year. To this should be added the costs arising from litigation (Department of Health, 2004). In care homes, one study found that more than two-thirds of residents were exposed to one or more medication errors (Barber et al., 2009), whilst in hospitals a prescribing error rate of almost 9% has been identified (Doran et al., 2010). In addition nearly a third of patients are non-adherent 10 days after starting a new medicine for a chronic condition, of whom 45% are intentionally non-adherent (Barber et al., 2004), a significant contributor to the £150 million per annum estimated avoidable medicines waste in primary care (York Health Economics Consortium and School of Pharmacy, 2010). The scale of the misadventure that these findings reveal, coupled with increasing concerns about the costs of drug therapy, creates an opportunity for a renaissance in clinical pharmacy practice, providing that it realigns strongly with the principles of medicines optimisation. Pharmacists and their teams are uniquely placed to help reduce the level of medication-related morbidity in primary care by virtue of their skills and accessibility, and by building on relationships with general practice.

Medicines optimisation

The aim of medicines optimisation is to help patients take their medicines appropriately and, by doing so, improve safety and outcomes, avoid unnecessary treatment and reduce wastage. Ultimately it supports patients in taking greater ownership of their treatment (Royal Pharmaceutical Society, 2013). At its heart are four guiding principles:

- communicating with the patient and/or his or her carer about the patient's choice and experience of using medicines to manage his or her condition;
- supporting the most appropriate choice of clinically and cost-effective medicines (informed by the best available evidence base);
- ensuring that medicines use is as safe as possible, including safe processes and systems, effective communication between professionals and the minimising likelihood of unwanted effects and interactions;
- making medicines optimisation part of routine practice by routinely discussing with patient, carers and other health professionals how to achieve the best outcomes from medicines.

By locating clinical pharmacy skills within a pharmaceutical care philosophy, medicines optimisation seeks to be the step change that will better realise the benefits of treatment with medicines and reduce both suboptimal use and MRPs. It is a patient-centred endeavour based firmly on professionalism and partnership.

Evidence supporting the unique clinical contribution of pharmacists has been building since the launch of pharmaceutical care in the 1990s. In the USA, for example, pharmacists' participation in physician ward rounds was shown to reduce adverse drug events by 78% and 66% in general medical (Kucukarslan et al., 2003) and intensive care settings (Leape et al., 1999), respectively. A study covering 1029 US hospitals was the first to indicate that both centrally based and patient-specific clinical pharmacy services are associated with reduced mortality rates (Bond et al., 1999). The services involved were medicines information, clinical research performed by pharmacists, active pharmacist participation in resuscitation teams and pharmacists undertaking admission medication histories.

In the UK the focus also has been on prevention and management of MRPs. Recognition that many patients either fail to benefit or experience unwanted effects from their medicines has elicited two types of response from the pharmacy profession. Firstly, to put in place, and make use of, a range of postgraduate initiatives and programmes to meet the developmental needs of pharmacists working in clinical settings; secondly, the re-engineering of pharmaceutical services to introduce schemes for medicines optimisation at an organisational level. These have ranged from specific initiatives to target identified areas of medication risk, such as pharmacist involvement in anticoagulation services, to more general approaches where the intention is to ensure consistency of medicines use, particularly across care interfaces. Medicines reconciliation on hospital admission ensures that medicines prescribed to in-patients correspond to those that the patient was taking prior to admission. Guidance recommends that medicines reconciliation should be part of standard care and that pharmacists should be involved as soon as possible after the patient has been admitted (National Institute for Health and Care Excellence [NICE], 2015). The process requires the name, dosage, frequency and route of administration to be established for all medicines taken prior to admission. The information collected as part of medicines reconciliation is a prerequisite for medication review that the NICE guideline defines as a

structured, critical examination of a person's medicines with the objective of reaching an agreement about treatment, optimising the impact of medicines, minimising the number of MRPs and reducing waste (NICE, 2015).

Pharmaceutical consultation

Structured postgraduate education has served to improve the knowledge of clinical pharmacists, but fully achieving the goals of pharmaceutical care has proved more challenging. Part of the difficulty has been the requirement to place the patient at the heart of the system, rather than being a relatively passive recipient of drug therapy and associated information. To deliver pharmaceutical care requires more than scientific expertise. It mandates a system that describes first the role and responsibilities of the pharmacist and provides the necessary infrastructure to support them in this role, and secondly a clear process by which the pharmacist can deliver his or her contribution to patient care.

Pharmaceutical care is predicated on a patient-centred approach to identifying, preventing or resolving medicine-related problems. Central to this aim is the need to establish a therapeutic relationship. This relationship must be a partnership in which the pharmacist works with the patient to resolve medication-related issues in line with the patient's wishes, expectations and priorities. Table 1.3 summarises the three key elements of the care process (Cipolle et al., 1998). Research in chronic diseases has shown that self-management is promoted when patients more fully participate in the goal-setting and planning aspects of their care (Sevick et al., 2007). These are important aspects to consider when pharmacists consult with patients. In community pharmacy in the UK, approaches to help patients use their medicines more effectively are the medicines use review (MUR) and the new medicines service (NMS). The MUR uses the skills of pharmacists to help patients understand how their medicines should be used, why they take them and to identify any problems patients have in relation to their medicines, providing feedback to the prescriber if necessary. Two goals of MUR are to improve the adherence of patients to prescribed medicines and to reduce medicines wastage. The NMS has been introduced to allow pharmacists to support patients with long-term conditions who have been recently started on a medicine to target medicines adherence early. Currently the service targets four key conditions/therapies: asthma and chronic obstructive pulmonary disease, type 2 diabetes, hypertension and antiplatelet or anticoagulant therapy (Pharmaceutical Services Negotiating Committee, 2013). Clinical guidance on medicines adherence emphasises the importance of patient involvement in decisions about medicines (NICE, 2009).

Recommendations include that healthcare professionals should:

- Adapt their consultation style to the needs of individual patients.
- Consider any factors that may affect patients' involvement in the consultation.
- Establish the most effective way of communicating with each patient.
- Encourage patients to ask about their condition and treatment.
- Be aware that consultation skills can be improved to enhance patient involvement.

Table 1.3 Key elements of the care process

Element	Purpose
Assessment	The main goal of assessment is to establish a full medication history and highlight actual and potential medication-related problems.
Care plan	The care plan should clearly state the goals to optimise care and the responsibilities of both the pharmacist and the patient in attaining the stated goals.
Evaluation	The evaluation reviews progress against the stated patient outcomes.

Medicines-taking behaviour

The need for a care process that ensures that the patient is involved at all stages has become clearer as the extent of non-adherence to medicines has been revealed. Significant proportions (between 30% and 50%) of patients with chronic conditions do not take their prescribed medicines as directed. Many factors are thought to influence a patient's decision to adhere to a prescribed regimen. These include the characteristics of the disease and the treatment used to manage it, the patient's beliefs about his or her illness and medicines, as well as the quality of the interaction between the patient and healthcare practitioners. Non-adherence can be categorised broadly into two types: intentional and unintentional. Unintentional non-adherence may be associated with physical or sensory barriers to taking medicines, for example, not being able to swallow or unable to read the labels, forgetfulness or poor comprehension. Traditionally pharmacists have played a key role in helping patients overcome these types of problems, but they have been less active in identifying and resolving intentional non-adherence.

Intentional (or deliberate) non-adherence may be because of a number of factors. Recent work in health psychology has shaped our understanding of how patients perceive health and illness, and why they often decide not to take their medicines. When people receive information about illness and its treatment, it is processed in accordance with their own belief systems. Often patients' perceptions are not in tune with the medical reality and when this occurs, taking medicines may not make sense to the individual. For example, a patient diagnosed with hypertension may view the condition as one that is caused by stress and, during periods of lower stress, may not take their prescribed medicines (Baumann and Leventhal, 1985). Consequently, a patient holding this view of hypertension may be at increased risk of experiencing an adverse outcome such as a stroke.

Research has shown that patient beliefs about the necessity of the prescribed medication and concerns about the potential long-term effects have a strong influence on medicines-taking behaviour (Horne et al., 2013). However, a patient's beliefs about the benefits and risks of medicines are rarely explored during consultation, despite evidence of an association between non-adherence

and the patient's satisfaction with the consultation process adopted by practitioners (Ley, 1988). Classifying patients as intentional or unintentional non-adherers does not fully explain the reasons for such behaviour. A recently proposed psychological framework takes into account a wider range of factors. Known as the COM-B framework (Michie et al., 2011), it proposes that for people to engage in a behaviour, they must have the capability (C), opportunity (O) and motivation (M) to do so. For example, a complex treatment regimen may be beyond the planning ability of a patient (capability barrier), especially if the patient fears disclosure about a health condition that is incorrectly perceived to have a detrimental effect on his or her ability to do his or her job (opportunity barrier). Over time non-adherence may have no discernible effect on the patient's health status, so he or she makes the decision to stop treatment completely (motivation barrier). Interventions designed to support behaviour change need to address any barriers within all three key components. Jackson et al. (2014) provide more examples of the COM-B framework applied to medicines adherence.

Consultation process

There are several comprehensive accounts of the functions required to satisfy each stage of the DUP, but few go on to explore how the pharmacist can create a therapeutic relationship with his or her patient. The ability of a pharmacist to consult effectively is fundamental to pharmaceutical care, and this includes establishing a platform for achieving adherence/concordance. Nurturing a relationship with the patient is essential to understanding the patient's medication-related needs.

Descriptions of pharmaceutical consultation have been confined largely to the use of mnemonics such as WWHAM, AS METTHOD and ENCORE (Box 1.2). These approaches provide the pharmacist with a rigid structure to use when questioning patients about their symptoms, but, although useful, serve to make the symptom or disease the focus of the consultation rather than the patient. A common misconception is that healthcare professionals who possess good communication skills are also able to consult effectively with patients; this relationship will not hold if there is a failure to grasp the essential components of the consultation technique. Research into patients' perceptions of their illness and treatment has demonstrated that they are more likely to adhere to their medication regimen, and be more satisfied with the consultation, if their views about illness and treatment have been taken into account and the risks and benefits of treatment discussed (Martin et al., 2005). The mnemonic approach to consultation does not adequately address the complex interaction that may take place between a patient and a healthcare practitioner.

Undertaking a pharmaceutical consultation can be considered as a series of four interlinked phases, each with a goal and set of competencies (Table 1.4). These phases follow a problem-solving pattern, embrace relevant aspects of adherence research and attempt to involve the patient at each stage in the process. This approach forms the basis of the medication-related consultation framework, a tool shown to improve the capability of pharmacists to consult (Abdel-Tawab et al., 2011). For effective consultation the practitioner also needs to draw upon a range of communication behaviours (Box 1.3). By integrating the agendas of both patient and pharmacist, the approach outlined earlier provides the vehicle for agreeing on the issues to be addressed and the responsibilities accepted by each party in achieving the desired outcomes.

Box 1.2 Mnemonics used in the pharmacy consultation process

WWHAM
Who is it for?
What are the symptoms?
How long has it been going on?
Action taken?
Medicines taken?

AS METTHOD
Age of the patient?
Self or for someone else?
Medicines being taken?
Exactly what do you mean (by the symptom)?
Time and duration of the symptom?
Taken any action (medicine or seen a healthcare practitioner)?
History of any disease?
Other symptoms?
Doing anything to alleviate or worsen the symptom?

ENCORE
Evaluate the symptom, its onset, recurrence and duration.
No medication is always an option.
Care when dealing with specific patient groups, notably the elderly, the young, nursing mothers, pregnant women, those receiving specific medication such as methotrexate and anticoagulants, and those with a particular disease, for example, renal impairment.
Observe the patient for signs of systemic disturbance and ask about presence of fever, loss of weight and any accompanying physiological disturbance.
Refer when in doubt.
Explain any course of action recommended.

The ability to consult with patients is a key process in the delivery of pharmaceutical care and consequently requires regular review and development, regardless of experience. To ensure these core skills are developed, individuals should use trigger questions to prompt reflection on their approach to consulting (Box 1.4).

Clinical pharmacy functions and knowledge

The following practical steps in the delivery of pharmaceutical care are based largely on the DUP. The 'select regimen' and 'drug administration' indicators have been amalgamated at step 3.

Step 1. Establishing the need for drug therapy

For independent prescribers this step includes establishing a diagnosis and then balancing the risks and benefits of treatment against the risks posed by the disease. Current practice for most pharmacists means that another professional, most frequently a

Table 1.4 Pharmaceutical consultation process

Element	Goal	Examples of associated competencies
Introduction	Building a therapeutic relationship	Invites patient to discuss medication or health-related issue Discusses structure and purpose of consultation Negotiates shared agenda
Data collection and problem identification	Identifying the patient's medication-related needs	Takes a full medication history Establishes patient's understanding of his or her illness Establishes patient's understanding of the prescribed treatment Identifies and prioritises patient's pharmaceutical problems
Actions and solutions	Establishing an acceptable management plan with the patient	Involves patient in designing management plan Tailors information to address patient's perception of illness and treatment Checks patient's understanding Refers appropriately
Closure	Negotiating safety netting strategies with the patient	Provides information to guide action when patient experiences problems with management plan Provides further appointment or contact point

Box 1.3 Consultation behaviours

- Apply active listening.
- Appropriately use open and closed questions.
- Respect patient.
- Avoid jargon.
- Demonstrate empathy.
- Deal sensitively with potentially embarrassing or sensitive issues.

Box 1.4 Key postconsultation questions

- Do I know more now about the patient?
- Was I curious?
- Did I really listen?
- Did I find out what really mattered to the patient?
- Did I explore the patient's beliefs and expectations?
- Did I identify the patient's main medication-related problems?
- Did I use the patient's thoughts when I started explaining?
- Did I share the treatment options with the patient?
- Did I help my patient to reach a decision?
- Did I check that my patient understood what I said?
- Did we agree?
- Was I friendly?

doctor, will have diagnosed the patient's presenting condition and any co-existing disease. The pharmacist's role, therefore, is often one of providing information to the independent prescriber on the expected benefits and risks of drug therapy by evaluating both the evidence base and individual patient factors. Pharmacists also draw on these concepts as they become more involved in prescribing and adjusting therapy for patients under their care.

The evidence for one specific mode of therapy may not be conclusive. In this circumstance the pharmacist will need to call on his or her understanding of the principles of pharmaceutical science and on clinical experience to provide the best advice possible.

Step 1.1. Relevant patient details

Without background information on the patient's health and social circumstances (Table 1.5) it is difficult to establish the existence of, or potential for, MRPs. When this information is lacking, a review solely of prescribed medicines will probably be of limited value and incurs the risk of making a flawed judgement on the appropriateness of therapy for that individual.

Current and co-existing conditions with which the patient presents can be established from various sources. In medical notes the current diagnosis (Δ) or differential diagnoses (ΔΔ) will be documented, as well as any medical history. Other opportunities to gather information come from discussion with the patient and participation in medical rounds. In primary care, primary care clinicians' computer systems carry information on the patient's diagnosis.

Once the diagnosis and past medical history (PMH) are established, it is then possible to identify the medicines that would be expected to be prescribed for each indication, based on contemporary evidence. This list of medicines may be compiled from appropriate national or international guidelines, local formularies and knowledge of current practice.

Step 1.2. Medication history

A medication history is the part of a pharmaceutical consultation that identifies and documents allergies or other serious adverse medication events, as well as information about how medicines are taken currently and have been taken in the past. It is the starting point for medicines reconciliation and medication review.

Obtaining accurate and complete medication histories has been shown to have a positive effect on patient care, and pharmacists have demonstrated that they can compile such histories with a high degree of precision and reliability as part of medicines reconciliation. The benefit to the patient is that prescribing errors of omission or transcription are identified and corrected early, reducing the risk of harm and improving care.

Discrepancies between the history recorded by the medical team and that which the pharmacist elicits fall into two categories: intentional (where the medical team has made a decision to alter the regimen) or unintentional (where a complete record was not obtained). Discrepancies should be clarified with the prescriber or referred to a more senior pharmacist. Box 1.5 lists the key components of a medication history.

Table 1.5 Relevant patient details

Factor	Implications
Age	The very young and the very old are most at risk of medication-related problems. A patient's age may indicate his or her likely ability to metabolise and excrete medicines, and has implications for step 2 of the drug use process.
Gender	This may alter the choice of the therapy for certain indications. It may also prompt consideration of the potential for pregnancy or breastfeeding.
Ethnic or religious background	Racially determined predispositions to intolerance or ineffectiveness should be considered with certain classes of medicines, for example, angiotensin-converting enzyme inhibitors in Afro-Caribbean people. Formulations may be problematic for other groups, for example, those based on blood products for Jehovah's Witnesses or porcine-derived products for Jewish patients.
Social history	This may impact on ability to manage medicines and influence pharmaceutical care needs, for example, living alone or in a care home, or availability of nursing, social or informal carers
Presenting complaint	The presenting complaint includes symptoms the patient describes and the signs identified by the doctor on examination. Pharmacists should consider whether these might be attributable to the adverse effects of prescribed or purchased medicines.
Working diagnosis	This should enable the pharmacist to identify the classes of medicines that would be anticipated on the prescription based on current evidence.
Medical history	Understanding the patient's other medical conditions and his or her history helps ensure that management of the current problem does not compromise a prior condition and guides the selection of appropriate therapy by identifying potential contraindications.
Laboratory or physical findings	The focus should be on findings that may affect therapy, such as: • renal function • liver function • full blood count • blood pressure • cardiac rhythm Results may convey a need for dosage adjustment or presence of an adverse reaction.

Step 1.3. Deprescribing

Given that many problems associated with medicines use often occur as a result of problematic polypharmacy, sometimes because of a lack of ongoing review, a new concept, namely that of deprescribing, has emerged. This has been defined by Reeve et al. (2015) as 'the process of withdrawal of an inappropriate medication, supervised by a healthcare professional with the goal of managing polypharmacy and improving outcomes' (p. 1264). This should now be seen as an important aspect of establishing the need for drug therapy to limit the adverse effects seen by the continued prescribing of inappropriate medicines.

Box 1.5 Key components of a medication history

1. Introduce yourself to the patient and explain the purpose of the consultation.
2. Identify any allergies or serious adverse reactions and record these on the prescription chart, care notes or patient medication record.
3. Ascertain information about prescribed and non-prescribed treatments from:
   - the patient's recall
   - medicines in the patient's possession
   - referral letter (usually from the patient's primary care doctor)
   - copy of prescriptions issued or a repeat prescription list
   - medical notes
   - contact with the appropriate community pharmacist or primary care doctor
4. Ensure the following are recorded:
   - generic name of medicine (unless specific brand is required)
   - dose
   - frequency
   - duration of therapy
5. Ensure items such as inhalers, eye drops, topical medicines, and herbal and homeopathic remedies are included because patients often do not consider these as medicines.
6. Ascertain the patient's medication-taking behaviour.
7. Consider practical issues such as swallowing difficulties, ability to read labels and written information, container preferences, and ordering or supply problems.
8. Document the history in an appropriate format.
9. Note any discrepancies between this history and that recorded by other healthcare professionals.
10. Ascertain whether these discrepancies are intentional (from patient, nursing staff, medical staff or medical notes).
11. Communicate non-intentional discrepancies to the prescriber.
12. Document any other important medication-related information in an appropriate manner, for example, implications of chronic renal failure, dialysis and long-term steroid treatment.

Step 2. Selecting the medicine

The issues to be tackled at this stage include clinical and cost-effective selection of a medicine in the context of individual patient care. The list of expected treatments generated at step 1 is now scrutinised for its appropriateness for the patient. This requires three separate types of interaction to be identified: drug–patient, drug–disease and drug–drug. The interactions should be prioritised in terms of likelihood of occurrence and the potential severity of outcome should they occur.

Step 2.1. Identify drug–patient interactions

Many medicines have contraindications or cautions to their use that relate to age groups or gender. Potential drug–patient interactions should be identified that may arise with any of

the medicines that could be used to treat the current and pre-existing conditions. Types of drug–patient interactions may include allergy or previous ADR, the impact of abnormal renal or hepatic function or chronic heart failure on the systemic availability of some medicines, and patients' preferences for certain treatment options, formulations or routes of administration.

Step 2.2. Identify drug–disease interactions

A drug–disease interaction may occur when a medicine has the potential to make a pre-existing condition worse. Older people are particularly vulnerable due to the co-existence of several chronic diseases and exposure to polypharmacy. Prevention of drug–disease interactions requires an understanding of the pharmacodynamic properties of medicines and an appreciation of their contraindications.

Step 2.3. Drug–drug interactions

Medicines may affect the action of other medicines in a number of ways. Those with similar mechanisms of action may show an enhanced effect if used together, whilst those with opposing actions may reduce each other's effectiveness. Metabolism of one medicine can be affected by a second that acts as an inducer or inhibitor of the cytochrome P450 enzyme system.

The practitioner should be able to identify common drug interactions and recognise those medicines with increased risk of potential interaction, such as those with narrow therapeutic indices or involving hepatic P450 metabolic pathways. It is important to assess the clinical significance of drug interactions and consider the options for effective management.

The list of potential evidence-based treatments should be reviewed for possible drug–patient, drug–disease and drug–drug interactions. The refined list can then be compared with the medicines that have been prescribed for the patient. The practitioner should explore any discrepancies to ensure the patient does not experience an MRP. This may necessitate consultation with medical staff or other healthcare professionals, or referral to a more senior pharmacist.

Step 3. Administering the medicine

Many factors influence the effect that a medicine has at its locus of action. These include the rate and extent of absorption, degree of plasma protein binding and volume of distribution, and the routes of metabolism or excretion. Factors that affect bioavailability may include the extent of absorption of the drug from the gastro-intestinal tract in relation to food and other medicines, or the amount adsorbed onto intravenous infusion bags and giving sets when used to administer medicines parenterally.

The liver has extensive capacity for drug metabolism, even when damaged. Nevertheless, the degree of hepatic impairment should be assessed from liver function tests and related to potential changes in drug metabolism. This is particularly important for medicines that require activation by the liver (prodrugs) or those whose main route of elimination is transformation into water-soluble metabolites.

Table 1.6 Pharmaceutical considerations in the administration of medicines

Dose	Is the dose appropriate, including adjustments for particular routes or formulations? Examples: differences in dose between intravenous and oral metronidazole, intramuscular and oral chlorpromazine, and digoxin tablets compared with the elixir
Route	Is the prescribed route available (is the patient nil by mouth?) and appropriate for the patient? Examples: unnecessary prescription of an intravenous medicine when the patient can swallow, or the use of a solid dosage form when the patient has dysphagia
Dosage form	Is the medicine available in a suitable form for administration via the prescribed route?
Documentation	Is documentation complete? Do nurses or carers require specific information to safely administer the medicine? Examples: appropriateness of crushing tablets for administration via nasogastric tubes, dilution requirements for medicines given parenterally, rates of administration and compatibilities in parenteral solutions (including syringe drivers)
Devices	Are devices required, such as spacers for inhalers?

Table 1.6 summarises the main pharmaceutical considerations for step 3. At this point the practitioner needs to ensure the following tasks have been completed accurately.

Step 3.1. Calculating the appropriate dose

Where doses of oral medicines require calculation, this is usually a straightforward process based on the weight of the patient. However, medicines to be administered parenterally may require more complex calculations, including knowledge of displacement values (particularly for paediatric doses) and determination of appropriate concentrations in compatible fluids and rates of infusion.

Step 3.2. Selecting an appropriate regimen

Giving medicines via the oral route is the preferred method of administration. Parenteral routes carry significantly more risks, including infection associated with vascular access. This route, however, may be necessary when no oral formulation exists or when the oral access is either impossible or inappropriate because of the patient's condition.

Although simple regimens (once- or twice-daily administration) may facilitate adherence, some medicines possess short half-lives and may need to be given more frequently. The practitioner should be familiar with the duration of action of regularly encountered medicines to ensure dosage regimens are optimally designed.

Step 4. Providing the medicine

Ensuring that a prescription is legal, legible, accurate and unambiguous contributes in large measures to the right patient receiving the right medicine at the right time. For the majority of pharmacists this involves screening prescriptions written by other professionals, but those acting as supplementary and independent prescribers need to be cognisant of guidance on prescribing, such as that contained within the British National Formulary, when generating their prescriptions.

In providing a medicine for an individual, due account must be taken of the factors that influence the continued availability and supply of the medicine within the hospital or community setting, for example, formulary and drug tariff status, primary/secondary shared care arrangements and whether the prescribed indication is within the product licence. This is particularly important with unlicensed or non-formulary medicines when information and agreement on continuation of prescribing, recommended monitoring and availability of supply are transferred from a hospital to a primary care setting.

Risks in the dispensing process are reduced by attention to products with similar names or packaging, patients with similar names, and when supplying several family members at the same time. Medicines should be labelled accurately, with clear dosage instructions and advisory labels, and presented appropriately for patients with specific needs, for example, the visually impaired, those unable to read English or those with limited dexterity.

Step 5. Monitoring therapy

Monitoring criteria for the effectiveness of treatment and its potential adverse effects can be drawn from the characteristics of the prescribed medicines used or related to specific patient needs. Close monitoring is required for medicines with narrow therapeutic indices and for the subset of drugs where therapeutic drug monitoring may be beneficial, for example, digoxin, phenytoin, theophylline and aminoglycosides. Anticoagulant therapy, including warfarin and unfractionated heparin, is associated with much preventable medication-related morbidity and always warrants close scrutiny.

Throughout this textbook, details are presented on the monitoring criteria that may be used for a wide range of medicines. Patients with renal or hepatic impairment or an unstable clinical condition need particular attention because of the likely requirement for dosage adjustment or change in therapy.

Step 6. Patient advice and education

A vast quantity of information on drug therapy is available to patients. The practitioner's contribution in this context is to provide accurate and reliable information in a manner that the patient can understand. This may require the pharmacist to convey the benefits and risks of therapy, as well as the consequences of not taking medicines.

Information about medicines is best provided at the time of, or as soon as possible after, the prescribing decision. In the hospital setting this means enabling patients to access information throughout their stay, rather than waiting until discharge. With many pharmacy departments providing medicines in patient packs, the patient can be alerted to the presence of information leaflets, encouraged to read them and ask any questions they may have. This approach enables patients to identify their own information needs and ensures that pharmacists do not create a mismatch between their own agenda and that of the patient. However, there will be a need to clearly explain the limitations of leaflets, particularly when medicines are prescribed for unlicensed indications.

Although the research on adherence indicates the primacy of information that has been tailored to the individual's needs, resources produced by national organisations, such as Diabetes UK (https://www.diabetes.org.uk) and British Heart Foundation (https://www.bhf.org.uk), may also be of help to patients and their family or carers. In addition, patients often require specific information to support their daily routine of taking medicines. All written information, including medicines reminder charts, should be dated and include contact details of the pharmacist to encourage patients to raise further queries or seek clarification.

Step 7. Evaluating effectiveness

The provision of drug therapy for the purpose of achieving definite outcomes is a fundamental objective of pharmaceutical care. These outcomes need to be identified at the outset and form the basis for evaluating the response to treatment. Practitioners delivering pharmaceutical care have a responsibility to evaluate the effectiveness of therapy by reviewing the earlier steps 1–6 and taking appropriate action to ensure the desired outcomes are achieved. Depending on the duration of direct engagement with a patient's care, this may be a responsibility the pharmacist can discharge in person, or it may necessitate transfer of care to a colleague in a different setting where outcomes can be assessed more appropriately.

Case study

The following case is provided to illustrate the application of several steps in the delivery of pharmaceutical care. It is not intended to be a yardstick against which patient care should be judged.

Case 1.1

Mr JB, a 67-year-old retired plumber, has recently moved to your area and has come to the pharmacy to collect his first prescription. He has a PMH of coronary heart disease and has recently had an elective admission where a drug-eluting coronary artery stent was inserted. He has a long history of asthma, which is well controlled with inhaled medicines.

Step 1. Establishing the need for drug therapy

What classes of medicines would you expect to be prescribed for these indications? (Answer is listed in Table 1.7.)

Table 1.7 The case of Mr JB: Potential drug interactions with the patient, the disease or other drugs

	Drug–patient interactions	Drug–disease interactions	Drug–drug interactions
Medicines that should be prescribed for coronary heart disease			
Aspirin	Previous history of dyspepsia	Aspirin should be used with caution in asthma	Combination of antiplatelet agents increases risk of bleeding
Clopidogrel	Previous history of dyspepsia		Combination of antiplatelet agents increases risk of bleeding
Statins			
β-Blockers		β-Blockers should be used with caution in asthma; if peak flows worsen, an alternative rate-controlling agent should be considered	Combination of different agents to control angina may lead to hypotension
Nitrates (glyceryl trinitrate spray)	Previous history of side effects (e.g., headache, flushing) may result in patient not using spray when required		
Medicines that may be prescribed for asthma			
β_2-Agonist inhalers	Patient's ability to use inhaler devices effectively	β_2-Agonists can cause tachycardia	
Corticosteroid inhaler			

Mr JB gives a complete medication history that indicates he takes his medicines as prescribed, he has no medication-related allergies, but he does suffer from dyspepsia associated with acute use of non-steroidal anti-inflammatory agents. He has a summary of his stent procedure from the hospital that indicates normal blood chemistry and liver function tests.

Step 2. Selecting the medicine

What drug–patient, drug–disease and drug–drug interactions can be anticipated? (See Table 1.7.)

Steps 3 and 4. Administering and providing the medicines

What regimen and individualised doses would you recommend for Mr JB? (Answer is listed in Table 1.8.)

This predicted regimen can be compared with the prescribed therapy and any discrepancies resolved with the prescriber. Step 4 (provision) in Mr JB's case would be relatively straightforward.

Steps 5, 6 and 7. Monitoring therapy, patient education and evaluation

What criteria would you select to monitor Mr JB's therapy, and what information would you share with the patient? What indicators would convey effective management of his condition? (Answer is listed in Table 1.9.)

Quality assurance of clinical practice

Quality assurance of clinical pharmacy has tended to focus on the review of performance indicators, such as intervention rates, or rely upon experienced pharmacists to observe and comment on the practice of others using local measures. The lack of generally agreed or national criteria raises questions about the consistency of these assessments, where they take place and the overall standard of care provided to patients. Following the Bristol Royal Infirmary Inquiry (2001) into paediatric cardiac surgery, there has been much greater emphasis on the need for regulation to maintain the competence of healthcare professionals, the importance of periodic performance appraisal coupled with continuing professional development and the introduction of revalidation.

The challenges for pharmacists are twofold: firstly, to demonstrate their capabilities in a range of clinical pharmacy functions and, secondly, to engage with continuing professional development in a meaningful way to satisfy the expectations of pharmaceutical care and maintain registration with, for example, the General Pharmaceutical Council in the UK. The pragmatic approach to practice and the clinical pharmacy process outlined throughout this chapter has been incorporated into a professional development framework, called the Foundation Pharmacy Framework (Royal Pharmaceutical Society, 2014), that can be used to develop skills, knowledge and other attributes irrespective of the setting of the pharmacist and their patients.

Table 1.8 The case of Mr JB: Possible therapeutic regimen

	Recommendation	Rationale
Medicines that should be prescribed for CHD		
Aspirin	75 mg daily orally after food	Benefit outweighs risk if used with PPI
Clopidogrel	75 mg daily orally after food	Benefit outweighs risk if used with PPI Length of course should be established in relation to previous stent
Lansoprazole	15 mg daily orally	Decreases risk of GI bleeds with combination antiplatelets Concerns about some PPIs reducing the effectiveness of clopidogrel makes selection of specific PPI important
Atorvastatin	40 mg daily orally	Higher doses are recommended if patient suffers an acute coronary event
Nitrates	2 puffs sprayed under the tongue when required for chest pain	
Bisoprolol	5 mg daily orally	Used for rate control to reduce anginal episodes; dose can be titrated against pulse and blood pressure
Ramipril	10 mg daily orally	To reduce the progression of CHD and heart failure
Medicines that may have been prescribed		
Salbutamol inhaler	2 puffs (200 micrograms) to be inhaled when required	Patient should follow asthma treatment plan if peak flow decreases
Beclometasone inhalers	2 puffs (400 micrograms) twice a day	Asthma treatment plan that may include twice a day increasing the dose of inhaled steroids if peak flow decreases

CHD, Coronary heart disease; GI, gastro-intestinal; PPI, proton pump inhibitor.

Table 1.9 The case of Mr JB: Monitoring criteria and patient advice

	Recommendation
Medicines that should be prescribed for CHD	
Aspirin	Ask patient about any symptoms of dyspepsia or worsening asthma
Clopidogrel	Ask patient about any symptoms of dyspepsia
Lansoprazole	If PPIs do not resolve symptoms, the primary care doctor should be consulted
Atorvastatin	Liver function tests 3 months after any change in dose or annually; creatine kinase only if presenting with symptoms of unexplained muscle pain; cholesterol levels 3 months after any change in dose, or annually if at target
Nitrates (GTN spray)	Frequency of use to be noted; increasing frequency that results in a resolution of chest pain should be reported to primary care doctor, and anti-anginal therapy may be increased *Any* use that does not result in resolution of chest pain requires urgent medical attention
Bisoprolol	Blood pressure and pulse monitored regularly, monitor peak flows on initiation
Ramipril	Renal function and blood pressure monitored within 2 weeks of any dose change or annually
Medicines that may have been prescribed for asthma	
Salbutamol inhaler	Salbutamol use should be monitored because any increase in requirements may require increase in steroid dose; monitor inhaler technique
Beclometasone inhaler	Monitor for oral candidiasis; monitor frequency of exacerbations and 'step up/step down' dose as required; monitor inhaler technique

CHD, Coronary heart disease; GTN, glyceryl trinitrate; PPI, proton pump inhibitor.

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2 Prescribing

Helen Marlow and Cate Whittlesea

Key points

- Prescribers need to assess the potential benefits and harms of treatment to support patients to obtain the best possible outcomes from their medicines.
- Patients should receive cost-effective medication appropriate to their clinical needs, in doses that meet their requirements and for an adequate period.
- Respect for patient autonomy, obtaining consent and sharing decision making is a fundamental part of the prescribing process.
- The consultation is a fundamental part of clinical practice and requires effective interpersonal reasoning and practical skills.
- Use of a consultation framework is recommended to ensure relevant issues are covered within the consultation.
- Prescribing is influenced by a complex mix of factors including evidence, external influences and cognitive biases, and these should be recognised.

To prescribe is to authorise, by means of a written prescription, the supply of a medicine. Prescribing incorporates the processes involved in decision making undertaken by the prescriber before the act of writing a prescription. Historically prescribing has been the preserve of those professionals with medical, dental or veterinary training. As the role of other healthcare professionals, pharmacists, nurses, optometrists, physiotherapists, podiatrists and therapeutic radiographers have expanded, prescribing rights have in turn been extended to them. The premise for this development has been that it better utilises the training of these professional groups, is clinically appropriate and improves patient access to medicines.

Regardless of the professional background of the individual prescriber, the factors that motivate them to prescribe a particular medicine are a complex mix of evidence of effectiveness and harms, external influences and cognitive biases. A rational approach to prescribing uses evidence, has outcome goals and evaluates alternatives in partnership with the patient. With the advent of new professional groups of prescribers (non-medical prescribers), there is a need for a systematic approach to prescribing and an understanding of the factors that influence the decision to prescribe a medicine. These issues will be covered in the following sections. Initially the fundamentals of rational and effective prescribing will be discussed followed by a brief outline of the acquisition of prescribing rights by pharmacists and the associated legal framework. The prescribing process and factors which influence it will also be covered.

Rational and effective prescribing

Prescribing a medicine is one of the most common interventions in health care used to treat patients. Medicines have the potential to save lives and improve the quality of life, but they also have the potential to cause harm, which can sometimes be catastrophic. Therefore, prescribing of medicines needs to be rational and effective to maximise benefit and minimise harm. This is best done using a systematic process that puts the patient at the centre (Fig. 2.1).

What is meant by rational and effective prescribing?

No universally agreed-on definition of good prescribing exists. The World Health Organization (WHO) promotes the rational use of medicines, which requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period and at the lowest cost to them and their community (de Vries et al., 1994). However, a more widely used framework for good prescribing has been described (Barber, 1995) and identifies what the prescriber should be trying to achieve, both at the time of prescribing and in monitoring treatment thereafter. The prescriber should have the following four aims:

- maximise effective,
- minimise risks,
- minimise costs,
- respect the patient's choices.

This model links to the four key principles of biomedical ethics – beneficence, non-maleficence, justice and veracity, and respect for autonomy – and can be applied to decision making at both an individual patient level and when making decisions about medicines for a wider population, for example, in a Drug and Therapeutics Committee. One of the strengths of this model is the consideration of the patient's perspective and the recognition of the inherent tensions among the four key aims.

Another popular framework to support rational prescribing decisions is known as STEPS (Preskorn, 1994). The STEPS model includes five criteria to consider when deciding on the choice of treatment:

- safety
- tolerability
- effectiveness
- price
- simplicity

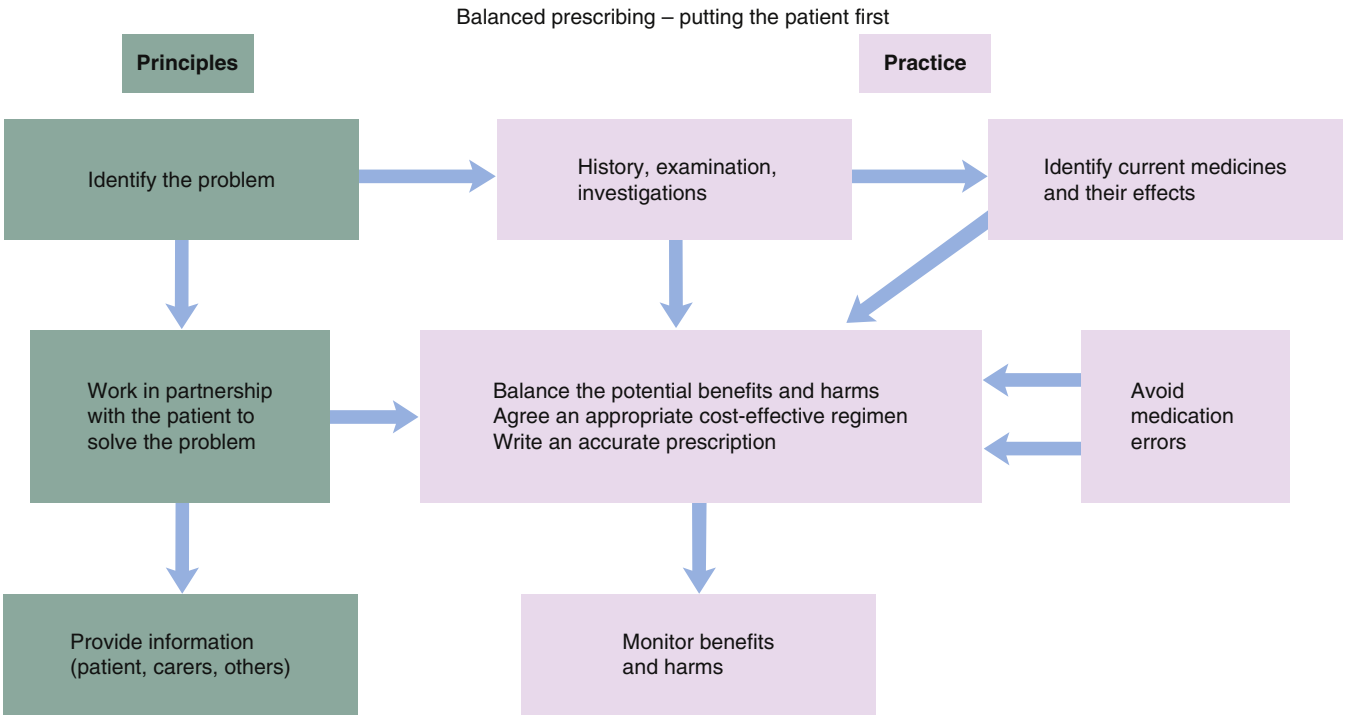

Fig. 2.1 A framework for good prescribing. (From Background Briefing. A blueprint for safer prescribing 2009 with kind permission from the British Pharmacological Society, London.)

Inappropriate or irrational prescribing

Good prescribing is sometimes defined as the lack of irrational or inappropriate prescribing. Prescribing can be described as irrational for many reasons; for example:

- poor choice of a medicine,
- inappropriate polypharmacy or co-prescribing of interacting medicine,
- prescribing for a self-limiting condition,
- prescribing without considering the risk of harm and managing the risk,
- continuing to prescribe for a longer period than necessary,
- prescribing too low a dose of a medicine,
- prescribing without taking account of the patient's wishes.

Inappropriate or irrational prescribing can result in serious morbidity and mortality, particularly when childhood infections or chronic diseases such as hypertension, diabetes, epilepsy and mental disorders are being treated. Inappropriate prescribing also represents a waste of resources and, as in the case of antimicrobials, may harm the health of the public by contributing to increased antimicrobial resistance. Finally, an over willingness to prescribe stimulates inappropriate patient demand and fails to help patients understand when they should seek out support from a healthcare professional.

Pharmacists as prescribers and the legal framework

Evolution of non-medical prescribing

In 1986 a report was published in the UK ('Cumberlege report') which recommended that community nurses should be given authority to prescribe a limited number of medicines as part of their role in patient care (Department of Health and Social Security, 1986). Up to this point prescribing in the UK had been the sole domain of doctors, dentists and veterinarians. This was followed in 1989 by a further report (the first Crown report) which recommended that community nurses should prescribe from a limited formulary (Department of Health [DH], 1989). The legislation to permit this was passed in 1992.

At the end of the 1990s, in line with the then UK Government's desire to give patients quicker access to medicines, improve access to services and make better use of the skills of healthcare professionals, the role of prescriber was proposed for other healthcare professionals. This change in prescribing to include non-medical prescribers (e.g. pharmacists and nurses) was developed following a further review (Crown, 1999). This report suggested the introduction of supplementary prescribers, that is, non-medical healthcare professionals who could prescribe, to provide appropriate treatment within a general care plan drawn up by another professional (usually a doctor) or team (Crown, 1999). This led to pharmacists and nurses qualifying as non-medical prescribers (initially as supplementary and then independent prescribers). Subsequently optometrists, physiotherapists, podiatrists and therapeutic radiographers were also able to qualify as independent prescribers.

Supplementary prescribing

The Health and Social Care Act 2001 allowed pharmacists and other healthcare professionals to prescribe. Following this legislation, in 2003 the Department of Health outlined the implementation guide allowing pharmacists and nurses to qualify as supplementary prescribers (DH, 2003). In 2005 supplementary prescribing was extended to physiotherapists, chiropodists/

Box 2.1 Overview of the requirements for a clinical management plan for supplementary prescribing

Legal requirements
Patient details • Name • Patient identification, e.g. NHS number • Patient allergies • Difficulties patient has with medicines
Disease and treatment • Condition • Class or name of medicines • Limitations on doses, strength or time of treatment • When to seek advice from or refer back to independent prescriber • Arrangements for notification of adverse drug reactions or incidents
Prescriber information • Name of independent prescriber (doctor or dentist) • Name of supplementary prescriber (pharmacist, nurse, physiotherapists, chiropodists/podiatrists, radiographers, dietitian and optometrists) • Start date • Review date

podiatrists, radiographers and optometrists (DH, 2005), with dietitians gaining prescribing rights in 2016 (National Health Service [NHS] England, 2016a). Paramedics are now awaiting legislation to become independent prescribers.

Supplementary prescribing is defined as a voluntary prescribing partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's consent. Currently a supplementary prescriber can be a nurse, pharmacist, chiropodist/podiatrist physiotherapist, radiographer, optometrist or dietitian. This prescribing arrangement also requires information to be shared and recorded in a common patient file. In this form of prescribing the independent prescriber, that is, the doctor or, if appropriate, the dentist, undertakes the initial assessment of the patient, determines the diagnosis and defines the initial treatment plan. The elements of this plan which are the responsibility of the supplementary prescriber are then documented in the patient-specific clinical management plan. The legal requirements for this are detailed in Box 2.1. Supplementary prescribers can prescribe controlled drugs and also both off-label and unlicensed medicines.

Non-medical independent prescribing

Following publication of a report on the implementation of nurse and pharmacist independent prescribing within the NHS in England (DH, 2006), pharmacists were enabled to become independent prescribers as defined under the Medicines and Human Use (Prescribing) (Miscellaneous Amendments) Order of May 2006. Independent prescribing is defined as 'prescribing by a practitioner (doctor, dentist, nurse, pharmacist) who is responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required including prescribing' (DH, 2006, p. 2).

Pharmacist independent prescribers were able to prescribe any licensed medicine for any medical condition within their competence except controlled drugs and unlicensed medicines. At that point there was restriction on Controlled Drugs including those in Schedule 5 (CD Inv.POM and CD Inv. P) such as co-codamol. At the same time nurses could also become qualified as independent prescribers (formerly known as Extended Formulary Nurse Prescribers) and prescribe any licensed medicine for any medical condition within their competence, including some Controlled Drugs. Since 2008 optometrists can also qualify as independent prescribers to prescribe for eye conditions and the surrounding tissue. They cannot prescribe for parenteral administration, and they are unable to prescribe Controlled Drugs. Physiotherapists can prescribe for human movement, performance and function, with podiatrists restricted to disorders of the feet, ankle and associated structures (Human Medicines Regulation, 2013). Therapeutic radiographers can prescribe within the overarching framework of cancer treatment (Human Medicines Regulation, 2016).

Following a change in legislation in 2010, pharmacist and nurse non-medical prescribers were allowed to prescribe unlicensed medicines (DH, 2010). In 2012 changes were made to the Misuse of Drugs Regulations 2001 relating to restriction on the types of controlled drugs which could be prescribed by both pharmacist and nurse independent prescribers. This allowed them to prescribe within their area of competence any Controlled Drug listed in Schedules 2–5 except diamorphine, cocaine and dipipanone for the treatment of addiction (DH, 2012).

From the above it should be evident that in the UK suitably qualified pharmacists can prescribe as either supplementary or independent prescribers. Pharmacist prescribing has been and is being considered by a number of countries. For example, legislative changes in New Zealand allowed suitably trained specialist pharmacists to become prescribers. In Canada pharmacist prescribing has been approved by provincial governments, although the scope does vary.

Accountability

Prescribers have the authority to make prescribing decisions for which they are accountable both legally and professionally. Accountability when prescribing covers three aspects: the law, the statutory professional body and the employer.

The law of Tort, the concept of a 'civil wrong', includes clinical negligence. In such a claim the patient needs to demonstrate that the prescriber caused them injury or damage. For this allegation to be substantiated the patient needs to prove that the prescriber owed them a duty of care, that this duty of care was breached and that this caused the injury identified and also that the injury was foreseeable. The law of Tort also permits actions for breach of confidentiality and also for battery should a patient be treated without consent. Therefore, prescribers (independent and supplementary) are legally and professionally accountable for their decisions. This includes decisions not to prescribe and also ensuring that the prescription is administered as directed. The legal responsibility for prescribing always lies with the individual who signed the prescription. In addition, prescribers also have a responsibility to ensure that the instructions are clear and not open to misinterpretation.

If a prescriber is an employee, then the employer expects the prescriber to work within the terms of his or her contract, competency and within the rules and policies, standard operating procedure, guidelines and so forth laid down by the organisation. Therefore, working as a prescriber, under these conditions, ensures that the employer has vicarious liability. So should any patient be harmed through the action of the prescriber and he or she is found in a civil court to be negligent, then under these circumstances the employer is responsible for any compensation to the patient. Therefore, it is important to always work within these frameworks because working outside these requirements makes the prescriber personally liable for such compensation. To reinforce this message it has been stated that the job descriptions of non-medical prescribers should incorporate a clear statement that prescribing forms part of the duties of their post (DH, 2006).

Ethical framework

Four main ethical principles of biomedical ethics have been set out for use by healthcare staff in patient–practitioner relationships (Beauchamp and Childress, 2001): respect for autonomy, non-maleficence, beneficence, and justice and veracity. These principles need to be considered at all points in the prescribing process.

Autonomy

Autonomy recognises an individual patient's right to self-determination in making judgements and decisions for himself or herself and encompasses informed patient consent. Respect for autonomy is therefore a form of personal liberty which freely permits a patient to choose whether he or she wishes to have treatment in accordance with his or her own plans.

Confidentiality. Confidentiality is a fundamental right with respect to patient autonomy. Therefore, patients have the right to confidentiality, and consent is required to disclose information regarding their health and treatment.

Consent. Obtaining consent from a patient for treatment can be divided into three components: voluntariness, information and competency. Consent, whether this is an investigation or treatment, can only be gained if the patient understands three important aspects: nature (i.e. what), purpose (i.e. why) and consequence. It also needs to be freely obtained. Consent is invalid when it is given under pressure or coercion. Therefore, it is important that consent is obtained for each act and not assumed because this is a routine assessment or procedure and therefore can be carried out automatically. It is essential that the patient understands his or her diagnosis, potential benefit, rationale and likelihood of success of the proposed treatment, and that reasonable care has been taken to ensure that the patient is aware of any material risks involved and of any reasonable potential alternative treatments. Therefore, a prescriber needs to discuss these aspects with the patient. In particular, care should be taken to understand what aspects of treatment and the risks involved would probably be deemed of significance by this particular patient to allow the patient to make a comparison with the proposed plan (Sokol, 2015). The prognosis if no treatment is prescribed should also be discussed. Such a wide-ranging discussion may require more than one appointment and reinforces the necessity for an ongoing patient–professional relationship focused on the needs of the patient. Since the Montgomery test case in 2015 this has now been applied in several other cases. Ethically the rulings demonstrate a shift to a more cooperative approach between patient and prescriber in the consultation (Chan et al., 2017).

Associated with this is the need to determine whether the patient has the competency to make decisions for himself or herself with respect to vulnerable groups, such as those who have learning disabilities, children and the elderly. Young people aged 16 and 17 years are normally presumed to be able to consent to their own treatment.

Gillick competence is used to determine whether children have the capacity to make healthcare decisions for themselves. Children younger than 16 years can give consent as long as they can satisfy the prescriber that they have capacity to make this decision. However, with the child's consent, it is good practice to involve the parents in the decision-making process. In addition a child younger than 16 years may have the capacity to make some decisions relating to their treatment, but not others. So it is important that an assessment of capacity is made related to each decision. There is some confusion regarding the naming of the test used to objectively assess legal capacity to consent to treatment in children younger than 16 years, with some organisations and individuals referring to Fraser guidance and others Gillick competence. Gillick competence is the principle used to assess the capacity of children younger than 16, whereas Fraser guidance refers specifically to contraception (Wheeler, 2006).

The Mental Capacity Act (2005) protects the rights of adults who are unable to make decisions for themselves. The fundamental concepts within this act are the presumption that every adult has capacity to make decisions for themselves, and that they must be given all appropriate help and support to enable them to make their own decision. To obtain valid consent, the prescriber must take practicable steps to ensure the patient understands the nature, purpose and reasonable or foreseeable consequences of the proposed investigation or treatment. Therefore, patients should be able to understand the information relevant to the decision they are making. They also need to be able to retain this information, use or assess the information as part of their decision-making process and communicate their decision. The five key principles are listed in Box 2.2. Therefore, any decision made on their behalf should be as unrestrictive as possible and must be in the patient's own interest, not biased by any other individual or organisation's benefit. Therefore, when taking consent, it is extremely important to plan and consider the information needs of the patient and to communicate this information using simple terms and basic language appropriate to the individual. This may require practical steps should the patient have problems communicating. Advice regarding patient consent is listed in Box 2.3. Although there is no statutory form to record assessment of capacity, information to record in the patient's medical record are the date, decision to be made, what information needed to be understood, practical steps taken to gain consent and confirmation that the patient did not have capacity to give consent together with the reason why this was not obtained.

Non-maleficence

At the heart of the principle of non-maleficence is the concept of not knowingly causing harm to the patient. The principle is

Box 2.2 Overview of the five principles of the Mental Capacity Act

- A person is assumed to have capacity unless it is established that he/she lacks capacity.
- A person should not be treated as unable to make a decision unless all practical steps to enable them to do this have been taken without success.
- A person cannot be treated as unable to make a decision because he/she makes an unwise decision.
- Acts or decisions made for or on behalf of a person who lacks capacity must be in that person's best interests.
- Before an act or decision is made, the purpose has to be reviewed to assess if it can be achieved as effectively in a way that is less restrictive of the person's rights/freedom of action.

Box 2.3 Advice on patient consent

- Take care when obtaining consent.
- Assess the patient and ensure information presented is appropriate to the patient.
- Use simple terms and basic language.
- Ensure information provided covers the nature, purpose and consequence of the investigation/treatment using the following questions (Sokol, 2015):
  - Does the patient know about the material risks of the treatment I am proposing?
    What sort of risks would a reasonable person in the patient's circumstances want to know?
    What sorts of risks would this particular patient want to know?
  - Does the patient know about reasonable alternatives to this treatment?
  - Have I taken reasonable care to ensure that the patient actually knows all this?
  - Do any of the exceptions to my duty to disclose apply here?
- Give the patient understandable information about all material risks that he or she is likely to consider significant.
- Ensure the patient has the opportunity to ask questions and consider his or her options.
- Document in the patient's notes the key elements of the discussion including advice and warnings provided.
- If higher levels of risk are involved, invite the patient to sign that they understand and accept the risks explained.
- Should your patient not have capacity to give consent, record your assessment in his or her medical record, including the reason why the patient was unable to give consent.
- Record in the patient's notes if he or she declines to undergo a procedure.

expressed in the Hippocratic Oath. This obligation not to harm is distinct from the obligation to help others. Although codes of all healthcare professionals outline obligations not to harm clients, many interventions result in some harm, however transitory. Sometimes one act can be described as having a 'double effect', that is, two possible effects: one good effect (intended) and one harmful effect (unintended). The harmful effect is allowed if proportionally it is less than the good effect. Therefore, it is important for prescribers to review both the potential positive effects of treatment (e.g. symptom control) and the negative effects (e.g. side effects). It is also important to consider both acts of commission and omission, because a failure to prescribe can also cause harm to the patient.

Beneficence

Beneficence is the principle of doing good and refers to the obligation to act for the benefit of others that is set out in codes of professional conduct, for example, Standards for pharmacy professionals (General Pharmaceutical Council, 2017). Beneficence refers to both physical and psychological benefits of actions and also relates to acts of both commission and omission. Standards set for professionals by their regulatory bodies such as the General Pharmaceutical Council can be higher than those required by law. Therefore, in cases of negligence the standard applied is often that set by the relevant statutory body for its members.

Justice and veracity

This last principle of justice and veracity is related to the distribution of resources to ensure that such division or allocation is governed by equity and fairness. This is often linked to cost-effectiveness of treatment and potential inequalities if treatment options are not offered to a group of patients or an individual. However, as a prescriber it is important to consider the evidence base for the prescribed medicine and also to review the patient as an individual to ensure the treatment offered adheres to this principle. This principle of fairness and freedom from discrimination therefore encompasses human rights including the need for assessment of medication as part of the Equality Act (2010). Healthcare professionals have a duty under this act to make reasonable adjustments to ensure that all patients have the same opportunity for good health. Therefore, a prescriber should also assess with the patient that the medication prescribed can be accessed by them. Veracity, or 'truth telling', underpins both effective communication and patient consent.

Professional frameworks for prescribing

Each professional regulatory body has standards to which their members must adhere. Members are accountable to such bodies for their practice and can be sanctioned by these bodies if their actions do not adhere to these standards. Therefore, individuals will be held accountable by their respective statutory body for their prescribing decisions.

The professional standards for pharmacists are defined within the 'Standards for Pharmacy Professionals' (General Pharmaceutical Council, 2017). In addition the Royal Pharmaceutical Society (2017) publishes 'Medicines, Ethics and Practice', a professional guide for pharmacists which provides advice on a wide range of areas encompassing core concepts and skills in addition to underpinning knowledge, legislation and professional bodies.

Off-label and unlicensed prescribing

For a medicine to be licensed for use in a specific country the manufacturer must obtain a marketing authorisation, formerly called the 'product license'. This details the patients, conditions

and purpose under which the medicine is licensed for use. Any medicine which does not have a marketing authorisation for the specific country where it is prescribed is termed 'unlicensed'. Unlicensed medicines prescribed include new medicines undergoing clinical trial and those licensed and imported from another country but not licensed in the country where they are to be used. It also includes 'specials', that is, medicines manufactured to meet a specific patient's needs, or produced when two licensed medicines are mixed together for administration to a patient.

However, if a licensed medicine is prescribed outside that specified in the marketing authorisation, then this use is described as 'off-label'. This happens in practice; for example, many medicines are not licensed for use in children but are prescribed for them. In addition some established medicines are prescribed for conditions outside their marketing authorisation (e.g. amitriptyline for neuropathic pain and azathioprine in Crohn's disease). The British National Formulary includes information on off-label use as an annotation of 'unlicensed use' to inform healthcare professionals. The details of a medicine's marketing authorisation are provided in the Summary of Product Characteristics.

The company which holds the marketing authorisation has the responsibility to compensate patients who are proven to have suffered unexpected harm caused by the medicine when prescribed and used in accordance with the marketing authorisation. Therefore, if a medicine is prescribed which is either unlicensed or off-label, then the prescriber carries professional, clinical and legal responsibility and is therefore liable for any harm caused. Best practice on the use of unlicensed and off-label medicines is described in Box 2.4. In addition all healthcare professionals have a responsibility to monitor the safety of medicines. Suspected adverse drug reactions (ADRs) should therefore be reported in accordance with the relevant reporting criteria.

Box 2.4 Advice for prescribing unlicensed and off-label medicines

Consider

- Before prescribing an unlicensed medicine, be satisfied that an alternative licensed medicine would not meet the patient's needs.
- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative.
- Before prescribing an unlicensed medicine or using a medicine off-label:
  - be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy;
  - take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up;
  - record the medicine prescribed and, where common practice is not being followed, the reason for prescribing the medicine; you may wish to record that you have discussed this with the patient.

Communicate

- You give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including knowing serious or common adverse drug reactions, to enable them to make an informed decision.
- Where current practice supports the use of a medicine outside the terms of its license, it may not be necessary to draw attention to the license when seeking consent. However, it is good practice to give as much information as patients or carers require or which they see as relevant.
- You explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of the medicine is innovative.

From Medicines and Healthcare products Regulatory Agency. 2009. Off-label use or unlicensed medicines: prescribers' responsibilities. Drug Safety Update 2:7 with kind permission from MHRA.

Prescribing across the interface between primary and secondary care

When a patient moves between care settings, there is a risk that a 'gap' in care will take place. These 'gaps' in care are almost always as a result of poor communication and frequently involve medicines, particularly when the patient is discharged from hospital into a community setting. To date there are few evidence-based solutions to these problems. A systematic review did identify randomised controlled trials of interventions designed to improve handover between hospital and primary care when patients were discharged. However, the complexity of interventions did not allow firm conclusions about which had positive effects (Hesselink et al., 2012). The National Institute for Health Care and Excellence (2015) in their guidance on medicines optimisation recommend that complete and accurate information on medicines should be shared and acted upon in a timely manner when patients transfer between care settings. They also make recommendations on what information should be shared and who should be involved in this process. The primary care prescriber with the responsibility for the continuing management of the patient in the community may be required to prescribe medicines with which they are not familiar. The prescriber should be fully informed and competent to prescribe a particular medicine for his or her patient. Supporting information from the hospital, in the form of shared care guidelines, can help inform the prescriber about medicines with which he or she may not be very familiar. Overall the decision about who should take responsibility for continuing care or prescribing treatment after the initial diagnosis or assessment should be based on the patient's best interests rather than on the healthcare professional's convenience or the cost of the medicine. However, when prescribers are uncertain about their competence to prescribe, where they consider they have insufficient expertise to accept responsibility for the prescription or where the product is of a very specialised nature and/or requires complex ongoing monitoring, it is legitimate for a prescriber to refuse to prescribe and make other arrangements for continued prescribing, for example, by asking the specialist to continue to prescribe. Guidance and principles for transferring information about medicines between care settings has been published by the Royal Pharmaceutical Society in conjunction with the Royal Colleges (Royal Pharmaceutical Society, 2012).

Clinical governance

Clinical governance is defined as 'the system through which NHS organisations are accountable for continuously improving

the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish' (DH, 1998, p. 33). It is a process embraced by the NHS to ensure that the quality of health care embedded within organisations is continuously monitored and improved. Clinical governance parallels corporate governance within commercial organisations and as such provides a systematic set of mechanisms such as duties, accountabilities and rules of conduct to deliver quality health care.

Clinical governance is described as having seven pillars:

- patient, service user, carer and public involvement
- risk management
- clinical audit
- staffing and management
- education, training and continuing professional development
- research and clinical effectiveness
- use of information

Within the NHS, standards of practice have been developed and monitored to ensure risks are managed and controlled. As part of this framework, the performance of staff is also assessed and remedial action taken, if required. NHS organisations have clinical governance requirements for their staff which include requirements for non-medical prescribing.

Professional bodies have also incorporated clinical governance into their codes of practice. The four tenants of clinical governance are: to ensure clear lines of responsibility and accountability, a comprehensive strategy for continuous quality improvement, policies and procedures for assessing and managing risks, and procedures to identify and rectify poor performance in staff. Suggested indicators for good practice are detailed in Box 2.5.

Box 2.5 Overview of clinical governance practice recommendations for prescribers

- Ensure effective communication with patients and carers to meet the patient's needs so that the patient can make informed choices about his or her treatment.
- Prescribe within competence (scope of practice).
- Obtain patient consent for investigations and management.
- Document in the patient's medical record a comprehensive record of the consultation and the agreed treatment plan.
- Undertake full assessment of patients competently and with consent.
- Prescribe safely, legally, appropriately, clinically and cost-effectively with reference to national and local guidelines.
- Assess and manage risk of treatment and associated investigations.
- Prescribe and refer in accordance with the clinical management plan if relevant.
- Ensure the secure storage of prescriptions and follow the relevant organisational procedures if they are lost or stolen.
- Ensure wherever possible separation of prescribing and dispensing and prescribing and administration.
- Audit prescribing practice.
- Identify and report incidents and adverse drug reactions.
- Participate and record continuing professional development relating to prescribing.
- Follow organisational procedures for dealing with the pharmaceutical industry regarding gifts and hospitality.

Competence and competency frameworks

Competence can be described as the knowledge, skills and attributes required to undertake an activity to a specific minimum standard within a defined environment. A competency framework is a group of competencies identified as essential to effectively perform a specific task. It can be used by an individual or an organisation to assess performance in a defined area. For example, it can be used for staff selection/recruitment, training and performance review.

The National Prescribing Centre competency framework for pharmacist prescribers was published in 2006 (Granby and Picton, 2006). In 2012 a prescribing competency framework was published to encompass all prescribers (independent and supplementary) which was subsequently reviewed and updated in 2016 (Royal Pharmaceutical Society, 2016). This framework is composed of 10 competencies assigned to 2 domains, the consultation and prescribing governance. The 10 competencies are:

- assess the patient,
- consider the options,
- reach a shared decision,
- prescribe,
- provide information,
- monitor and review,
- prescribe safely,
- prescribe professionally,
- improve prescribing practice,
- prescribe as part of a team.

Each of these competencies is supported by a series of statements, all of which an individual needs to demonstrate to achieve overall competency (Table 2.1). Prescribers can review their prescribing performance using the 10 competencies and the associated 64 statements using this framework as a self-assessment tool. Unlike the previous frameworks, some aspects of applying professionalism were not included. However, seven example statements (e.g. 'adapts consultations to meet the needs of different patients/carers') were provided within a separate section to encourage prescribers to reflect on professional practice linked to prescribing (Royal Pharmaceutical Society, 2016). The framework is particularly useful when structuring ongoing continuing professional development because it also allows prescribers to identify and reflect on strengths and areas for development.

The prescribing process

Consultation

The consultation is a fundamental part of the prescribing process, and prescribers need to understand and utilise this to help them practice effectively. The medical model of disease, diagnosis and prescribing is often central to practice, but an understanding of the patient's background together with his or her medical beliefs and anxieties is equally important in helping the prescriber

Table 2.1 Overview of the competency framework for all prescribers (Royal Pharmaceutical Society, 2016)

Domain	Competency	Statements
The consultation	Assess the patient.	8 statements For example, accesses and interprets all available and relevant patient records to ensure knowledge of the patient's management to date
	Consider the options.	10 statements For example, considers all pharmacological treatment options including optimising doses, as well as stopping treatment (appropriate polypharmacy, deprescribing)
	Reach a shared decision.	6 statements For example, explores the patient/carer understanding of a consultation and aims for a satisfactory outcome for the patient/carer and prescriber
	Prescribe.	13 statements For example, prescribes a medicine only with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions, and unwanted effects
	Provide information.	5 statements For example, ensures that the patient/carer knows what to do if there are any concerns about the management of their condition, if the condition deteriorates or if there is no improvement in a specific time frame
	Monitor and review.	4 statements For example, ensures that the effectiveness of treatment and potential unwanted effects are monitored
Prescribing governance	Prescribe safely.	6 statements For example, prescribes within own scope of practice and recognises the limits of own knowledge and skill
	Prescribe professionally.	6 statements For example, accepts personal responsibility for prescribing and understands the legal and ethical implications
	Improve prescribing practice.	3 statements For example, reflects on own and others' prescribing practice, and acts upon feedback and discussion
	Prescribe as part of a team.	4 statements For example, acts as part of a multidisciplinary team to ensure that continuity of care across care settings is developed and not compromised

Seven example behaviours identified as applying professionalism are also provided to encourage reflection of professional practice linked to prescribing, for example, undertakes the consultation in an appropriate setting taking account of confidentiality, consent, dignity and respect.

understand his or her own role and behaviours alongside those of his or her patients. Each patient's own beliefs, values, experience and expectations are important to acknowledge, explore and incorporate into all consultations. All prescribers should employ a non-judgemental approach to the consultation and listen to patients' beliefs and concerns (National Institute for Health and Care Excellence [NICE], 2012). Consideration should also be given to the consultation environment to ensure the patient's privacy is respected and also to how to maximise the patient's participation in the consultation. Some patients might like a family member or friend to be present or participate in a consultation, and this should be discussed and accommodated. A broad range of practical skills are needed in the consultation:

Interpersonal skills: the ability to communicate and make relationships with patients, considering the most effective communication method, including large print, symbols, Braille pictures, etc. and the avoidance of jargon; summarising information, checking the patient has understood important information and giving the patient opportunities to ask questions should also be incorporated into the consultation

Reasoning skills: the ability to gather appropriate information, interpret the information and then apply it both in diagnosis and management

Practical skills: the ability to perform physical examinations and use clinical instruments

The style in which the consultation is undertaken is also important. The paternalistic prescriber–patient relationship is no longer appropriate. This has been replaced in modern health care by a more patient-centred focus that ensures patient autonomy and consent. This model is based on an equal role for both patient and prescriber and is supported by policies which promote patient empowerment and self-care/management. This uses a task-orientated approach to keep consultation times to a reasonable

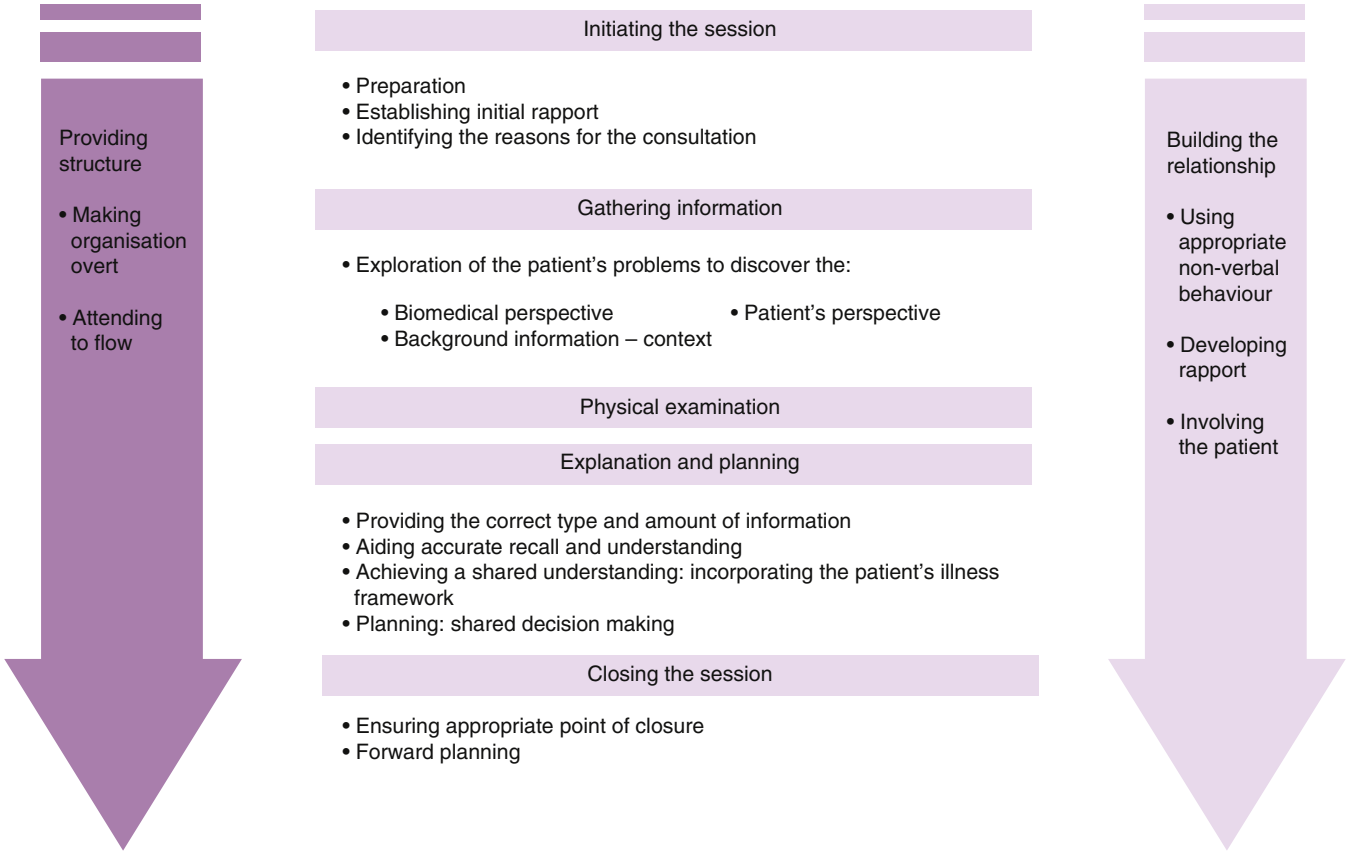

Fig. 2.2 Calgary–Cambridge consultation framework (Silverman et al., 2005). (Reproduced with kind permission from the Radcliffe Publishing Ltd., Oxford.)

duration and to set parameters to ensure a realistic expectation from the consultation.

An example of this is the Calgary Cambridge framework which can be used to structure and guide patient consultations (Silverman et al., 2005). The framework is represented in Fig. 2.2. The five key stages of the consultation are:

- initiating the session
- gathering information
- physical examination
- explanation and planning
- closing the session

In addition to these stages two key tasks are performed throughout the consultation. These are 'providing structure' and 'building the patient–prescriber relationship'. These two tasks are vital in ensuring an effective consultation. For a patient–prescriber communication to be effective, it is important that this focuses on interaction between the patient and the prescriber and is not just passive transmission of information. Feedback from the patient about the information received is essential for effective communication.

Building relationships

Non-verbal communication is important and can be used by the prescriber to gain information from the patient. Facial expressions and body posture can give clues about how the patient is feeling (e.g. anxious or tired). Proximity and eye contact are also important to determine whether the patient is actively engaged in the conversation or is distracted. Such non-verbal clues (e.g. anxiety, tiredness and pain) can then be explored verbally with the patient.

Prescribers also need to review their own non-verbal communication to ensure this reinforces the verbal message they are giving to the patient. For example, doctors who face the patient, make eye contact and maintain an open posture were regarded by their patients to be more interested and empathic (Harrigan et al., 1985). Also healthcare professionals in primary care who demonstrated non-verbal intimacy (close distance, leaning forward, appropriate body orientation and touch) had increased patient satisfaction (Larsen and Smith, 1981).

Because eye contact is an important non-verbal form of communication, obtaining information from patient records and documenting the consultation could undermine these skills. Therefore, it is important to read notes in advance of the consultation and avoid writing up the outcome while the patient is speaking. Indicating to the patient that references need to be made to their record or information documented ensures the patient is informed about the break in the consultation. This strategy should be adopted for both paper and computer-based records.

Developing rapport is also essential to building an effective patient–prescriber relationship. This can be achieved by providing an accepting response to the patient's concerns and

expectations. This is achieved by acknowledging the patients' views, valuing their contribution and accepting this information in a non-judgemental way. This does not necessarily mean that the prescriber agrees with the information, but that he or she accepts that this is a legitimate view from the patient's perspective. This can be reinforced by summarising the patient's view. The prescriber should acknowledge the patient's coping efforts and self-care. Avoiding jargon and explaining complex concepts in simple terms, to enable patients to understand the diagnosis and management, is also important.

Providing structure

Providing structure is important in the patient–prescriber consultation to enable the five key stages to be effectively completed. The prescriber needs to establish the boundaries for the consultation. This includes the time available for the consultation, the topics covered and how to finish the consultation. Therefore, because the power in the consultation is with the prescriber, it is the prescriber's responsibility to guide the consultation and involve the patient. This is to ensure that a patient-centered collaborative partnership is established. This can be achieved by using problem identification, screening and agenda-setting skills. The use of a logical sequence, signposting from one part of the consultation to the next and including an initial and end summary, will provide an effective structure to the consultation.

Initiating the session

During the first stage of the consultation the prescriber needs to greet the patient and confirm his or her identity. Prescribers should also ensure that the environment for the consultation is appropriate for maintaining eye contact and ensuring confidentiality. Prescribers should also introduce themselves, their role and gain relevant consent. During this stage the prescriber must demonstrate respect for the patient and establish a patient-centered focus. Using initially open and then closed questions, the prescriber needs to identify the patient's problem and/or issues. By adopting this approach and actively listening, the prescriber is able to confirm the reason for the consultation and identify other issues. This allows the prescriber to negotiate an agenda for the next stages of the consultation through agreement with the patient, taking into account both the patient's and the prescriber's needs. This initial stage is vital for the success of the consultation because many patients have hidden agendas which if not identified at this stage can lead to these concerns not being addressed. Beckman and Frankel (1984) studied doctors' listening skills and identified that even minimal interruptions by the doctors to the initial patient's statement at the beginning of the consultation prevented the patients' concerns from being expressed. This resulted in either these issues not being identified at all, or they were raised by the patient late in the consultation.

Gathering information

The aim of this stage is to explore the problem identified from both the patient's and the prescriber's perspective to gain background information which is both accurate and complete. Britten et al. (2000) identified that lack of patient participation in the consultation led to 14 categories of misunderstanding between the prescriber and the patient. These categories included patient information unknown to the prescriber, conflicting information from the patient and communication failure with regard to the prescriber's decision. During this stage, the illness framework, identified by exploring patients' ideas, concerns, expectations and experience of their condition and effect on their life, is combined with the information gained by the prescriber through their biomedical perspective. This encompasses signs, symptoms, investigations and underlying pathology. Assimilation of this information leads the prescriber to a differential diagnosis. By incorporating information from both viewpoints, a comprehensive history detailing the sequence of events can be obtained using questioning, listening and clarification. This ends with an initial summary where the prescriber invites the patient to comment and contribute to the information gathered.

Physical examination

At the start of the physical examination stage it is important to again obtain the patient's consent for any examination by explaining the process and rationale for the assessment. The environment (e.g. room temperature and screening for the examination) is important, and the prescriber should review this to ensure the patient's comfort. Guidance on maintaining clear sexual boundaries for pharmacy professionals has been published which includes advice on the use of chaperones (General Pharmaceutical Council, 2012).

Explanation and planning

The explanation and planning stage of the consultation incorporates three aspects: the differential diagnosis/hypothesis, the prescriber's management plan (investigations and alternative treatments), and explanation and negotiation of the plan of action with the patient.

In one UK study, doctors were found to overestimate the extent to which they completed the tasks of discussing the risk of medication, checking the ability of the patient to follow the treatment plan and obtaining the patient's input and view on the medication prescribed (Makoul et al., 1995).

To successfully accomplish this stage of the consultation, the prescriber needs to use a number of skills and also to involve the patient. Prescribers should ensure they give the correct type and amount of information. This is done by assessing the patient's prior knowledge employing both open and closed questions. By organising the information given into chunks which can be easily assimilated, the prescriber can then check that the patient understands the information given. Questioning the patient regarding additional information they require also helps to ensure the patient's involvement and to maintain rapport. The prescriber must determine the appropriate time to give explanations and also allow the patient time to consider the information provided. Signposting can also be a useful technique to employ during this stage. Once again the language used should be concise, easy to understand and avoid jargon. Using diagrams, models and written information can enhance and reinforce patient understanding.

The explanation should be organised into discreet sections with a logical sequence so that important information can be repeated and summarised.

To achieve shared understanding and shared decision making, it is important to incorporate the patient's perspective by relating the information given to the patient's illness framework. The patients also need to have the opportunity to ask questions, raise doubts and obtain clarification. This is especially important because national surveys of patients have identified that many patients, particularly those with long-term conditions, are less likely to report being involved in their own care (Care Quality Commission, 2016). Discussing with patients their beliefs, culture, abilities and lifestyle is important when discussing treatment options, for example, fasting during Ramadan or use of memory aids to support adherence. Prescribers should also explain their rational for the management plan identified and also discuss possible alternatives. By involving and negotiating with the patient in this way, a mutually acceptable treatment plan can be identified which allows patients to take responsibility for their own health.

Box 2.6 summarises the issues the prescriber should consider before prescribing a medicine.

Box 2.6 Issues the prescriber should reflect upon before prescribing a medicine (National Prescribing Centre, 1998)

- What is the drug?
  - Is it novel?
  - Is it a line extension?
- What is the drug used for?
  - What are the licensed indications?
  - Any restrictions on initiation?
  - Does first line mean first choice?
- How effective is the drug?
  - Is there good evidence for efficacy?
  - How does it compare with existing drugs?
- How safe is the drug?
  - Are there published comparative safety data?
  - Has it been widely used in other countries?
  - Are the details contained in the Summary of Product Characteristics understood?
  - Are there clinically important drug interactions?
  - Are there monitoring requirements?
  - Can it be used long-term?
- Who should not receive this drug?
  - Are there patients in whom it is contraindicated?
- Does the drug provide value for money?
  - Is there good evidence of cost-effectiveness compared with other available interventions?
  - What impact will this drug have on the healthcare budget?
- What is its place in therapy?
  - What advantages are there?
  - Are the benefits worth the cost?
  - Are there some patients who would particularly benefit?

Closing the session

The effectiveness of the end of a consultation is as important as the preceding stages. A number of steps are undertaken during the closing stage. These include agreeing to a contract with the patient as to the next steps to be taken by both patient and prescriber, for example, additional investigations and/or referral. Safety net strategies are also employed and discussed so the patient can identify unexpected outcomes or treatment failure and also understand who and how to contact the prescriber or another healthcare professional if appropriate. The end summary is an essential component of this stage and is used to briefly and accurately identify the management plan established during the previous stage in the consultation. This is followed by a final check that the patient has understood and consented to this management plan. At the end of the consultation the patient is given another opportunity to ask any final questions.

Communicating risks and benefits of treatment

Shared decision making supports patients to actively participate in their care. Before this stage of the consultation is reached, the healthcare professional has to use the best available evidence about treatment and be able to apply it to the individual patient in front of them, taking into account their needs, values and preferences. This requires the healthcare professional to discuss and provide information about the risks, benefits and consequences of treatment options, check that the patient understands the information, encourage the patient to clarify what is important to them and check that their choice is consistent with this. This ensures patient's consent to treatment is informed, and that the patient has an opportunity to participate in shared decision making about his or her treatment.

It is important to be able to communicate the risks and benefits of treatment options in relation to medicines. This should be done without bias and should avoid personal anecdotal information. Most patients want to be involved in decisions about their treatment, and would like to be able to understand the risks of side effects versus the likely benefits of treatment before they commit to the inconvenience of taking regular medication. An informed patient is more likely to be concordant with treatment, reducing waste of healthcare resources including professional time and the waste of medicines which are dispensed but not taken. Healthcare professionals need to recognise that the patient's values and preferences may be different from those of the healthcare professional, and that they should avoid making assumptions about patients. This may result in the patient making a treatment decision that is different from the healthcare professional's preferred option.

Communicating risk is not simple (Paling, 2003). Many different dimensions and inherent uncertainties need to be taken into account, and patients' assessment of risk is primarily determined by emotions, beliefs and values, not facts. This is important, because patients and healthcare professionals may ascribe different values to the same level of risk. Healthcare professionals need to be able to discuss risks and benefits with patients in a context that would enable the patient to have the best chance of understanding those risks. It is also prudent to inform the patient that virtually all treatments are associated with some harm and that there is almost always a trade-off between benefit and harm. How healthcare professionals present risk and benefit can affect the patient's perception of risk.

The National Institute of Health and Care Excellence (NICE, 2012) recommends using the following principles when discussing risks and benefits with patients:

- personalise risks and benefits as far as possible;
- use absolute risk rather than relative risk (e.g. the risk of an event increases from 1 in 1000 to 2 in 1000, rather than the risk of the event doubles);
- use natural frequency (e.g. 10 in 100) rather than a percentage (10%);
- be consistent in the use of data (e.g. use the same denominator when comparing risk: 7 in 100 for one risk and 20 in 100 for another, rather than 1 in 14 and 1 in 5);
- present a risk over a defined period (months or years) if appropriate (e.g. if 100 people are treated for 1 year, 10 will experience a given side effect);
- include both positive and negative framing (e.g. treatment will be successful for 97 of 100 patients and unsuccessful for 3 of 100 patients);
- be aware that different people interpret terms such as 'rare', 'unusual' and 'common' in different ways, and use numerical data if available;
- think about using a mixture of numerical and pictorial formats (e.g. numerical rates and pictograms).

Visual patient decision aids are becoming increasingly popular as a tool that healthcare professionals can use to support discussions with patients by increasing their knowledge about expected outcomes and helping them to relate these to their personal values (National Prescribing Centre, 2008). Further information about using patient decision aids can be found at: http://ipdas.ohri.ca or http://sdm.rightcare.nhs.uk (NHS-specific information on patient decision aids and shared decision making).

Adherence

Adherence has been defined as the extent to which a patient's behaviour matches the agreed recommendation from the prescriber. When a patient is non-adherent this can be classified as intentional or unintentional non-adherence (NICE, 2009). Adherence/non-adherence is a variable behaviour, rather than a trait characteristic, and is best understood in terms of the patient's encounter with his or her specific treatment. To facilitate optimal adherence, both perceptual factors (e.g. beliefs, preferences and incentives), which are associated with intentional non-adherence, and practical factors (e.g. capacity and resources), which are associated with unintentional non-adherence, need to be addressed.

Unintentional non-adherence occurs when the patient wishes to follow the treatment plan agreed with the prescriber but is unable to do so because of circumstances beyond his or her control. Examples of this include forgetting to take the medicine at the defined time or an inability to use the device prescribed. Strategies to overcome such obstacles include medication reminder charts, use of multi-compartment medication dose systems, large print for those with poor eyesight and aids to improve medication delivery (e.g. inhaler aids, tube squeezers for ointments and creams, and eye drop administration devices). A selection of these devices is detailed in a guide to the design of dispensed medicines (National Patient Safety Agency, 2007).

Intentional non-adherence occurs when the patient decides he or she does not wish to follow the agreed treatment plan. This may occur because of the patient's beliefs, perceptions or motivation. Therefore, it is important that all of these aspects are included in the discussion between the patient and the prescriber when the treatment plan is developed. Patients need to fully appreciate their medical condition and its prognosis to understand the rationale for the treatment options discussed. The benefits of the treatment plan, the effect of not taking the treatment, as well as the side effects all need to be explicitly explored with the patient. Patient decision aids and medicine-specific patient information leaflets can be used to support this discussion. However, evidence is inconclusive as to whether written medicines information is effective in changing knowledge, attitudes and behaviours related to medicine taking (Nicolson et al., 2009). The patient's previous experience of medicines and associated side effects should be explored because this gives the prescriber vital information about perceptions and motivation. Adherence to existing prescribed medication should be explored non-judgementally. For example, asking the patient how often he or she missed taking doses at the prescribed time over the previous 7 days would enable the prescriber to assess adherence but also explore lifestyle factors or side effects which may impact on the patient. These can then be discussed and strategies developed to optimise adherence.

More than 40% of working-age adults are unable to understand or make use of everyday health information because of limited health literacy. Reduced health literacy is associated with poorer health outcomes including increased risk of morbidity, premature death, poorer understanding of how to take medicines and increased non-adherence. Prescribers need to recognise patients' health literacy needs and employ a range of communication tools and strategies to support their needs (Public Health England, 2015).

Studies have demonstrated that between 35% and 50% of medicines prescribed for chronic conditions are not taken as recommended (NICE, 2009). Therefore, it is the prescriber's responsibility to explore with patients their perceptions of medicines to determine whether there are any reasons why they may not want to or are unable to use the medicine. In addition, any barriers which might prevent the patient from using the treatment as agreed, for example, manual dexterity, eyesight and memory, should be discussed and assessed. Such a frank discussion should enable the patient and prescriber to jointly identify the optimum treatment regimen to treat the condition. In addition, information from the patient's medical records can be used to assess adherence. For example, does the frequency of requests for repeat medication equate to the anticipated duration of use?

Review of unused medicines can be undertaken, and it is also important to assess the patient's administration technique on an ongoing basis for devices (e.g. asthma inhalers) to optimise correct technique. This can be achieved, for example, by carrying out a medicines reconciliation on hospital admission when the patient's prescribed medicines are compared with what the patient was taking before admission through discussion with the patient and/or carers and review of primary care records.

Because it is likely that at some point all patients will forget to take their medicine, it is important to give all patients information on what to do should a dose be missed. For individuals who are taking medication for treatment of a chronic condition, adherence

should not be assumed; therefore, assessment of adherence should form an ongoing discussion at each consultation.

Medication review

Medication review has been defined as 'a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste' (NICE, 2015, p. 22).

It is important that medicines are prescribed appropriately and that patients continue to achieve benefits from their medicines. The regular review of medicines is a key part of a good prescribing process and has many potential benefits for patients, including improving the management of the patient's medical condition, optimising the use of medicines, reducing risk of ADRs and involving the patient more actively in his or her treatment and care.

Often medicines prescribed regularly on a long-term basis are for patients with multiple comorbidities. This often results in individual patients being prescribed many medicines, a term known as 'polypharmacy'. Polypharmacy is important because evidence suggests that being on multiple medicines increases a person's risk of harm and contributes to hospital admissions (NICE, 2015). Using a medication review process to reduce the number of inappropriate medicines a patient is taking (deprescribing) and optimise appropriate medication can minimise unwanted harms from medicines (including falls) and reduce costs. In UK primary care, repeat prescribing systems enable patients on long-term regular medication to obtain further supplies of their medicine without routinely having to see their primary care doctor or prescriber. Robust systems and processes are required for this repeat prescribing to ensure the safe and efficient use of medicines. Reviewing a patient's medication forms is an essential element of a robust repeat prescribing process.

Specific groups of patients are recommended for a structured medication review (NICE, 2015), including all patient groups who are taking multiple medicines (polypharmacy), patients with chronic or long-term conditions and older people. Different types of medication review are required to meet the needs of patients for different purposes. A medication review can vary from a simple review of the prescription to an in-depth structured clinical medication review. NICE (2015) recommends that a structured medication review should be carried out by a healthcare professional with a sufficient level of knowledge of processes for managing medicines and therapeutic knowledge on medicines use. The scope of this review includes the following:

- the patient's and carer's (if appropriate) views and understanding about their medicines;
- the patient's and carer's (if appropriate) concerns, questions or problems with their medicines;
- all prescribed, over-the-counter and complementary medicines that the patient is taking or using, and what these are for;
- how safe the medicines are, how well they are working, how appropriate they are and whether their use is in line with national guidance/evidence;
- whether the patient has had or has any risk factors for development of ADRs;
- what monitoring is needed.

Characteristics of the different types of medication review are described in Table 2.2.

The key elements of a structured medication review are (All Wales Medicines Strategy Group, 2014; Scottish Government, 2015):

- identify aims and objectives of drug therapy;
- identify essential drug therapy;
- assess if the patient is taking unnecessary drug therapy;
- check if the therapeutic objectives are being achieved;
- determine if the patient is at risk of ADRs or suffering an actual ADR
- consider if drug therapy is cost-effective;
- determine the patient's willingness and ability to take their drug therapy;
- agree on actions to stop, reduce dose, continue or start drug therapy;
- communicate actions with all relevant parties;
- monitor and adjust regularly.

NO TEARS (Lewis, 2004) (Table 2.3) is a simpler tool for carrying out structured medication review. There are a number of

Table 2.2 Characteristics of types of medication review

Type of review	Purpose of the review	Requires patient to be present	Access to patient's full clinical notes
Level 1 Prescription review	Technical review of patient's list of medicines, e.g. dose optimisation, anomalies, changed items, cost-effectiveness	Not essential (any resulting changes to prescribed medicines must involve the patient/carer)	Not normally (community pharmacist can use Summary Care Record)
Level 2 Treatment review	Address issues relating to the patient's medicine-taking behaviour and use of medicines, e.g. dose modification, stopping medicines	Usually (any resulting changes to prescribed medicines must involve the patient/carer)	Possibly (community pharmacist may not have access to patient's full clinical notes)
Level 3 Clinical medication review	Address issues relating to the patient's use of medicines in the context of his or her clinical condition	Yes	Yes

Medication reviews include all medicines, including prescription, complementary and over-the-counter medicines. Treatment and prescription review may relate to one therapeutic area only.
Adapted from Medicines Partnership, 2002.

Table 2.3 The NO TEARS approach to medication review

NO TEARS	Questions to think about
Need and indication	Why is the patient taking the medicine, and is the indication clearly documented in the notes? Does the patient still need the medicine? Is the dose appropriate? Has the diagnosis been confirmed or refuted? Would a non-drug treatment be better? Does the patient know what his or her medicines are for?
Open questions	Use open questions to find out what the patient understands about his or her medicines, and what problems the patient may be having with them.
Tests and monitoring	Is the illness under control? Does treatment need to be adjusted to improve control? What special monitoring requirements are there for this patient's medicines? Who is responsible for checking test results?
Evidence and guidelines	Is there new evidence or guidelines that mean I need to review the patient's medicines? Is the dose still appropriate? Do I need to do any other investigations or tests?
Adverse effects	Does the patient have any side effects? Are any of the patient's symptoms likely to be caused by side effects of medicines, including over-the-counter and complementary medicines? Are any of the patient's medicines being used to treat side effects of other medicines? Is there any new advice or warnings on side effects or interactions?
Risk reduction and prevention	If there is time, ask about alcohol use, smoking, obesity, falls risk or family history for opportunistic screening. Is treatment optimised to reduce risks?
Simplification and switches	Can the patient's medicines regimen be simplified? Are repeat medicines synchronised for prescribing at the same time? Explain any changes in medicines to the patient.

published tools and websites to support improving polypharmacy and deprescribing. These tools incorporate guidance on assessing appropriateness or need for medicines and assessing risk of medicines (e.g. anticholinergic burden score). Examples of such tools can be found at: http://www.polypharmacy.scot.nhs.uk and http://www.prescqipp.info.

Factors that influence prescribers

A prescriber is subject to various influences which may impact their decision making when deciding whether to prescribe a medicine and which medicine to prescribe. Some of these influences may result in poor decision making; therefore, it is important to have an understanding of these influences and how they may impact on prescribing decisions. A range of influences that affect the prescribing decisions made by primary care doctors have been identified (Fig. 2.3).

Patients and prescribing decisions

The prescribing and use of medicines is strongly influenced by cultural factors that affect patients and prescribers alike. Issues such as whether the patient expects a prescription or whether the prescriber thinks the patient expects a prescription both influence the decision to prescribe. Patients may want a prescription for a whole variety of reasons, some of which are more valid than others. Beyond wanting a medicine for its therapeutic effect, a prescription for a medicine may demonstrate to the patient that his or her illness is recognised, may be seen as a symbol of care, may offer legitimacy for time off work because of illness or may fit with their health beliefs. Patients who frequently consult and receive a prescription are more likely to repeat the experience and expect a prescription at the next consultation.

A number of studies have found that doctors sometimes feel under pressure from patients to prescribe, although patients may not always expect a prescription from the doctor. However, even though patients often expect to receive a medicine, they also have more complex agendas that need to be explored in the consultation. Patients may have mixed attitudes towards medicines, and reluctance to take medicines is quite common. Although a medicine may be prescribed for its pharmacological effect, there may be other associated reasons to prescribe for a patient, for example, to end the consultation, to avoid doing anything else or having to say no, to maintain contact with the patient as a response to carer anxiety or to fulfil the patient's expectation.

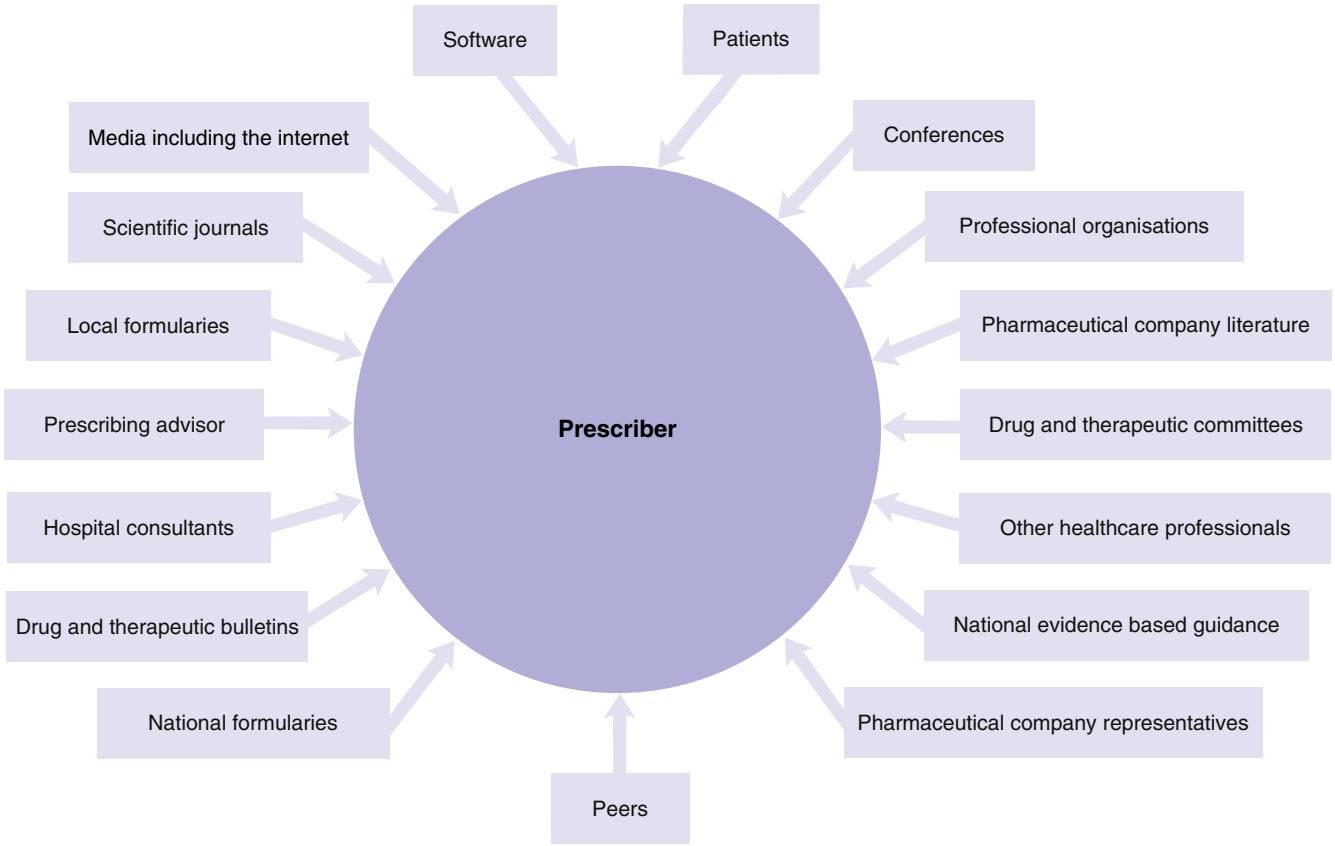

Fig. 2.3 Influences on prescribing decisions.

The informed patient

Health care is moving to a position of greater shared decision making with patients and development of the concept of patient autonomy. This is being supported through the better provision of information for patients about their prescribed medicines. The European Union directive 2001/83 (European Commission, 2001) requires that all pharmaceutical products are packaged with an approved patient information leaflet, which provides information on how to take the medicine and possible adverse effects. Patients are increasingly using the Internet and social media to learn about health and medicines. This can be challenging for healthcare professionals, particularly when the quality of information sources used may be highly variable. When media coverage does not provide balanced coverage, for example, reporting regarding the safety of measles, mumps and rubella (MMR) vaccine, this can have important consequences. In this case there was a rapid decline in MMR vaccination rates in children and a subsequent mumps outbreak (Gupta et al., 2008).

Direct advertising of medicines to patients is allowed in the USA and New Zealand, but not in Europe. Advertising medicines in this way is clearly effective in increasing sales of medicines, as evidenced by the increased spending and prescriptions for advertised drugs, compared with non-advertised drugs in these countries. This has led to concern that direct-to-consumer advertising encourages unnecessary and inappropriate use of medication. In the UK, education for patients may be provided by the manufacturer through sponsored disease awareness campaigns, but there is concern these encourage individuals to seek advice or treatment from their doctor for previously undiagnosed conditions. These campaigns may also help to raise awareness of conditions that have not been well managed in the past. However, they can also act in a way to promote prescription medicines. Such campaigns, which may be established by a drug company with or without the endorsement of a patient group, often take place at the same time as a drug's launch and may involve aggressive promotion. As a consequence there have been calls to control the influence of companies on the production of disease awareness campaigns that impact on the individual patient, who then exerts pressure on the prescriber for a specific medicine.

Healthcare policy

National policy and guidelines, for example, guidance from the NICE and Scottish Intercollegiate Guidelines Network in the UK, have a significant influence on prescribing and uptake of new medicines (NHS England, 2016b). The uptake of guidance and impact on prescribing can show considerable variation between individual clinicians and healthcare organisations. A range of complex factors have been identified that affect the impact of national guidance (Kings Fund, 2006), for example, prescriber's knowledge, attitude and behaviour, lack of staff, resources or managerial leadership, attitudes of patients, environmental factors, such as the regulatory environment, and the structure of reimbursement mechanisms.

Colleagues

Several studies have found that healthcare professionals in primary care (both doctors and nurses) rely on advice from trusted colleagues and opinion leaders as a key source of information on how to manage patients. It has been estimated that 40% of prescribing in primary care was strongly influenced by hospitals because the choice of medicine prescribed in general practice was often guided by hospital specialists through their precedent prescribing and educational advice (National Audit Office, 2007). The pharmaceutical industry recognises the value of identifying 'key opinion' leaders amongst the medical community and will try to cultivate them to influence their peers and fellow clinicians by paying them for a consultancy, lecture fees, attendance at medical conferences, supporting research and writing articles favourable to that company's products.

Pharmacists, in both primary and secondary care, themselves have an influence on prescribing through their roles as clinical pharmacists, or as part of their work advising on prescribing in primary care. Pharmacists are often regarded as trusted colleagues, and as such can have an important influence on prescribing. In whichever sector they are working, pharmacists need to be aware that their advice and decisions may be influenced by exactly the same factors that influence the prescriber.

Pharmaceutical industry

The pharmaceutical industry has a very wide and important influence on prescribing decisions affecting every level of healthcare provision, from the medicines that are initially discovered and developed through clinical trials to the promotion of medicines to the prescriber and patient groups, the prescription of medicines and the compilation of clinical guidelines. There are more than 8000 pharmaceutical company representatives in the UK who are trying to persuade prescribers to prescribe their company's product. This represents a ratio of about 1 representative for every 7.5 doctors (House of Commons Health Committee, 2005), with 1 representative for every 4 primary care doctors (National Audit Office, 2007). Whilst representatives from the pharmaceutical industry can provide useful and important new information to prescribers about medicines, the information presented is not without bias and rarely provides any objective discussion of available competitor products.

The influence of the pharmaceutical industry extends well beyond the traditional selling approach of using representatives and is increasingly sophisticated. The pharmaceutical industry spends millions on advertising, company-sponsored information in medical journals and supplements, sponsorship to attend conferences and meetings, and medical education. More than half of postgraduate education and training for doctors in the UK is sponsored by the pharmaceutical industry. The wide variety, volume and intensity of marketing activities the industry engages in is an important influence on prescribing by healthcare professionals. But when asked whether they are influenced by the pharmaceutical industry, prescribers usually deny that drug promotion affects their own prescribing practices, although they do believe that it affects other prescribers' prescribing habits. This is clearly not the case, because research has shown that even use of modest samples, gifts, and food exerts a significant influence on prescriber behaviour.

Cognitive factors

Most prescribing decisions are made using the processes our brains develop to handle large volumes of complex information quickly. This rapid decision making is aided by heuristics, strategies that provide shortcuts to quick decisions. This type of decision making largely relies on a small number of variables that we believe are important based on information collected by brief reading in summary journals (e.g. *Prescriber*, *Drug and Therapeutics Bulletin*), articles in popular doctors' and nurses' magazines mailed free of charge and talking to colleagues. However, it is important to recognise that cognitive biases affect these heuristics (or shortcuts) involved in rapid decision making, and that experts, as well as generalists, are just as fallible to cognitive biases in decision making (Makhinson, 2010). More than 50 cognitive biases and affective biases in medical decision making have been described. Some examples of cognitive biases that may affect prescribing decisions are listed in Table 2.4.

Table 2.4 Examples of types of cognitive biases which influence prescribing

Type of cognitive bias	Description
Novelty preference	The belief that the progress of science always results in improvements and that newer treatments are generally better than older treatments
Over optimism bias	Tendency of people to overestimate the outcome of actions, events, or personal attributes to a positive skew
Confirmation bias	Information that confirms one's already firmly held belief is given higher weight than refuting evidence
Mere exposure effect	More familiar ideas or objects are preferred or given greater weight in decision making
Loss aversion	To weigh the avoidance of loss more greatly than the pursuit of an equivalent gain
Illusory correlation	The tendency to perceive two events as causally related, when in fact the connection between them is coincidental or even non-existent