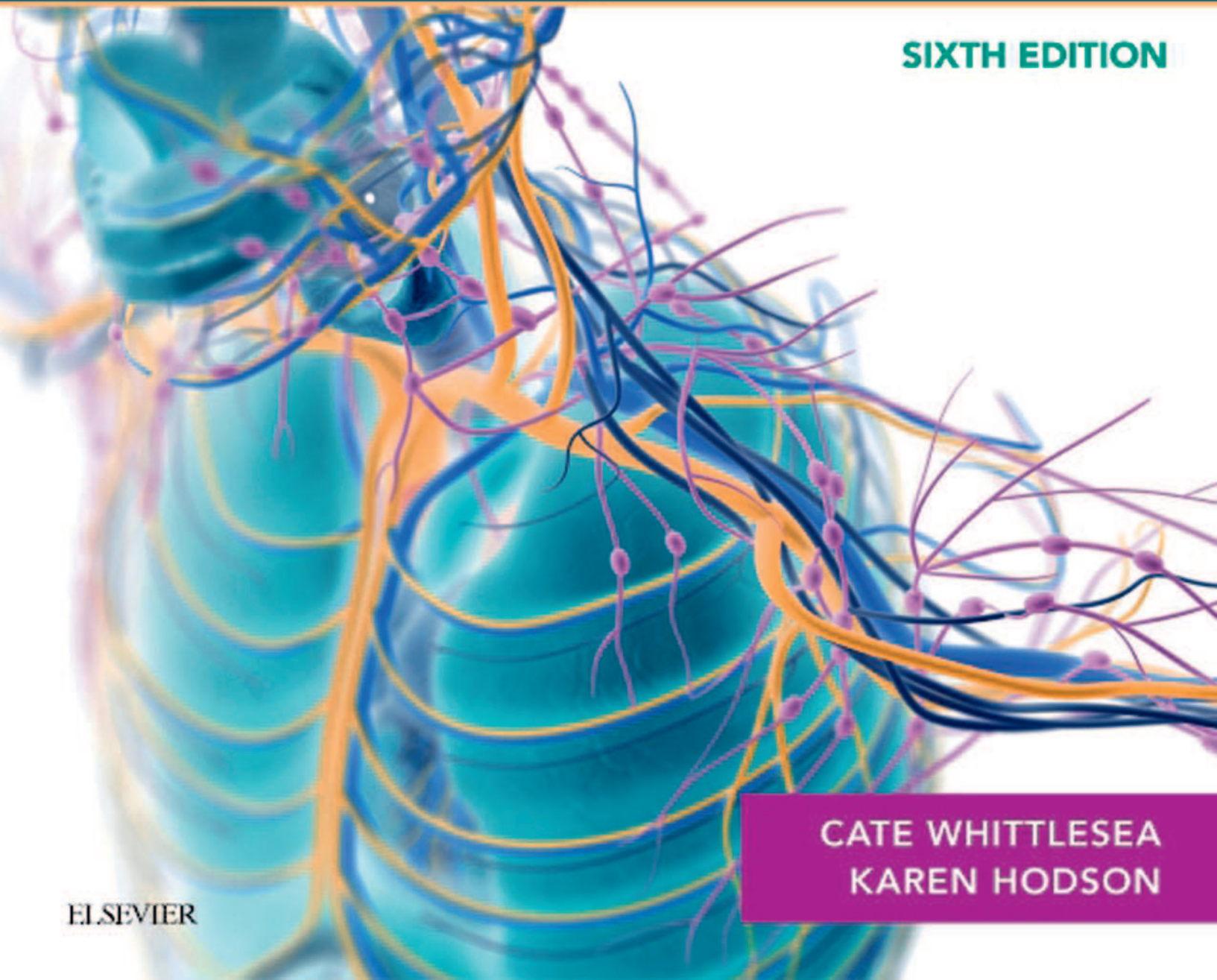
CLINICAL PHARMACY AND THERAPEUTICS

SIXTH EDITION



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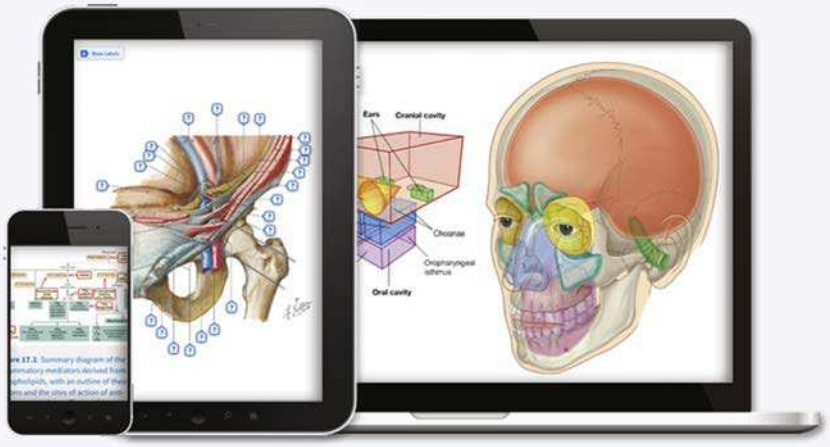

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SIXTH EDITION

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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.

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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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