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Clinical pharmacy

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Introduction

Managing medicines safely, effectively and efficiently is central to the delivery of high-quality care that is focused on the patient and gives value for money.[1] Over the past two decades, growing evidence from within and outside the UK has demonstrated the positive impact of clinical pharmacy services on patient outcomes; the Department of Health recognised that pharmacists' clinical skills and expertise are an integral part of delivering better services to patients in the 2008 pharmacy White Paper, and reinforced this in 2010, identifying their role in optimising the use of medicines.[2, 3] Examples include reductions in medication-related adverse events, lower treatment costs, better patient outcomes, reduced length of stay and reduced readmission rates.[4–6]

However, simply attempting to develop and implement best practice as opportunities permit is becoming increasingly unacceptable as the regulatory framework surrounding medicines management becomes more demanding. In addition to working towards delivery of numerous national recommendations, hospitals are also now required to register with the Care Quality Commission and meet the medicines management standards detailed in its essential standards of quality and safety (see Chapter 1). The standards detail regulations, outcomes and prompts to protect patients against the risks associated with the unsafe use and management of medicines, in accordance with regulation 13 of the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*.[7] Compliance with the standards can only be achieved with the delivery of high-quality clinical pharmacy services.

What is clinical pharmacy?

Clinical pharmacy is defined as the area of practice in which pharmacists provide patient care that optimises medication therapy and promotes health,

wellness and disease prevention.[8] The practice of clinical pharmacy embraces the concepts of both pharmaceutical care, first introduced by Hepler and Strand,[9] and medicines management, which encompasses the entire way in which medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.[10]

Hepler and Strand's definition of pharmaceutical care, 'the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve the patient's quality of life', included pharmacist input in the design, implementation and monitoring of a therapeutic plan, in collaboration with the patient and other healthcare professionals, and helped to change the focus of clinical pharmacy activities from processes to therapeutic outcomes. Despite widespread acceptance, use of the term 'pharmaceutical care' in the UK does not always follow the rigorous definition of Hepler and Strand, but is often used simply to imply a patient-focused approach to clinical pharmacy practice.[11] In some respects, the term 'clinical pharmacy' is somewhat outdated as the National Health Service (NHS) recognises that the term 'clinician' refers to all healthcare staff involved with the care of patients. Pharmacy, by definition, is a clinical profession and thus clinical pharmacy is a patient-centred service where the pharmacist is a key member of the multidisciplinary clinical team.[12]

The history of clinical pharmacy in the UK

Clinical pharmacy is now practised in all healthcare settings, but its main origins lie in the hospital sector. Until the mid-1960s, hospital pharmacists were mostly engaged in traditional pharmaceutical activities such as dispensing and manufacturing.[11] Then, the increasing range and sophistication of medicines available, awareness of medication errors and the widespread use of ward-based prescription charts brought pharmacists out of the dispensary and on to the wards in increasing numbers.

This was initially described as 'ward pharmacy' and was mostly a post hoc process with the emphasis on the safe and timely supply of medicines in response to medical and nursing demands. However, the service quickly evolved into something significantly more proactive, seeing pharmacists interacting with patients and other healthcare professionals and directly intervening in the patient care process.[13] The growth in these services over the 1970s and 1980s was said to represent a change in hospital pharmacy from product orientation to patient orientation and was formally acknowledged as 'clinical pharmacy' in the 1986 Nuffield report.[14] The report welcomed these changes and recommended an increased role for hospital pharmacists through the development of clinical pharmacy services.

The recommendations made in the Nuffield report were officially recognised in a 1988 Health Services circular that outlined the main aims of the Department of Health with respect to hospital pharmacy:

> the achievement of better patient care and financial savings through the more cost-effective use of medicines and improved use of pharmaceutical services obtained by implementing a clinical pharmacy service.[15]

A number of key areas where pharmacist input could assist other clinicians and benefit patients were highlighted, including contributing to prescribing decisions, monitoring and modifying drug therapy, counselling patients and involvement in clinical trials. The document acknowledged that, by helping to ensure patient safety and appropriate use of medicines, clinical pharmacy services could prove to be cost-effective.

As clinical pharmacy services expanded, there was increasing specialisation, with the expertise of individual pharmacists in certain therapeutic areas contributing to more significant developments in service provision. The speed of progress was demonstrated in a review undertaken in the early 1990s, which showed that the majority of NHS hospitals in the UK provided clinical pharmacy services and most hospital pharmacists participated in ward-based clinical pharmacy activities.[14] However, the range of clinical pharmacy services varied enormously, from almost 100% of hospitals having pharmacists who monitored drug therapy to less than 10% for services such as infection control, clinical audit or medical staff education. Since then, the widespread development of clinical pharmacy services has continued, with significant expansion in the number and range of services provided at most hospitals.

Wide variations in the extent and nature of hospital clinical pharmacy services were also noted in the Nuffield report and large differences still exist across much of the UK.[10] This lack of uniformity applies not just to clinical pharmacy, but also covers almost every aspect of hospital pharmacy services. The absence of specific directions from government and from the pharmacy profession, coupled with the varying degrees of success with which individual pharmacy managers in each hospital have been able to develop services, has allowed diversity to flourish with wide variations in the proportion of time spent on clinical pharmacy activities, ranging from less than 30% of pharmacist time at some hospitals to over 70% of pharmacist time at others.[10] The Audit Commission recommended that hospitals undertake reviews of their staffing levels and consider whether there were adequate resources to provide all aspects of clinical pharmacy services, so it is likely that the national figures on implementation of clinical pharmacy services will be changing for some time.

One of the differences between hospital and community pharmacy is the location of the patient and how this affects the dynamics of providing clinical pharmacy services. Most hospitals provide their pharmaceutical services to

patients on (but not exclusively) wards of various kinds. Thus, in order to deliver care the pharmacist needs to visit the ward and interact with the patient, doctor, nurse and others, as well as have access to consult and contribute to the patient's medical records.

Clinical pharmacist presence on wards allows dialogue with patients and professionals in addition to ensuring supplies of medicines are adequate for patients' needs, and that medicines are stored appropriately and safely. Pharmacy technicians, assistants and others work with ward staff to provide effective supply of commonly used items and, with the pharmacists, are increasingly leading the introduction of the reuse of patients' own drugs (PODs) schemes to reduce waste and, where appropriate, patient self-medication to support concordance.

The importance of communicating requests for medicines and the need to record administration of medicines have led to the universal usage of the ward prescription chart. Various reports on the value of recording the prescription and administration of medicines emanated from situations where there was no record of them having been given. Requiring nurses and doctors to record the administration of medicines offered the rudiments of an audit trail for medicines.

The design and use of these charts have consumed much time and energy from a variety of clinicians in order to produce a hybrid document that serves the multiple purposes of conveying: (1) patient details such as identification, age, weight, gender and allergies; (2) prescribing details such as medicine, form, dose, route and frequency of administration and previous medicines; and (3) medicine administration details including who administered (nurse, doctor, patient), when and by which route. It also serves to indicate when a medicine has not been given. An alert from the National Patient Safety Agency on reducing harm from omitted and delayed medicines in hospital requires all healthcare organisations to identify a list of critical medicines where timeliness of administration is crucial.[16] It also requires them to ensure that medicine management procedures include guidance on the importance of prescribing, supplying and administering critical medicines, timeliness issues and what to do when a medicine has been omitted or delayed. Incident reports should be regularly reviewed and an annual audit of omitted and delayed critical medicines should be undertaken to ensure that system improvements to reduce harms from omitted and delayed medicines are made. Figure 9.1 is an extract from a typical hospital inpatient medicines chart.

The Welsh NHS took this one step further in 2004 with the introduction of a new all-Wales prescription chart, accompanied by prescription-writing standards and an e-learning tool installed on the intranet systems of hospital trusts and included in medical degree teaching.[17]

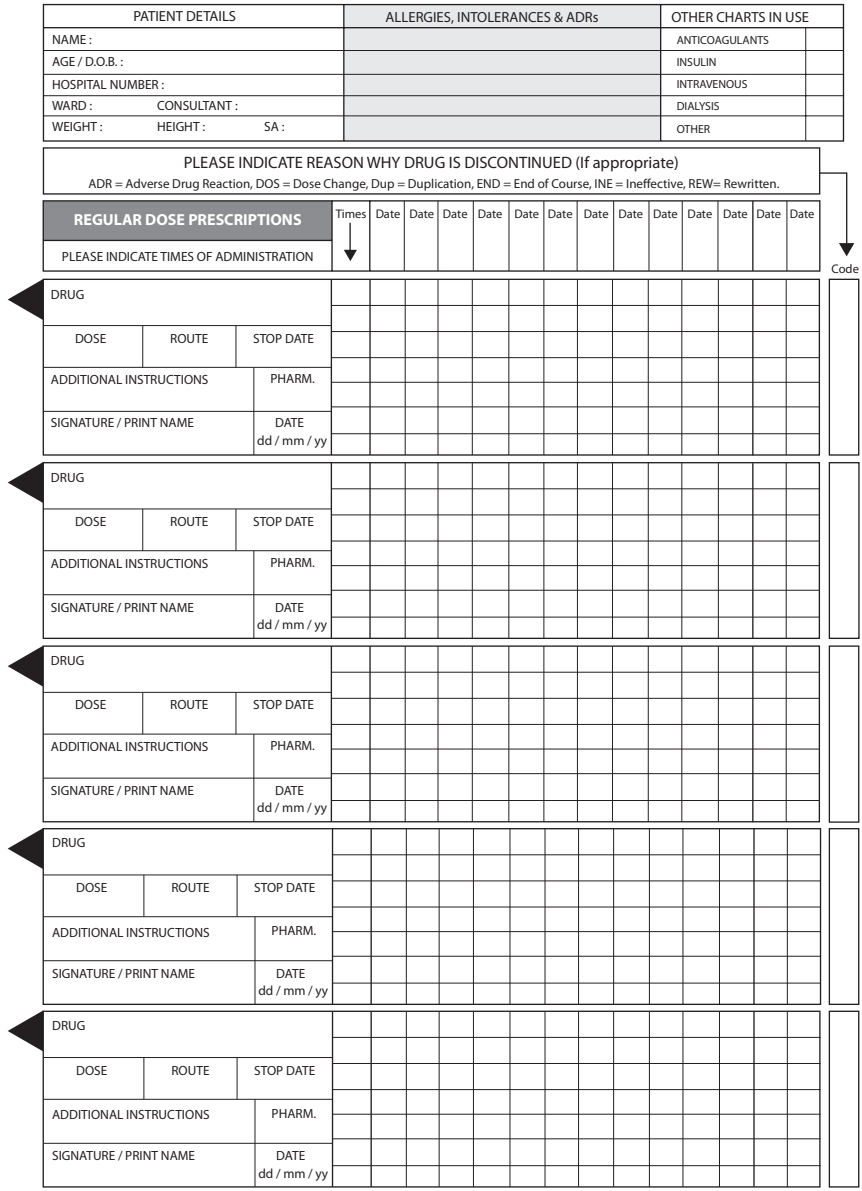

Figure 9.1 Hospital inpatient prescription sheet.

The important sets of prescription form data are essential for the efficient and effective delivery of pharmaceutical care to the patient and also form the basis for the development of electronic prescribing systems within the NHS.[18] This is discussed further in Chapter 15.

Prescription monitoring

The core of pharmacists' contribution to appropriate prescribing and medication use is made whilst undertaking near-patient clinical pharmacy activities. Checking and monitoring patients' prescriptions on hospital wards is frequently the starting point for this process and on most hospital wards the prescription card and clinical observation charts (temperature, pulse rate, blood pressure, and so on) are typically kept at the end of the patient's bed. This allows the clinical pharmacist to interact with the patient whilst reviewing the contents of the prescription.

The prescription is reviewed for medication dosing errors, appropriateness of administration route, drug interactions, prescription ambiguities, inappropriate prescribing and many other potential problems. Formal assessments of prescription charts in hospitals have shown that there are wide variations in the quality of prescribing and pharmacists are able to identify and resolve many clinical problems. Patients can be questioned on their medication histories, including allergies and intolerances, efficacy of prescribed treatment, side-effects and adverse drug reactions (ADRs). The routine presence of medical and nursing staff on the ward allows the pharmacist to communicate easily with other members of the healthcare team who value the prescription-monitoring service that clinical pharmacists provide.[19, 20] Patients' notes are also accessible, to enable the pharmacist both to check important information that may affect their healthcare and to record details of any clinical pharmacy input made.

Prescribing advice to medical and nursing staff

Prescribing advice can be provided by medicines information pharmacists within the pharmacy department or by pharmacists undertaking their clinical pharmacy duties in patient areas such as outpatient clinics or the wards. This latter role may also include attendance at medical ward rounds. The advice given can include help with choice of medicine, dose, method of administration, side-effects, interactions, monitoring requirements and many other aspects of medicines use. Studies examining prescribing advice given by clinical pharmacists have shown high rates of acceptance from medical staff, demonstrating that the role is both valued and effective.[21, 22]

Medication errors and adverse drug reaction reporting

Despite the important role of clinical pharmacy services, patients receiving drug therapy may still experience unintended harm or injury as a result of

medication errors or from ADRs. Adverse events (from any cause) occur in around 10% of all hospital admissions and medication errors account for one-quarter of all the incidents that threaten patient safety.[23] A study commissioned by the General Medical Council identified a mean prescribing error rate of 8.9 per 100 medication orders.[24]

Contributing to the avoidance or resolution of adverse medication events is an important part of any hospital pharmacist's clinical duties. This requires a multisystem approach, often incorporated into a hospital's clinical risk management strategy. Important lessons can be learned from analysis of medication-related incidents and from near-misses (that is, those that do not develop sufficiently to result in patient harm or are detected prior to patient harm). Chapter 12 considers these issues in further detail.

Even when the prescribed and administered treatment is correct and no errors have occurred, a small proportion of patients can still suffer from ADRs. Clinical pharmacists have an important role to play in the detection and management of ADRs and, more recently, directly reporting ADRs to the Committee on Safety of Medicines via the Yellow Card scheme. Their involvement can help to increase the number of ADR reports made, particularly those involving serious reaction.[25, 26] However, even in hospitals with formal ADR schemes, gross underreporting of reactions still remains a major problem.[27]

Medication history-taking and medicines reconciliation

Taking a medication history from patients and prescribing on admission have traditionally been done by junior doctors, but published work suggests that pharmacists are able to take more accurate medication histories than medical staff.[28–30] The crucial role of clinical pharmacists in undertaking medicines reconciliation for patients on admission to hospital has been endorsed by the National Institute for Health and Clinical Excellence (NICE) and the National Patient Safety Agency.[31] The guidance recognised the increased risk of morbidity, mortality and economic burden to health services caused by medication errors and noted that errors occur most commonly on transfer between care settings, particularly at the time of admission, with unintentional variances of up to 70%. It recommended that pharmacists should be involved in medicines reconciliation as soon as possible after hospital admission, noting this is a cost-effective intervention. Reconciliation was defined as:

- collecting information on medication history (prior to admission) using the most recent and accurate sources of information to create a full and current list of medicines

- checking or verifying this list against the current prescription chart in the hospital, ensuring any discrepancies are accounted for and acted on appropriately
- communicating through appropriate documentation any changes, omissions or discrepancies.

With the increasing use of information technology, access to patients' summary care record from their general practitioner surgery offers a timely and accurate method for obtaining this important information. The pharmacist can also question patients on concordance with prescribed treatment, check their own medicines to ensure suitability for reuse in hospital of POD and self-medication schemes and help to identify whether or not an admission is due to prescribing errors or ADRs. Pharmacy technicians are increasingly involved in supporting these roles.[31] This is discussed further later in the chapter.

A report commissioned by NICE included economic evaluation modelling of several different methods of medicines reconciliation and stated that: 'in terms of effectiveness, the pharmacist-led reconciliation intervention is predicted to prevent the most medication errors. This reduction is shown to reduce costs associated with errors by £3002 [per 1000 prescription orders] compared to the baseline scenario'.[32]

For planned admissions to hospital (for example, elective surgery), the medication history-taking role can be moved to an earlier stage in the patient care process. Preadmission clinics have traditionally been used to assess patients' suitability for surgery, but are also increasingly used to make other preparations for admission. Clinical pharmacists can work alongside medical and nursing staff, to help ensure that full and accurate details of medication are recorded and that either patients bring their own medication with them on admission or that medicines not routinely stocked by the hospital pharmacy can be ordered in advance.[33, 34] For patients on clearly defined treatment pathways, early discharge planning and advance preparation of discharge medication can also help to reduce delayed discharges and this can also involve pharmacists prescribing the discharge medication.[35]

Patient education and counselling, including achieving concordance

One of the key themes of the 2010 White Paper is empowering patients to take an active role in managing their own care.[4] This is also one of the themes of many of the NHS–National Institute for Health Research collaborations for leadership in applied health research and care that focus on translating research into practice.[36]

Helping patients to understand their medicines and how to take them is a major feature of clinical pharmacy. Patient compliance, defined as adherence to the regimen of treatment recommended by the doctor, has been a concern of healthcare professionals for some time.[37] Adherence to treatment, particularly for long-term chronic conditions, can be poor and tends to worsen as the number of medicines and complexity of treatment regimens increase. NICE noted that between a third and half of all medicines prescribed for long-term conditions are not taken as recommended and estimated that the cost of admissions resulting from patients not taking medicines as recommended was between £36 million and £196 million in 2006–2007.[38, 39]

In recent years, use of the term 'compliance' in the context of medication has been criticised because it implied that patients must simply follow the doctor's orders, rather than making properly informed decisions about their healthcare. The term 'concordance' has been proposed as a more appropriate description of the situation.[40]

Concordance is a new approach to the prescribing and taking of medicines. It is an agreement reached after negotiation between a patient and healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are taken.

This change in approach aims to optimise the benefits of treatment by helping patients and clinicians collaborate in a therapeutic partnership. However, if patients are to make informed choices, then the need for comprehensive patient education becomes more pressing.

Concordance with treatment is dependent on a complex interplay of beliefs, trust and understanding, with non-adherence falling into two overlapping categories:[38]

1 intentional: the patient decides not to follow the treatment recommendations
2 unintentional: the patient wants to follow the treatment recommendations, but practical problems prevent the patient from doing so.

Many surveys have found that patients often know little about the medicines they are taking. Several studies examining patient counselling and education have shown that clinical pharmacists can help to improve patients' knowledge of their treatment.[41, 42] The contribution made can also improve patient adherence to treatment.[41, 43] Improved adherence should lead to improved outcomes and evidence has been collected to demonstrate this.[41, 43, 44]

In addition to providing face-to-face education and counselling on medicines, clinical pharmacists can also help patients by contributing to the preparation of written material and audiovisual demonstrations, or by using computer programs.[45–48]

How patients take their medicines is a crucial component of whether the desired outcomes will be achieved. Key to this is the health beliefs of individuals and the relationship with their healthcare providers that are necessary in order to ensure this happens. Society is moving away from a paternalistic approach to healthcare to a more empowered one. Thus, whereas a course of treatment used to be accepted obediently by patients, treatment is now negotiated and options, risks and benefits are discussed and, where necessary, consent is obtained. Thus there is a greater need for information and education of patients and/or carers in order for them to be able to make informed decisions about their treatment. Indeed, the 2010 White Paper emphasised the importance of patient involvement, and included the phrase 'nothing about me, without me'.[4]

Self-administration schemes

Schemes which allow patients to self-administer their medicines whilst in hospital have been attempted in selected groups or settings.[49, 50] The schemes have several purposes:

- a diagnostic role – checking to see if patients can cope with their medicines regimen
- an educational role – giving diminishing levels of support prior to discharge, allowing patients to gain skills and confidence with their medicines
- an empowering role – allowing patients to provide self-care as they would at home.

Schemes may also allow nursing staff to focus on other issues and mean that access to medicines is improved. This is particularly important where timing of doses can affect patient experience or safety, for example insulin use or analgesia. However, whilst these schemes may seem attractive, evidence of their benefits is limited and considerable effort may be required to assess patients' suitability.[51] Clinical pharmacists and pharmacy technicians can support nursing staff in establishing and running self-administration schemes. A POD scheme, though not essential, can be a useful precursor to such schemes.

Integrated medicines management

'Integrated medicines management' is a term that has been used to describe bringing together several elements of clinical pharmacy services which have been shown to be effective in dealing with medicines management problems, delivering additional input at key phases of a patient's stay: admission, inpatient monitoring and counselling and discharge. By

focusing additional clinical pharmacy input to selected patients (that is, those taking at least four medicines, those on defined high-risk medicines, patients 65 years or older and on antidepressants, and those with a previous admission within the last 6 months), reduced length of stay and a decreased rate of readmission have been demonstrated, providing efficiency savings to the health economy in addition to improved clinical outcomes for patients.[6]

Pharmacokinetics and therapeutic drug level monitoring

Pharmacokinetics addresses the absorption, distribution, metabolism and excretion of drugs in patients. A sound knowledge of the pharmacokinetic profiles of different drugs enables the pharmacist to assess the dosing requirements for certain drugs in patients in extremes of age and in the presence of impairment of kidney and liver function. Clinically important drug interactions and adverse reactions can sometimes be predicted. Dosing calculations of aminoglycoside antibiotics are usually made by employing pharmacokinetic principles.

A number of medicines in common use have a narrow therapeutic index; that is, the difference between the lowest effective dose and a potentially toxic dose can be quite small. In many cases it is necessary or desirable to undertake therapeutic drug level monitoring (TDM) to ensure that patients can be treated safely. TDM services include the measurement of drug levels in the patient's blood and the application of clinical pharmacokinetics to optimise drug therapy. There is a wide range of medicines that fall into this category, but TDM services typically include aminoglycoside antibiotics, anticonvulsants, immunosuppressants, digoxin, lithium and theophylline. Monitoring drug levels in patients can also provide an important indicator as to whether they are taking their medicine. Clinical pharmacy input into TDM services can range from the provision of simple advice to other clinicians on when to take samples and how to interpret results, to fully fledged services that may include collection and laboratory analysis of the blood sample.[52–54]

Anticoagulant services

Clinical pharmacy input into anticoagulant therapy is now a widely accepted part of clinical practice in many hospitals. Some anticoagulant services were initially set up as collaborative ventures with medical staff, but pharmacists now manage many services. Although the exact nature of services provided by the pharmacist may vary slightly from hospital to hospital, the role of the pharmacist in anticoagulation has been clearly established: (1) ensuring complete documentation and referral information

is present; (2) interviewing patients and assessing factors that may affect anticoagulant control, particularly disease states and drug interactions; (3) monitoring and adjusting anticoagulant doses to maintain the international normalised ratio within agreed therapeutic targets; (4) identifying clinical problems that require referral to a physician; (5) patient counselling and education; (6) providing a regular point of contact for patients with concerns about their treatment; (7) day-to-day clinic management training and education for physicians and pharmacists; and (8) research and audit. Clinical pharmacists can provide high-quality cost-effective anticoagulant services for both hospital inpatients and outpatients. Evaluations of services provided show that pharmacist anticoagulant control is at least as good as, and in some cases better than, that achieved by medical staff.[55, 56] However, the introduction of new oral antithrombin and Xa inhibitors, which do not require the same level of laboratory monitoring, are increasingly likely to offer a viable alternative to these traditional anticoagulant services.

In more recent years, the use of anticoagulants for prevention of venous thromboembolism (VTE) has become much more important as the risks to patients have become better recognised. NICE published a clinical guideline on VTE across all adult specialties in January 2010.[57] In England, from April 2010, the national Commission for Quality and Innovation payment framework includes reducing avoidable death, disability and chronic ill health from VTE as one of two national goals.[58] These documents seek to ensure that appropriate risk assessments have been carried out on admission to hospital so that patients can be identified for thromboprophylaxis, and mechanical measures, where necessary. This is not restricted to those involved in anticoagulant services and so clinical pharmacists from all disciplines will play a significant part in ensuring compliance with the national guidance. The particular contribution that pharmacy can make is set out in *Venous Thromboembolism Prevention, a Patient Safety Priority,* published by the Department of Health along with the All-Party Parliamentary Thrombosis Group.[59]

Personalised medicine

The fact that not all patients respond to the expected benefits of medicines and some have disproportionately adverse effects from them is leading to the development of personalised medicines services. Good clinicians have always tailored treatment to individual patients' needs, but this typically relied on trial and error. Personalised medicine can start from using biomarkers rather than clinical outcomes as surrogate markers of effectiveness and a new specialty of pharmacogenetics that aims to assess phenotypic differences in responding to and handling drugs that may account for a significant

proportion of the variation in patient response. A Parliamentary Office of Science and Technology review noted that:

> Personalised medicine holds both promise and cause for concern. Selective treatment may limit access to those most likely to benefit, whereas following a 'one size fits all' approach to medical research and development may have benefited the widest number of potential patients. Nevertheless, explaining the environmental, genetic and other biological sources of human variation will alter the way diseases are diagnosed, drugs are developed, and the matching of therapeutic cells and tissues to patients.[60]

However, economic considerations, regulation of biological tests and the speed of clinical education and training will all influence the rate and degree to which personalised medicine will be incorporated into drug development and clinical practice.

Education and training

As hospital clinical pharmacy services expanded, there was a growing recognition of the need for postgraduate training for pharmacists. Postgraduate courses in clinical pharmacy started at Bradford, London and Manchester universities in the 1970s and others quickly followed.[61–63] This included the development of part-time courses, which resulted in a significant increase in the numbers of pharmacists being able to receive postgraduate training in clinical pharmacy. The majority of UK NHS hospitals now employ clinical pharmacists with advanced postgraduate qualifications and many clinical pharmacists also contribute to the teaching on postgraduate courses. The training and education that hospital pharmacists receive are covered in more detail in Chapter 17. Clinical pharmacy services also include the regular provision of training and education for other healthcare staff at most hospitals – a service that is valued highly.[13]

Medicines formularies

The role of the pharmacist in the development of medicines formularies is covered in more detail in Chapter 11. Pharmacists providing clinical services are responsible for ensuring that prescribers' practices comply with formulary recommendations. Clinical pharmacists' detailed knowledge of medicines and the regular contact they have with doctors, nurses and patients mean that they are ideally placed to influence prescribing on the wards. A key feature of successful medicines rationalisation is the ongoing communication between prescribers and pharmacists who encourage self-audit and peer review.[64]

Clinical outcomes

In 1966 Donabedian published his seminal work that described three distinct aspects of quality in healthcare: (1) outcome; (2) process (healthcare technologies); and (3) structure (resources for delivery of care).[65] He concluded that: 'Outcomes, by and large, remain the ultimate validation of the effectiveness and quality of medical care'. Standardised mortality rates have become a crude outcome measure but are used to describe a healthcare organisation's overall success. Other recent outcome measures include meticillin-resistant *Staphylococcus aureus* bacteraemia rates and *Clostridium difficile* infections which have a direct relevance to antimicrobial stewardship (AMS). More recently, patient-reported outcome measures (PROMs) have been advocated as a relevant outcome measure to describe patients' satisfaction in their healthcare provider.[66] Four elective procedures were initially proposed for PROMS data evaluation – hernia repair, hip and knee replacement and varicose veins – but a growing range of long-term conditions including diabetes, asthma, chronic obstructive pulmonary disease, epilepsy, heart failure and stroke are being added. These long-term conditions have medication effectiveness at their core and will offer considerable potential for clinical pharmacy involvement. At the time of writing, in England, consultation has begun on how an outcomes-based approach can be built into the routine running of the NHS. It will be interesting to see how medicines use and the role of clinical pharmacists can contribute to this agenda.

Professional and clinical audit

The range and complexity of healthcare services being provided to patients mean that there is now a need to look more critically at the effectiveness of what is being delivered.[67] Professional self-examination in healthcare dates back more than a century, but the widespread implementation of clinical audit started in earnest in the early 1990s.[68] This resulted from a number of important factors: (1) public expectations that professionals can deliver and maintain high standards of care; (2) government pressures to make healthcare professionals more accountable; and (3) the need to enhance and maintain professional credibility.

Clinical pharmacists can be involved in many different types of audit. These may range from topics including audit of clinical services themselves (for example, clinical pharmacy interventions) or may examine which treatments are used and how they are implemented within the framework of drug use evaluations. Audit aims to improve patient outcomes by examining how current clinical practice compares to agreed standards of care, implementing any changes necessary and then re-examining practice to ensure that real improvements have been made.

The most obvious benefits of good clinical audit include improvements in the quality of service and treatment. In addition, enhanced professional standing, improved communication with colleagues, increased knowledge, improved work satisfaction, publication opportunities and even promotion have all been put forward as other positive aspects that should encourage healthcare staff to get involved.

Clinical audit is pivotal in patient care: it brings together professionals from all sectors of healthcare to consider clinical evidence, promote education and research, develop and implement clinical guidelines, enhance information management skills and contribute to better management of resources – all with the aim of improving the quality of care of patients.[69]

Outpatient clinical pharmacy services

The traditional role of outpatient prescription dispensing is being replaced in many hospitals by clinical pharmacy input into the clinics themselves. This practice follows the logic that hospitals should only dispense medicines to those outpatients in immediate need and the Audit Commission has recommended that primary and secondary care should work together to limit the practice of outpatient dispensing to eliminate much of the confusion that is commonly generated when two doctors are prescribing to the same patient.[10] This allows hospitals to utilise some of the resources saved to implement more beneficial pharmacy services and many hospitals pharmacists now actively manage medication for selected outpatients, including those on anticoagulation (see above), lithium, rheumatology medication, lipid-lowering agents, transplant medicines and many others.[70–73]

Primary–secondary care interface

Community-based pharmacy services are covered in Chapter 14. However, good-quality clinical pharmacy does not begin and end at the traditional barriers between hospital and community practice. The overall aim of such services is to provide patients with a smooth transition as they move between the primary and secondary care sectors during admission to, or discharge from, hospital, a process often described as 'seamless care'. The efficient and accurate transfer of information is an essential part of this process if unintended changes in medication are to be avoided. This needs to involve good communication links between other hospital colleagues, general practitioners and community pharmacists in addition to direct patient contact.[74] Other clinical pharmacy services that can contribute to seamless care include patient follow-up and domiciliary visiting, coordinating appropriate use of compliance aids, the availability of telephone helplines for patients and the establishment of joint primary–secondary care treatment protocols managing

intravenous medication at home, out-of-hours services and influenza pandemic planning.[75, 76]

The role of pharmacy technicians in clinical pharmacy services

The role of pharmacy technicians is already well established in departmental activities such as dispensing and aseptic services. However, the expansion of clinical pharmacy services in hospital would not be possible without the additional support that can be provided by hospital pharmacy technicians. In a similar manner to the way in which ward pharmacy services provided by pharmacists evolved into clinical pharmacy, pharmacy technicians' roles are becoming increasingly clinical in nature and can include a wide range of activities.[31, 77–79] Current activities undertaken by pharmacy technicians, in collaboration with pharmacists, include:

- medication supply
- checking medication in POD schemes
- patient counselling and education, including the provision of patient aids where appropriate, as well as medication charts and monitored-dose systems to aid compliance
- supporting patient self-medication
- medicines information
- discharge planning for patients, including communication with primary care colleagues where appropriate
- involvement in clinical trials and good clinical practice governance
- preparation of medicines formularies and guidelines
- training and education
- liaison with clinical teams on medicines management and expenditure
- AMS.

Whilst this last subject will be addressed under strategic medicines management (Chapter 11), it is important to note that AMS was the first ever clinical pharmacy programme to receive national, ring-fenced, governmental funding. The importance of AMS is highlighted in national reports and is enshrined within statute in the *Health and Social Care Act 2008*.[80, 81] Guidance for compliance with criterion 9 states that healthcare providers 'have and adhere to policies, designed for the individual's care and provider organisations that will help to prevent and control infections'. Notably:

- Local prescribing should, where appropriate, be harmonised with that in the *British National Formulary*. Local guidelines for primary and secondary care should be observed.

- All local guidelines should include information on a particular drug's regimen and duration.
- Procedures should be in place to ensure prudent prescribing and AMS. There should be an ongoing programme of audit, revision and update. In healthcare this is usually monitored by the antimicrobial management team.

Antimicrobial stewardship

A systematic team approach to AMS should be adopted in all healthcare institutions in order to ensure optimal use and minimum toxicity in the use of antimicrobials. Evidence-based standards should be agreed and form the basis of an education programme for all users. Audit of the effectiveness of AMS should be regularly undertaken and fed back to users for review and action.

Where empirical use is considered a stepwise approach should be adopted:

Is there an infection?

Before an antimicrobial is selected the following questions should be asked:

- Is there an infection present? Physical and biomarkers must be considered and, whilst many of these are non-specific, a number together can indicate an infection is present. For example, CURB-65 is such a cluster of markers commonly used in the diagnosis of community-acquired pneumonias. It is an objective scoring system based on presence or absence of confusion, blood urea, respiratory rate, blood pressure and patient age.[82]
- What is the likely organism?
- Is it susceptible to antibacterial agents?
- Will the selected agent reach the site of infection at the required concentration?
- Is the route of administration appropriate?
- Is the duration of treatment appropriate?
- Is there a stop/switch strategy?

Which antimicrobial?

The choice of agent depends on a number of factors but the general principles behind selection are: (1) only use an agent that is likely to work in the infection being treated; (2) ensure that it is one that has the narrowest antibacterial spectrum; and (3) ensure that the dose, route and duration of therapy are optimised. Ideally, a laboratory sensitivity report should drive selection but intuitive choice can be made from likely portal of entry. Once a sensitivity report has been received then appropriate switching to a narrow-spectrum agent should be promoted. Intravenous to oral switching should be made as

soon as possible using explicit agreed criteria. This can reduce both cost and complications and allow patients to be discharged more quickly.

Surgical prophylaxis – reducing surgical site infections

Surgical site infections have been shown to compose up to 20% of all healthcare-associated infections. At least 5% of patients undergoing a surgical procedure develop a surgical site infection; surgical site infections can double the length of time a patient stays in hospital and thereby increase the costs of healthcare by up to £7000. If the timing of your first dose of antimicrobial surgical prophylaxis is right then the likelihood of acquiring a surgical site infection is markedly reduced. Giving the first dose of antibacterial surgical prophylaxis within 60 minutes prior to incision reduces surgical site infections to a minimum.

Services linked to clinical specialties

In much the same way that clinical specialties are firmly established in medicine and surgery, the same is now true for clinical pharmacy. This has been helped by the manner in which clinical specialties have been managed in hospitals, often divided into divisions or directorates along clinical lines, to which a pharmacist can be attached. Part of the responsibilities for such pharmacists will be strategic, managerial and financial: (1) appropriate governance and risk management procedures; (2) monitoring and auditing the use of medicines; (3) supporting the management of the medicines budget; and (4) contributing to the preparation of business cases for new drugs. The UK Clinical Pharmacy Association is a good source of information on pharmacy input to specific clinical specialties and has a number of active special interest groups accessible via its website.[83]

Ongoing development of clinical pharmacy services

Optimising the use of medicines in hospitals is central to the delivery of high-quality patient care. Medication errors in hospitals are still unacceptably common and medicines continue to become increasingly complex and more costly. In addition, this is likely to become a significant issue with payment by results non-elective reimbursement systems, which may result in hospitals not being paid for suboptimal clinical outcomes of care.

The future of medicines management is inextricably linked with clinical pharmacy, with much of the value that pharmacists can add being information provision and monitoring quality. Although there is still a long way to go, the Healthcare Commission noted that many positive improvements have been made since the 2001 report from the UK Audit Commission's

investigation into medicines management in hospitals.[1] Despite the significant progress that has been made in recent years, the Department of Health recognises that there are further challenges requiring attention, and progress in some areas has been slow:[2]

- ensuring the more effective use of medicines
- people who need urgent access to medicines are not always getting them when needed
- accessing the right medicines at the right time – of crucial importance for people at all stages of their lives, but particularly in end-of-life care
- preventing admissions that could be avoided with proper medicines use
- there are still too many problems with medicines when people leave hospital and return home.

Pharmacy services in the future will need to be designed around the needs of patients, not organisations, integrated with other healthcare services, with an emphasis on the need to bring care as near to the patient's home as possible. There needs to be a greater contribution of the skills hospital clinical pharmacists have developed to the whole patient pathway, making care truly seamless. Clinical pharmacy must also be designed to make the best use of staff and their skills and take advantage of modern technologies. Although computers and automated dispensing systems can help undertake some of this work, there are limitations to the possible achievements of technology and there is no substitute for direct contact with patients. Clinical pharmacy services in hospital have changed significantly over the past few decades, but re-engineering the way in which patient care is delivered is an ongoing process. Many of the changes are designed to free up hospital pharmacists' time to focus even more on the delivery of clinical care. Despite their limitations, the use of electronic prescribing and automated dispensing systems can help pharmacists to devote more of their time to patient care. Revision and further expansion of the pharmacy technician and pharmacy assistant roles also need to play a major part in this strategy.

The long-term vision for clinical pharmacy is a service contributing to a health service that offers patients fast and convenient care, that is available when they need it, tailored to their individual requirements and delivered to a consistently high standard. Delivering a successful clinical pharmacy service will bring major benefits to patients and pharmacists alike, but effective medicines management involves the whole organisation and requires multidisciplinary team working supported by an effective strategy. However, the Healthcare Commission found evidence that a significant proportion of healthcare professionals do not understand how pharmacy staff can contribute to the care of patients.[1] It is essential to address this gap to ensure that all healthcare staff and patients gain the maximum benefit from their pharmacy service.

References

1. Healthcare Commission. *The Best Medicine. The Management of Medicines in Acute and Specialist Trusts. Acute Hospital Portfolio Review*. London: Healthcare Commission, 2007.
2. Department of Health. *Pharmacy in England. Building on Strengths – Delivering the Future*. London: Department of Health, 2008.
3. Department of Health. *Equity and Excellence: Liberating the NHS*. London: Department of Health, 2010.
4. Kucukarslan S, Peters M, Mlynarek M *et al*. Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medical units. *Arch Intern Med* 2003; 163: 2014–2018.
5. Bond C, Raehl C, Franke T. Interrelationships among mortality rates, drug cost, total cost of care and length of stay in United States hospitals: summary and recommendations for clinical pharmacy services and staffing. *Pharmacotherapy* 2001; 21: 129–141.
6. Scullin C, Scott M, Hogg A *et al*. An innovative approach to integrated medicines management. *J Eval Clin Pract* 2007; 13: 781–788.
7. Care Quality Commission. *Guidance about Compliance. Essential Standards of Quality and Safety*. London: Care Quality Commission, 2010.
8. American College of Clinical Pharmacy. The definition of clinical pharmacy. *Pharmacotherapy* 2008; 28: 816–817.
9. Hepler C, Strand L. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm* 1990; 47: 533–543.
10. Audit Commission. *A Spoonful of Sugar – Medicines Management in NHS Hospitals*. London: Audit Commission, 2001.
11. Calvert R. Clinical pharmacy – a hospital perspective. *Br J Clin Pharmacol* 1998; 47: 231–238.
12. Department of Health. *A First Class Service, Quality in the New NHS*. London: The Stationery Office, 1998.
13. Cotter S, Barber N, McKee M. Professionalisation of hospital pharmacy: the role of clinical pharmacy. *J Soc Admin Pharm* 1994; 11: 57–67.
14. Clucas K, chair. *Pharmacy: A Report to the Nuffield Foundation*. London: Nuffield Foundation, 1986.
15. Department of Health. *Health Services Management. The Way Forward for Hospital Pharmaceutical Services*. HC(88)54. London: HMSO, 1988.
16. National Patient Safety Agency. Rapid response report NPSA/2010/RRR009. Reducing harm from omitted and delayed medicines in hospital. Available online at: http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66720. (accessed 16 March 2010).
17. Anonymous. New all-Wales drug chart looks set to increase patient safety. *Hosp Pharm* 2005; 12: 184–185.
18. NHS Executive. *Information for Health. An Information Strategy for a Modern NHS 1998-2005*. London: The Stationery Office, 1998.
19. Bentley A, Green R. Developing pharmaceutical services; the nursing view. *Br J Pharm Pract* 1981; 3: 4–9.
20. Cavell G, Bunn R, Hodges M. Consultants' views on the developing role of the hospital pharmacist. *Pharm J* 1987; 239: 100–102.
21. Cairns C, Prior F. The clinical pharmacist: a study of his hospital involvement. *Pharm J* 1983; 320: 16–18.
22. Trewin V, Town R. Pharmacist effectiveness at case conferences. *Br J Pharm Pract* 1986; 8: 298–304.
23. Department of Health. *Building a Safer NHS for Patients. Implementing an Organisation with a Memory*. London: The Stationery Office, 2001.
24. Dornan T, Ashcroft D, Heathfield H *et al*. *An Indepth Investigation into Causes of Prescribing Errors by Foundation Trainees in Relation to their Medical Education*. EQUIP study. Final report to the General Medical Council. Manchester: University of Manchester School of Pharmacy and Pharmaceutical Sciences and School of Medicine, 2009.

25. Winstanley P, Irvin L, Smith J *et al*. Adverse drug reactions: a hospital pharmacy-based reporting scheme. *Br J Clin Pharmacol* 1989; 28: 113–116.
26. Lee A, Bateman D, Edwards C *et al*. Reporting of adverse drug reactions by hospital pharmacists: pilot scheme. *Br Med J* 1997; 315: 519.
27. Green C, Mottram D, Rowe P *et al*. Adverse drug reaction monitoring by United Kingdom hospital pharmacy departments: impact of the introduction of 'yellow card' reporting for pharmacists. *Int J Pharm Pract* 1999; 7: 238–246.
28. Dodds L. An objective assessment of the role of the pharmacist in medication and compliance history taking. *Br J Pharm Pract* 1982; 4: 12–24.
29. Hebron B, Jay C. Pharmaceutical care for patients undergoing elective ENT surgery. *Pharm J* 1998; 260: 65–66.
30. Gleason K, Groszek J, Sullivan C *et al*. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health-Syst Pharm* 2004; 61: 1689–1695.
31. National Institute for Health and Clinical Excellence. *NICE Patient Safety Guidance 1. Technical Patient Safety Solutions for Medicines Reconciliation on Admission to Hospital*. London: National Institute for Health and Clinical Excellence, National Patient Safety Agency, 2007.
32. Karnon J, Campbell F, Czoski-Murray C. Model-based cost-effectiveness analysis of interventions aimed at preventing medication error at hospital admission (medicines reconciliation). *J Eval Clin Pract* 2009; 15: 299–306.
33. Hick H, Deady P, Wright D *et al*. The impact of the pharmacist on an elective general surgery pre-admission clinic. *Pharm World Sci* 2001; 23: 65–69.
34. Oliver S, Ashwell S. Pharmacists prescribing take home medication. *Pharm J* 2000; 265: 22.
35. Department of Health. *Pharmacy in the Future – Implementing the NHS Plan*. London: The Stationery Office, 2000.
36. National Institute for Health Research website: http://www.nihr.ac.uk/infrastructure/Pages/infrastructure_clahrcs.aspx.
37. Bloom B. Daily regimen and compliance with treatment. *Br Med J* 2001; 323: 647.
38. National Institute for Health and Clinical Excellence. *Medicines Adherence. Involving Patients in Decisions about Prescribed Medicines and Supporting Adherence*. NICE clinical guideline 76. London: NICE, 2009.
39. National Institute for Health and Clinical Excellence. *NICE Costing Statement. Medicines Adherence: Involving Patients in Decisions about Prescribed Medicines and Supporting Adherence*. Accompanying medicines adherence clinical guideline 76. London: NICE, 2009.
40. Royal Pharmaceutical Society of Great Britain. *From Compliance to Concordance: Towards Shared Goals in Medicine Taking*. London: RPSGB, 1997.
41. Varma S, McElnay J, Hughes C *et al*. Pharmaceutical care of patients with congestive heart failure: interventions and outcomes. *Pharmacotherapy* 1999; 19: 860–869.
42. Johnston M, Clarke A, Mundy K *et al*. Facilitating comprehension of discharge medication in elderly patients. *Age Ageing* 1986; 15: 304–306.
43. Goodyer L, Miskelly F, Milligan P. Does encouraging good compliance improve patients' clinical condition in heart failure? *Br J Clin Pract* 1995; 49: 173–176.
44. Al-Eidan F, McElnay J, Scott M *et al*. Management of *Helicobacter pylori* eradication – the influence of structured counselling and follow-up. *Br J Clin Pharmacol* 2002; 53: 163–171.
45. Sandler D, Mitchell J, Fellows A *et al*. Is an information booklet for patients leaving hospital helpful and useful? *Br Med J* 1989; 298: 870–874.
46. McElnay J, Scott M, Armstrong A *et al*. Audiovisual demonstration for patient counselling in the use of pressurised aerosol bronchodilator inhalers. *J Clin Pharm Ther* 1989; 14: 135–144.
47. Daly M, Jones S. Preliminary assessment of a computerised counselling program for asthmatic children. *Pharm J* 1991; 247: 206–208.
48. Raynor D, Booth T. Blenkinsopp A. Effects of computer generated reminder charts on patients' compliance with drug regimens. *Br Med J* 1993; 306: 1158–1161.
49. Wood S, Calvert R, Acomb C *et al*. A self-medication scheme for elderly patients improves compliance with their medication regimens. *Int J Pharm Pract* 1992; 1: 240–241.

50. Lowe C, Raynor D, Courtney E *et al*. Effects of a self-medication programme on knowledge of drugs and compliance with treatment in elderly patients. *Br Med J* 1995; 310: 1229–1231.
51. Wright J, Emerson A, Stephens M *et al*. Hospital inpatient self-administration programmes: a critical literature review. *Pharm World Sci* 2006; 28: 140–151.
52. Bourne J, Farrar K, Fitzpatrick R. Practical involvement in therapeutic drug monitoring. *Pharm J* 1985; 234: 530–531.
53. Brown A. Establishment of a pharmacy-run TDM service. *Br J Pharm Pract* 1986; 8: 154–159.
54. Campbell D. A clinical pharmacokinetics service. *Hosp Pharm* 1999; 6: 206–208.
55. Booth C. Pharmacist-managed anticoagulation clinics: a review. *Pharm J* 1998; 261: 623–625.
56. Boddy C. Pharmacist involvement with warfarin dosing for inpatients. *Pharm World Sci* 2001; 23: 31–35.
57. National Institute for Health and Clinical Excellence. *Reducing the Risk of Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism) in Patients Admitted to Hospital*. Clinical guideline 92. London: NICE, 2010.
58. Department of Health. *Using the Commissioning for Quality and Innovation (CQUIN) Payment Framework – An Addendum to the 2008 Policy Guidance for 2010/11*. London: Department of Health, 2010.
59. Ayra R (ed.) *Venous Thromboembolism Prevention, A Patient Safety Priority*. London: King's Thrombosis Centre, 2009.
60. Parliamentary Office of Science and Technology. Postnote. Personalised medicine. 2009; 329: 1–4: available online at: http://www.parliament.uk/documents/upload/postpn329.pdf (accessed 30 March 2010).
61. University of Bradford PGCert/PGDip/MSc in Clinical Pharmacy (Hospital) Course Prospectus 2006. Bradford: University of Bradford, 2006.
62. Anonymous. Postgraduate education for hospital pharmacists. *Pharm J* 1978; 220: 525–526.
63. Noyce P, Hibberd A. Launch of the London MSc in clinical pharmacy. *Pharm J* 1980; 225: 4733–4734.
64. Baker J. Seventeen years' experience of a voluntary based drug rationalisation program in hospital. *Br Med J* 1988; 297: 465–469.
65. Donabedian A. Evaluating the quality of medical care. *Milbank Memorial Fund Q* 1966; 44: 166–206.
66. Devlin N, Appleby J. *Getting the Most out of PROMS. Putting Health Outcomes at the Heart of NHS Decision Making*. London: King's Fund, 2010.
67. *Moving to Audit: What Every Pharmacist Needs to Know about Professional Audit*. Dundee: Postgraduate Office, Ninewells Hospital and Medical School, 1993.
68. Davies H. Developing effective clinical audit. *Hosp Med* 1999; 60: 748–750.
69. Teasdale S. The future of clinical audit: learning to work together. *Br Med J* 1996; 313: 574.
70. Dean J, Acomb J. A pharmacist managed lithium clinic. *Hosp Pharm* 1995; 2: 150–152.
71. Jones S, Pritchard M, Grout C *et al*. A rheumatology drug monitoring clinic. *Pharm J* 1999; 263: 25.
72. Williams H . Pharmacist-led lipid management clinic. *Pharm J* 1999; 263: 26.
73. Morlidge C. Pharmacist-run renal medication review clinics. *Br J Renal Med* 2001; 6: 25–26.
74. Care Quality Commission. *National Study. Managing Patients' Medicines after Discharge from Hospital*. London: Care Quality Commission, 2009.
75. Brown J, Brown D. Pharmaceutical care at the primary–secondary interface in Portsmouth and South East Hampshire. *Pharm J* 1997; 258: 280–284.
76. Child D. How well do you collaborate across the primary/secondary care interface? *Pharm Manage* 2009; 25: 3–7.
77. Colaluca A, Glet R, Smith D *et al*. Inpatient counselling – a technician's role. *Br J Pharm Pract* 1988; 10: 334–340.
78. Dosaj R, Mistry R. The pharmacy technician in clinical services. *Hosp Pharm* 1998; 5: 26–28.
79. Edwards L. The role of the directorate liaison technician. *Hosp Pharm* 2001; 8: 115–116.

80. Department of Health and Health Protection Agency. *Clostridium difficile – How to Deal with the Problem*. London: Department of Health and HPA, 2008.
81. Department of Health. *The Health and Social Care Act 2008: Code of Practice for the NHS on the Prevention and Control of Healthcare Associated Infections and Related Guidance*. London: Department of Health, 2009.
82. Lim W, van der Eerden M, Laing R *et al*. Defining community acquired pneumonia severity on presentation to hospital: an international derivation and validation study. *Thorax* 2003; 58: 377–382.
83. UK Clinical Pharmacy Association website: http://www.ukcpa.org/.

Further reading

Department of Health. *Pharmacy in England. Building on Strengths – Delivering the Future*. London: Department of Health, 2008.

Healthcare Commission. *The Best Medicine. The Management of Medicines in Acute and Specialist Trusts. Acute Hospital Portfolio Review*. London: Healthcare Commission, 2007.

National Institute for Health and Clinical Excellence, National Patient Safety Agency. *NICE Patient Safety Guidance 1. Technical Patient Safety Solutions for Medicines Reconciliation on Admission to Hospital*. London: National Institute for Health and Clinical Excellence, National Patient Safety Agency, 2007.