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(formerly Computers in Health Care)

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Principles of Electronic Prescribing

Springer

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Series Preface

This series is directed to healthcare professionals who are leading the transformation of health care by using information and knowledge to advance the quality of patient care. Launched in 1988 as Computers in Health Care, the series offers a broad range of titles: some are addressed to specific professions such as nursing, medicine, and health administration; others to special areas of practice such as trauma and radiology. Still other books in the series focus on interdisciplinary issues, such as the computer-based patient record, electronic health records, and networked healthcare systems.

Renamed Health Informatics in 1998 to reflect the rapid evolution in the discipline now known as health informatics, the series continues to add titles that contribute to the evolution of the field. In the series, eminent experts, serving as editors or authors, offer their accounts of innovation in health informatics. Increasingly, these accounts go beyond hardware and software to address the role of information in influencing the transformation of healthcare delivery systems around the world. The series also increasingly focuses on "peopleware" and the organisational, behavioural, and societal changes that accompany the diffusion of information technology in health services environments.

These changes will shape health services in the new millennium. By making full and creative use of the technology to tame data and to transform information, health informatics will foster the development of the knowledge age in health care. As coeditors, we pledge to support our professional colleagues and the series readers as they share the advances in the emerging and exciting field of health informatics.

Kathryn J. Hannah
Marion J. Ball

Preface

The purpose of this book is to provide electronic prescribing (EP) systems implementers with an overview of the clinical and professional issues involved with the use of EP systems, and a discussion of the key systems design principles involved. The book does not assume any detailed clinical or IT knowledge on the part of the reader; as such, it provides general guidance on possible applications of EP systems. However, the book should not be used a substitute for detailed analysis of a specific EP system by analysts with appropriate domain expertise within a healthcare setting; the author accepts no liability for issues arising from the use of the book inappropriately in this way.

This book is the result of several years of reflection and work in the area of electronic prescribing and medicines management. It represents a major project for me, as a pharmacist, a health informatician and as a writer. However, in my experience, major undertakings such as this are rarely the sole work of one person. I would therefore like to make a number of acknowledgements, and to thank a number of people whose assistance and support has been invaluable in the production of this book.

I would like to thank those hospital staff who were willing to be interviewed and to share their experiences of electronic medicines management with me:

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I am especially indebted, however, to those people with whom I have worked most closely on electronic prescribing, pharmacy and medicines management projects over the past five years. In a sense, my expertise reflects theirs. They are (in no particular order): George Brown, Tom Bolitho, Clive Spindley, Tim Botten, Sue Braithwaite, Julie Randall and Raghu Kumar.

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Charlton, Banbury, Oxfordshire
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Chapter 1
Philosophical and Social Framework of Electronic Medicines Management

Introduction

Electronic prescribing (EP) involves the use of computer systems to facilitate the prescription, supply and administration of medicines within a hospital. EP systems are able to capture a full prescribing history for a patient in a transferrable manner, and open up the potential for use of databases and decision support tools to assist the prescriber in medicine selection.

Over the last ten to twenty years, EP systems have been developed and used in a number of countries around the world, but their use is by no means widespread. Currently, in the United Kingdom, only a handful of acute hospitals have full EP systems throughout the hospital. There are, however, further hospitals with EP in certain wards and specialities only. EP systems – and in particular, computerised decision support tools to aid prescribing – have been pioneered in the United States, and there is much research documentation on their use in a US context. Nevertheless EP systems have still not been widely adopted in the US, for various reasons (Fig. 1.1).

However, because of sociopolitical developments on a global scale, healthcare providers around the world are increasingly concerned with cost-effectiveness, the increased likelihood of litigation and the need for clinical governance and transparency in healthcare processes. Consequently, there will be an increasing emphasis on the clinical application of information technology to help healthcare providers streamline their business processes and achieve outcome targets. An area of healthcare where there is a critical need to use IT for these purposes is the prescribing and supply of medicines in secondary care. Use of departmental systems to manage the discrete activities of particular departments or specialisms in hospitals is now well established. Hospitals around the world routinely use systems to manage and process pathology and radiology order requests, and have systems for pharmacy management. Patient administration systems (PAS) to manage admissions and discharge and to facilitate the patient pathway or "patient journey" in secondary care are also in routine use. However, the area of EP and medicines management is one where there has been less technology adoption to date.

There are now compelling – but, at points, contestable – data concerning the role of EP systems in risk reduction and optimising business processes in hospitals, which will
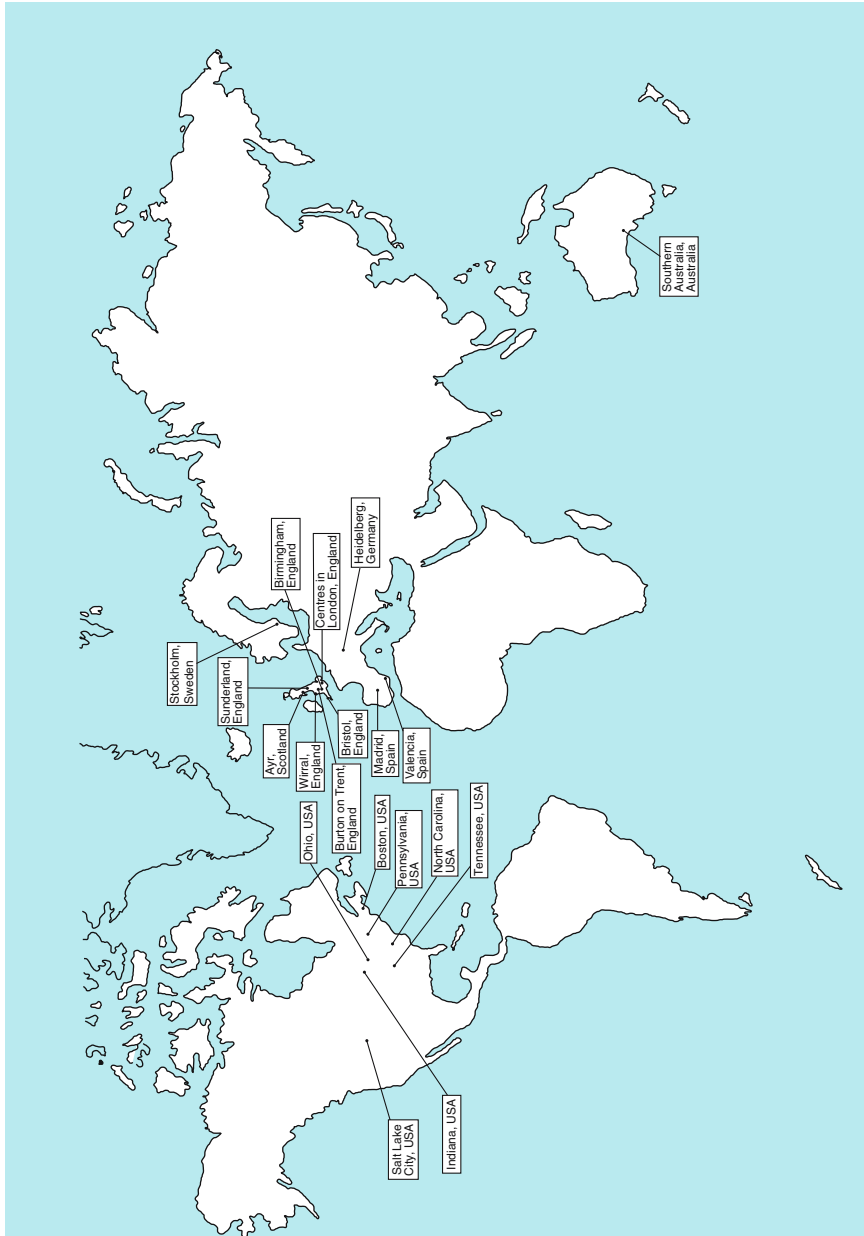
Fig. 1.1 Published experience of EP systems around the world

be discussed in later chapters of this book. For this reason, there is an increasing interest in the benefits of EP systems from both healthcare professionals and healthcare provider managers. Elsewhere in Europe, regional and national healthcare IT programmes have been established to address population healthcare issues.[1] Over the next few years, it is hoped that the Connecting for Health (CfH) IT programmes for the National Health Service (NHS) in England will implement EP systems at all hospitals in England.[2] Furthermore, successful establishment of regional or national programmes will generate further interest in EP at European and international level. There is therefore likely to be an exponential growth in the significance of EP over the next ten years.

Furthermore, in any given health economy, a broad constituency of professionals are involved in the design, implementation, management and maintenance of EP systems, depending on the technology employed, the structure and organisation of the healthcare system concerned, and the roles of the different professionals within the system. This would include healthcare professionals (doctors, nurses, pharmacists and other healthcare professionals), healthcare managers and administrators, IT specialists from within the health system or software vendors, drug data suppliers and other stakeholders, such as government regulatory bodies or the pharmaceutical industry.

This book will discuss issues associated with secondary care EP systems to date, the basic principles of design and implementation of these systems, and how their design and configuration can impact on benefits realisation, hospital workflow and clinical practice. While the book explores the current benefits and potential role of EP systems in hospitals, and describes interfaces with other secondary care systems (for example pharmacy systems and pathology systems), discussion of primary care IT systems for medicines management – in particular, the electronic transfer of prescriptions (eTP) in community pharmacy – is outwith the scope of the book. There is, however, an expectation that, in future, secondary care and primary care systems will be able to communicate with each other.

This book will necessarily refer to the published literature to illustrate the recognised benefits of EP systems and the potential applications of such systems, described in each chapter. Nevertheless, the book is not intended to provide an exhaustive review or quantitative analysis of published studies.

This chapter will set the scene by exploring some of the social, political and philosophical issues that attend the use of electronic systems in healthcare, and in particular, EP systems.

Definitions and Terminology

Since electronic systems for medicine prescribing have been developed independently in different countries, under the auspices of different healthcare systems, it is inevitable that there will be variations in terminology. Furthermore, terms that are not synonymous may be used interchangeably or in an indiscriminate manner.

A recent UK definition of *electronic prescribing* is as follows:

> The utilisation of electronic systems to facilitate and enhance the communication of a prescription or medicine order, aiding the choice, administration and supply of a medicine

through knowledge and decision support, and providing a robust audit trail for the entire medicines use process

Connecting for Health Electronic Prescribing Baseline Specification.[3]

This is a useful working definition for an EP system because it takes into account the capacity of an EP system to add value to the patient's prescribing history through use of clinical decision support tools, and also the process of storage and communication of medicine orders. It is an appropriate description of some of the EP systems in current use in the UK. It is also a suitable definition for many of the US EP systems that are available at present.

However, in the US, the term *computerised physician order entry* (CPOE) is often used in the literature to describe computer applications that are used for EP. This term is often used synonymously with EP. However, CPOE is a broader term that can encompass the transmission of other clinical order types, such as pathology tests or radiology tests, as well as medication orders. However, when applied to medication orders, CPOE only addresses the prescribing element of the medication use process,[4] together with the electronic transmission of the medicine order. Strictly speaking, the term CPOE does not embrace the database and decision support elements of an EP system, which are regarded by many commentators as an essential aspect of an EP system.

In the US, the provision of medication in response to prescriber orders and the management of the supply of medicines is the role of *pharmacy information systems*.[5] These systems are designed to manage information relating to the use of medicines in patient care and include functionality for online order entry, pharmacist review, medication profiles, label printing, stock or inventory control and reporting (medication use reports, dispensing reports etc.). Since some pharmacy information systems may be used to facilitate EP, with online order entry and, in some cases, clinical decision support tools, some commentators consider them as EP applications. However, this is in contrast to the UK, where there is a more clear demarcation between pharmacy systems, which are well developed and universally used, and EP systems, which are still in their infancy.

In Europe, the European Committee for Standardisation has defined electronic prescriptions in terms of the exchange of prescription messages between prescribers and dispensers, and between healthcare providers and official authorities as permitted by national regulations.[6]

This definition focuses on the dissemination of prescription information between stakeholder organisations, following recognised messaging conventions and in accordance with national laws, thus reflecting the European Union emphasis on removing barriers to commerce across the EU. It does not mention clinical decision support, and is concerned with the business and commercial aspects, rather than the clinical aspects, of the medicines use process.

The definitions and terms used have different emphases and, when used correctly, reflect different aspects of the whole medicines use process. Overall, it is clear from a discussion of the terminology that EP is a complex discipline, the success of which relies on the successful interplay of system design, data support and clinical practice.

In addition, the term *electronic medicines management* should be considered. Electronic medicines management is a broader term than EP, since it encompasses all medicine-related activities – including selection, supply, medicine administration and monitoring of medicine use – not just the act of prescribing. It is therefore a useful description of many contemporary EP systems, which are comprehensive in their scope, and are designed to support and manage all medicine-related activities in a hospital. However, the term *medicines management* is one that has largely been coined by the UK pharmacy profession and has little currency outside the UK and outside the pharmacy profession.

In addition to the definitions of the overall process of EP, it is recognised that the descriptors and nomenclatures used within the EP systems must conform to recognised standards in order for the systems to be internally consistent in their operation and intraoperable with other systems. Controlled terminologies, as they relate to EP systems in particular, will be discussed in the chapter on data support. However, it has to be recognised that the major harmonisation endeavours for healthcare IT – for example, Health Level Seven (HL7) and the International Standards Organisation (ISO) TC 215 – seek to address process issues beyond the prescribing of medicines in a clinical scenario. So, for example, the ISO TC 215 standard for identification of medicinal products (structures and controlled vocabularies for ingredients (substances))[7] lists international pharmacovigilance (reporting of side effects of drugs), clinical trials, product regulatory approval and environmental protection or toxicology as business use cases for controlled vocabulary for medicines, as well as EP.

The Benefits of Automated Systems

In the earliest days of computer technology, automated systems were developed in order to store and retrieve information. With the advent of solid state technology, where for the first time it was possible to build computers that were powerful enough to handle large volumes of data with optimal speed, but small enough to be of practical use in a working environment, organisations began to see the potential of computer-based systems to replace bulky paper records.

Computer-based systems also bring the possibility of fast and accurate retrieval of information, based on appropriate indexing and coding methodology. There is also the potential to post messages against certain records according to keywords and other attributes, which is potentially useful in clinical applications. Indexing and coding can present procedural issues in the design of a simple database, concerning classification, accessioning etc.; in the area of medicines and therapeutics information, the use of indexing methodology to provide clinical decision support is potentially a very complex – and critical – science. Data structures and coding systems for medicines data will be discussed in detail in a later chapter, together with use cases and known problem scenarios.

A review of experience of EP applications in the UK[8] has demonstrated that EP implementations have resulted in the following benefits:

- Availability of a fully electronic prescribing history.
- Improvement in legibility and completeness of prescriptions.
- Improvement of hospital business processes due to electronic dissemination of prescriptions.
- Availability of electronic decision support tools at the point of prescribing.
- Comprehensive audit trail of prescribing decisions made.
- Reduction in the rate of medication errors.

Some of these benefits have also been reflected in the major quantitative studies of systems in the US. These benefits will be discussed in detail in subsequent chapters.

The benefits of EP systems are far-reaching in significance, in terms of effects on risk management and risk reduction, and also financial cost. However, it is acknowledged by experts in the field that realisation of these benefits is dependent on system design. Given the likely growth of interest in electronic medicines management, a discussion of design issues with electronic medicines management systems, and their impact on benefits, will be timely for the many groups of professionals likely to be involved.

Automated systems offer advantages over traditional paper-based systems in three main areas:

- Accuracy – Automated systems can support the consistent use of medicine nomenclature, the accurate recording, display and transmission of prescription information, and the accurate display of clinical warnings as a result of a logical system of trigger points. In short, EP systems automate repetitive processes or monotonous processes, which are prone to human error when carried out manually.[9] Thus automated systems are able to contribute to risk management objectives in hospital prescribing.
- Standardisation of data – Automated systems allow patient data to be captured and stored according to standard formats and conventions. This facilitates the electronic transfer of patient data, and the production of comprehensive management reports. The production of management reports by hospitals and healthcare providers is an issue of great political significance in many healthcare economies where there is a need for governments and the public to be aware of healthcare issues and outcomes. However, reporting is an area of clinical IT where there are often many methodological and technical obstacles to be surmounted. It is hoped that EP systems in development will address important deliverables in management reporting. However, in standardising patient data, electronic systems therefore have the capacity for what has been described as "mass customisation."[9] In healthcare terms, this means that, although the system handles large amounts of patient data, it is able to produce an individual care plan based on the specific personal requirements of each patient.
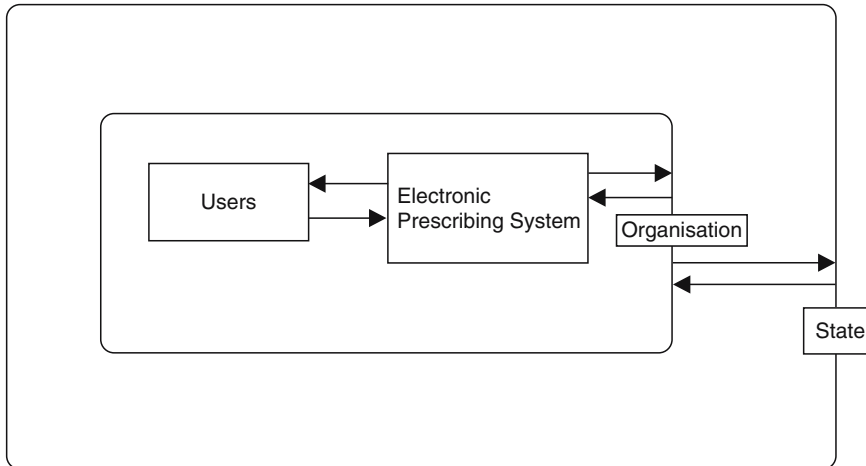
Fig. 1.2 Relationships between the EP system, the user, the healthcare provider and the state

• Facilitating changes in working practices – Automated systems have the capacity
  to process prescription information accurately and at scale, and are able to facili-
  tate the display of that information in different contexts, according to system
  design and hardware availability. They are therefore able to make possible new
  ways of working for individuals and organisations. Because the system takes
  care of the routine recording, computational and transmission aspects of pre-
  scription information management, organisation processes may be restructured
  so that health professionals can engage with near-patient clinical activities,
  which require intuitive human qualities (Fig. 1.2).

EP and the Individual

Given that electronic systems have the potential to improve health outcomes,
through increased accuracy of prescription information management and dissemi-
nation, and to revolutionise working practices, the implementation of an EP system
may have a significant impact on individual users – the healthcare professionals
involved with the prescription, supply and administration of medicines. The intro-
duction of an EP system will also have consequences for the working lives of hos-
pital managers, healthcare informaticians and IT professionals and other health
provider staff who are not patient-facing.

Many individual healthcare professionals will appreciate the potential benefits of
an EP system; they will see the potential for a system to improve health outcomes and
reduce risk in their particular area of practice. This will be especially the case for
consultant medical staff whose performance may well be monitored using the

intervention and health outcome information for their patient list. However, in an increasingly regulated healthcare environment, other healthcare professionals will see the value of EP systems in helping them to achieve performance objectives and to comply with ethical, legal and professional requirements. Some healthcare professionals, however, may be concerned about adverse effects on their sphere of practice, with the political and litigation implications that those adverse effects might entail. For this reason, they may be concerned about the capacity for electronic systems to generate new and uncharacterised errors, which is well recognised in the literature.[10]

Furthermore, an individual's attitude towards the implementation of an electronic system is often not related to whether or not they are familiar with the documented research evidence for the use of such systems. This suggests that factors other than system knowledge and familiarity affect a person's attitude to the introduction of an electronic system.

An automated system will introduce a new way of doing one or more business processes within an organisation, and therefore bring about changes in working practices. There is therefore a requirement that individuals are trained on the new system and, as mentioned earlier, a new system can facilitate new ways of working in more general terms.

A number of factors influence an individual's willingness to engage with a new way of working, and their resistance to change. These include:

1. An individual's personal response to innovations and changes of any kind. In marketing theory, it is recognised that, by character, some individuals are innovators, some early adopters, some early majority, some late majority and some laggards.[11] For an information product, it is known that the proportions of these groups are 2.5%, 13.5%, 34%, 34% and 16% respectively.
2. An individual's personal view of technology. Some people may be "technophobes" for any number of reasons, such as a bad experience with a previous computer system, either at work or at home, or a feeling of disempowerment because, in the consumer world, large corporate bodies are using IT systems aggressively to manipulate their customer base and achieve their commercial goals.
3. The threat of a change to an individual's status or position within the organisation. With an EP system, some people in the organisation – in particular, lower paid staff such as pharmacy support staff and healthcare assistants – may feel that their jobs are at risk, because of automation. EP and pharmacy automation generally do not lead to reduction in posts, however, as will be discussed in Chapter 3. In addition, some people may feel that the change in working practice is one way of another professional group exercising power over them, or that they are having to do extra work so that another professional group can reap the benefits.
4. An individual's bewilderment and confusion concerning the exact role and operation of a new system. It is to be hoped that this barrier to successful implementation can be at least partly removed by a thorough programme of training and orientation.

In addition to the implementation process itself, the routine use of an EP system may have a profound influence on the working processes of individual healthcare professionals. Conversely, the success of the system may be influenced by the

way in which individual health professionals work with it. A number of factors can be identified.

- A functionally-rich EP system will make a larger amount of clinical data available to healthcare professionals at the point of patient care.[12] This may necessitate the acquisition of new skills in clinical data evaluation, which may have implications for continuing professional development (CPD). This may also lead to a state of "information saturation" for busy health professionals, which could cause increased levels of stress in daily practice.
- An EP system may well enable new and unfamiliar ways of working. These may be beneficial to health professions in the long run, but may be stressful in the short term. Moreover, without good management, especially proactive change management, with the introduction of clear procedures, new ways of working may initially introduce more critical incidents that they resolve.
- An EP system may be used to facilitate new ways of doing with critical incident-based CPD. This is beneficial at a time when health professionals are increasingly regulated in terms of the amount and format of CPD and with the use of CPD as the basis for professional accreditation.
- It is recognised that people are less likely to question the accuracy and authenticity of information when it is displayed on a computer system, than when it is recorded in medical notes or on a drug chart, perhaps in a poorly legible or ambiguous manner. This effect may lead to complacency in clinical practice in future, when EP systems are universally available, where the assumption that "the computer is always right" leads to errors and near misses. Clinical users will need to gain confidence in the due diligence process surrounding the implementation of EP software, but at the same time will need to retain a level of vigilance when presented with data by an EP system. An EP system will never replace the clinical judgement of an experienced health professional.
- As mentioned previously, decision support functions within an EP system are an important way in which the EP system "adds value" to the prescribing process. However, as experience with currently-used general practice (GP), hospital pharmacy and community pharmacy systems suggests, systems often provide a highly detailed level of decision support on a range of parameters – sensitivity checking, drug interactions, drug disease interactions, contraindications etc. – but they may not be configured to display warnings according to clinical significance, or to display only the warnings that are relevant to the patient in question. In some cases, with drug interaction warnings, a system might display all reciprocal warnings; for example, the system will display two warning messages, showing that there is a drug interaction between aspirin and warfarin, and also between warfarin and aspirin. The result is that, on prescribing a medicine, an EP system user may be presented with an exhaustive list of warnings, many of which are duplicated, or are of questionable relevance, and will be required to click an acknowledgement of each one. This can lead to what has been termed as "warning fatigue," where the user becomes inattentive concerning the warnings displayed, due to the presence of irrelevant warnings, and will inadvertently ignore a significant warning. Warning

fatigue is an important cause of decision support failure in EP systems; data providers, system implementers and researchers are undertaking ongoing research into the nature of the problem, and its possible solutions by making changes to the data structure or the user interface.

The introduction of an EP system may have consequences for hospital managers and health provider staff who are not patient-facing and who would not be routine users of an EP system. Many healthcare managers will understandably see the successful implementation and use of an EP system as:

(a) An important factor in the reduction of clinical and organisational risks, and thus the risk of litigation;
(b) A means of improving clinical governance and information governance so that hospital management has accurate information on actual health outcomes in the organisation.

Nevertheless, some managers will see an EP system as a "quick fix" for one or more longstanding problems in the organisation. These managers are likely to become frustrated when they realise that the process of change itself is often a slow one, and will become impatient at the amount of low-level detail that needs to be considered with an EP system implementation. Other hospital managers may see the implementation of an EP system as a means of achieving their targets at the expense of the working practices of other professional groups in the hospital, or may see the system as a way of imposing an organisational or ideological agenda on some groups of staff, which will bring them into conflict with one or more other groups of staff.

EP and the Organisation

As can be seen in the previous section, the issues and problems that affect an individual when an EP system is implemented are inextricably linked with the issues that face the organisation as a whole, when a system is introduced. An organisation is, to a greater or lesser extent, the sum of its individuals. This section examines some of the organisational issues facing hospitals and other secondary care health providers when an EP system is implemented.

The earliest prescribing and medical information systems in the UK were designed for use in general practice and their use in primary care has become widespread, following the introduction of Read codes, which enabled the common classification of medical terms for audit purposes,[13] and which in turn facilitated the electronic storage and transmission of patient information, including information about their prescriptions. GP systems have been on the market for over 20 years and have adapted to changes in medical practice in primary care during that time. Furthermore, the databases provided by leading third-party data suppliers were originally designed to meet the needs of primary care computer systems; primary care systems suppliers are still the chief consumers of third party drug databases.

This begs the important question: why has EP and medicine or prescribing information management not developed in a similar way in secondary care? Why is EP largely still in its infancy in secondary care health providers around the world, when the technologies to enable it have existed for some time?

The lack of adoption of EP systems in secondary care is, in many respects, due to organisational issues. A primary care medical practice – even a large one, such as a ten-partner practice in a large town – represents a discrete working unit, where practice personnel are expected to work as a team, and the partners and practice manager have control over the systems in place within the practice. In this environment, the choice, implementation and maintenance of an electronic system is a relatively easy matter. Stakeholder engagement ("buy-in") with the new system is easier to achieve with a small, well-defined practice team, the installation of the system can be project-managed in a relatively controlled manner, and the logistics of training personnel does not present major problems.

It is a different scenario with an average acute hospital. Hospitals are larger, comprising of a number of distinct wards and departments. There are a range of clinical and non-clinical professions in a hospital and, historically, the working practices of each profession have been governed by the profession itself, rather than engagement in multidisciplinary teams, and this fosters professional segregation and rivalry, rather than multidisciplinary working. In many hospitals, the hospital management structures are heterogenous, at best, and may be unable to hold together the divergent professional interests and departmental agendas in the organisation.

From a political perspective, this diffuse organisational structure considerably increases the problems associated with the change management required to introduce a new system across the hospital. When there are a number of distinct and separate stakeholders, it is essential for implementers to secure stakeholder engagement, and ensure that all professional agendas are acknowledged. Failure to do this can lead to an important stakeholder being disenfranchised, with disastrous consequences for the implementation project. Moreover, the implementation of a new system may exacerbate existing rivalries between professional groups. This is especially the case if one professional group has a greater role in the implementation than does another.

The implementation and roll-out of an EP system within a hospital represents a major business project, and will require formal project management and project structure – the standard methodology for which is PRINCE 2, in the UK healthcare environment. A clinical IT project will require engagement with stakeholders, process redesign and training of users in the new system. This in itself will be stressful for those directly involved in the project team. Secondly, it is recognised that the most successful EP implementations in hospitals are ones where every effort has been made to engage all stakeholders – doctors, pharmacists, nurses, managers, IT staff and others – and to encourage them to take ownership of the new system.[14] Conversely, it is often the case that, if one particular professional group drives the project, according to its own agenda, the implementation is less likely to be successful.

Because of the segregation of the professions in the NHS, historically healthcare applications used in the NHS have been designed for use in a particular department,

to manage a discrete, well-defined process. This approach was taken with both pharmacy systems and pathology systems, which were the earliest systems to be implemented in NHS hospitals. Moreover, such systems often began as "home grown", designed by innovative health professionals, with IT expertise.[15]

Consequently, IT systems in the NHS have in the past been subject to "silo" development in individual departments – i.e. as separate systems with no ability for interaction or integration with other departmental systems. As time has gone by, concerns have been raised about the ability of these systems to share patient data throughout the hospital, the capacity of the different systems to introduce inconsistencies in data handling and the difficulties of configuring these departmental systems to operate in other hospitals.

In response to these issues, it has become common for clinical software vendors to provide appropriate interfaces so that their system is intraoperable with other hospital systems. Thus, the vendor of an EP system would typically need to provide interfaces with the hospital's PAS, to gain access to patient demographic data, and with the hospital's pharmacy system, to allow seamless transfer of prescription information to the pharmacy department. However, such interfaces are problematic in that they are often complex to build and require thorough testing. A key objective of large IT programmes, such as the England CfH programme, is to surmount issues relating to connectivity and intraoperability. The aim of CfH is to introduce a large, unified IT system that will deal with all hospital business processes (possibly by means of a service-oriented architecture) across a whole hospital site and beyond. The issues facing national and regional government IT programmes will be reviewed in the next section.

In addition to the organisational issues highlighted earlier, there are other factors that limit implementation of EP within healthcare enterprises. These include:

1. The financial cost, especially with commercial systems. This is linked with the fact that the EP software may be sold by a vendor as part of a larger integrated system, and the healthcare provider may only wish to purchase the EP component.
2. Legal issues and due diligence process concerns of healthcare providers. These will be discussed in detail later in the chapter
3. Political issues – paradoxically, one factor that has limited clinical system innovation in the UK has been the forthcoming implementation of Connecting for Health CfH clinical systems. For this reason, many UK health trusts have put a freeze on implementation of new clinical systems pending the introduction of CfH compliant systems, despite the fact that such systems may be some years from being ready for implementation.

EP and the State

As mentioned earlier, electronic systems for use in healthcare applications have traditionally been developed within the NHS on a "silo" basis – i.e. as separate systems, where intraoperability is dependent on the resilience of hospital servers

and networks, and the availability of robust interfaces with associate symptoms. Even with the technical ability to link systems, there may be issues with actual information exchange due to lack of standardisation of data and data structure.

The silo development of hospital systems has had profound implications for management of healthcare at government level. The duplication of basic demographic data, and the need to re-key basic patient details in certain cases, has in the past provided a huge workload burden on health providers. The use of different systems in different parts of the country means that, when an individual moves to another region, or is treated in a different hospital, their electronic patient record (EPR) has to be rebuilt on a new system, potentially introducing inconsistencies. Furthermore, if a patient is treated as an emergency away from home, their medical information stored in electronic form at their local hospital is not available to the professionals involved in the emergency situation. In addition to issues surrounding the treatment of individual patients, silo development of systems in the health services have hindered the collation of data for public health reporting purposes. Governments need to gain an accurate picture of the health needs – and health outcomes – of the population. A well-publicised, and emotive, example of this in the UK is the situation with reporting of cancer statistics, where in the past, there have been inconsistencies and gaps in information available to the Department of Health on cancer incidences and outcomes.[16] The introduction of the National Cancer Dataset (CDS) provided a standard framework for reporting of cancer epidemiological data, and has gone some way to resolving this issue. Many of the oncology systems and radiology systems providers have rebuilt their databases to incorporate the data conventions of the CDS.

There is therefore a strong political argument for the introduction of clinical IT as part of a regional or national healthcare IT programme. Such a programme has the potential to:

(a) Provide seamless operation of clinical systems across the region or country and thus facilitate consistent patient care.
(b) Provide standard user interfaces that are used by all health professionals; this is a factor that will reduce operational risks due to human error.
(c) Provide a consistent framework for public health management reporting and clinical governance across a region or country.

As mentioned earlier in the chapter, a number of regional programmes have been implemented to a greater or lesser extent elsewhere in Europe. In the UK, the Connecting for Health programme (formerly the National Programme for IT (NPfIT)) has been running since 2002, with the aim of delivering a range of healthcare functions across the UK NHS. Nevertheless, the programme has attracted strong criticism, as it has exceeded its budget and has not met its expected targets in time. Furthermore, some have questioned whether the earliest deliverable from the programme, the Choose and Book appointment allocation system, is fit for purpose. In general terms, large-scale IT projects such as this are often not successful, because they are associated with a high level of political and logistical inertia, due

to the engagement of the many stakeholders involved, and the scale of the project process that has to be managed. Also, when concerns about deliverability are raised, public opinion about the programme is diminished and stakeholder morale is lowered, leading to a downward spiral in programme efficacy. The problem is compounded with the UK CfH project, in which it is based on a three-tier system – CfH have engaged a number of local service providers (LSPs), who are contracted to deliver the technological infrastructure, and who have subcontracted healthcare software vendors to provide the software. This structure has increased the number of stakeholders, and therefore the amount of political friction associated with the programme, and it is likely that this has impacted on programme delivery schedules. Also, major concerns have been expressed about the ability of software vendors to produce software that is fit for purpose for UK clinical use within the projected timeframe of the project.

When the CfH programme was first introduced, it had the effect of slowing down clinical system innovation. A number of NHS Trusts in the UK stopped ongoing implementation projects, with the intention of adopting the CfH software when it was available. When it became clear that CfH solutions were going to take a long time to develop, some NHS Trusts opted to implement interim solutions, especially in specialist areas such as oncology and radiology, which were further ahead in the CfH roadmap. These Trusts realised that there were clear managerial and clinical benefits from implementing an interim system, on the basis that they might use such a system for more than five years, before the corresponding CfH solution becomes available. The UK government acknowledged this by conducting a benchmarking process on available oncology systems in 2006. It is now recognised that more general functionality, such as EP and medicines administration, will be delayed under the CfH programme and, for this reason, some UK healthcare providers are becoming impatient with the national programme. The Royal Liverpool and Broadgreen University Hospitals Trust has chosen to implement an EP system independently of CfH, and therefore at its own cost, because of concern with the national programme and in order to fit with their other technical priorities in the Trust.[17] The Shrewsbury and Telford NHS Trust have implemented an electronic transcribing system that has been developed within the Trust, and they may proceed to develop EP and medicines administration from this solution, should the CfH solution not be forthcoming.[18]

The United States health system also faces a major challenge in the development of EP systems. An urgent priority for the US government is to manage expenditure on chronic diseases, in particular in the large proportion of low-waged Americans whose treatment is funded by the government insurance schemes Medicare and Medicaid. EP systems have the capacity to optimise cost effective medicine use but, since only 5–18% of US healthcare providers are using EP systems,[19] there will need to be a greater adoption of EP systems before EP has a significant impact on prescribing in the Medicare or Medicaid populations. For this reason, recent legislation has been introduced to encourage more widespread adoption of EP systems, largely by setting standards of intraoperability across the wide range of software vendors in the US marketplace.[19]

Legal Requirements for EP Systems

An important area where the requirements of the state have an impact on EP systems is concerning the legal framework for prescribing. Many countries have laws restricting the right to prescribe, supply and personally administer medicines to certain professional groups, in order to safeguard the public and also to regulate the costs of, and the supply chain for medicines. As it is beyond the scope of this book to provide a full review of legal provisions around the world, and their implications for EP systems, this section will be restricted to an overview of the legal framework for prescribing in the UK, in order to illustrate some of the underlying issues for EP system designers.

The prescription, supply and administration of medicines in the UK are primarily regulated by the Medicines Act 1968, and its dependent legislation. The UK law defines prescription only medicines (POMs) as those medicines where a legally valid prescription from a clinician is required before the medicine can be supplied to a patient for self-administration. However, in the UK, any medicine – including over the counter (OTC) medicines, and unlicensed medicines – may be prescribed (subject to any specific local restrictions). Consequently, when configuring drug datasets, implementers should not make the legal category of a medicine alone a condition for prescribability.

There is a provision in the law indicating that a medicine written on a hospital chart for administration by a nurse to a hospital inpatient is, in fact, an "order to administer" a medicine, rather than a prescription. Consequently, electronic medicine orders for outpatient and discharge supply legally constitute prescriptions, whereas electronic medicine orders for inpatients are orders for administration, which do not, in fact, need to conform fully to prescription regulations. Nevertheless, it has been regarded as good practice for all medicine orders generated in hospitals to comply with the legal requirements.

A legal prescription in the UK has the following attributes:

(a) It must be legible ("written in ink or otherwise so as to be indelible").
(b) It must be dated.
(c) It must include the name and address of the patient, and their age if under 12.
(d) It must be signed in ink by the prescriber.

The legal requirements for a prescription should be considered in the design of the dispensing screens of an EP system. It should be noted that provision (d) has hindered the use of UK hospital EP systems in the past, in which electronic outpatient and discharge prescriptions needed to be signed by hand to validate them. However, recently the law has been changed to permit electronic signatures, so that all electronic medicine orders can be handled electronically.

In the UK, some medicines are subject to specific controls under the Misuse of Drugs Act, 1971, and subsequent measures. These are known as controlled drugs, and are primarily medicines with an abuse potential, for example, opiates and stimulants. With these medicines, the following requirements apply in addition:

(a) It must specify the prescriber's address.
(b) It must include the dose and, for a preparation, the form and strength of the preparation.
(c) It must include the total quantity in words and figures.

Again, these data items must be included in the prescription profile or dispensing screen for controlled drugs. In the UK, there is a requirement to maintain registers of the receipt and supply of controlled drugs. In recent years, this requirement has enhanced to include the recording of:

(a) Running balances
(b) The name of the supplying pharmacist
(c) The name of the person collecting the medicine

These enhancements enable a more fuller audit trail of the supply of controlled drugs to be established. The future use of electronic controlled drug registers has been discussed in the UK.[20] If so, there would be a future requirement for EP systems to interface with these electronic records, and system designers would need to consider this.

A significant proportion of medicines used in hospitals are for unlicensed, or "off label" use, where the manufacturer does not have regulatory approval to promote it for that use. In some cases, a licensed medicine is used for an unlicensed indication, or in a patient group where it does not have a license – the use of medicines licensed for adults in children is a common scenario. Alternatively, a completely unlicensed medicine is supplied by a manufacturer for a specific purpose, possibly for compassionate reasons. It should be noted that it is not illegal to prescribe unlicensed medicines, but that the prescriber, rather than the drug company, takes full responsibility for prescribing the drug. Consequently, it is desirable for EP systems to indicate clearly to a prescriber if a product is unlicensed.

EP Systems and Professional Liability

Medicine is one of the most highly regulated areas of professional practice and, with an increasingly litigation-conscious culture and a corresponding increase in defensive practice on the part of health professions, awareness of professional liability will increase in forthcoming years. As a general principle, each individual practitioner is legally responsible for his or her decisions and actions as a healthcare professional, and the use of electronic systems as prescribing, dispensing and decision support tools does not detract from this. Indeed, software vendors should include a disclaimer in their documentation to the effect that EP software is a tool and is not intended to replace the clinical judgement of the practitioner.

However, while clinical users must still use their clinical judgement when prescribing electronically, they need to have sufficient confidence in the software to be able to use it routinely in a busy clinical environment. This confidence comes from rigorous testing of system configuration and software operations, prior to live use

of the software, and detailed documentation of the pre-implementation configuration and testing of the software. This is called the "due diligence" process – so called because, if the healthcare provider were taken to court as a result of an error facilitated by the software, they would use the testing and acceptance documentation for their defence, to show that, in legal terms, they had "exercised due diligence" in assessing the risks of implementing the software.

It is possible that an EP system could facilitate a critical incident as a result of the operation of the software or its configuration. In this situation, the software vendor may be liable along with the practitioner and the healthcare provider. It is essential then that software vendors utilise appropriate clinical expertise when designing an EP system, that they have appropriate arrangements in place for the provision of drug data for their EP system (see Chapter 5), and that they ensure that appropriate due diligence documentation is generated, as part of the implementation project management.

Confidentiality and Consent

Health professionals and health providers who hold personal information about their patients and clients have a duty of confidence to the people about whom the information is held (the subjects of the information). In addition, there is an ethical obligation to maintain professional standards of confidentiality for many health professions. The general rule is that information given or received in confidence for one purpose may not be used for another purpose, or disclosed to a third party without the subject's consent. The duty of confidence continues after the death of the subject, and after a professional has ceased professional practice.

The use of EP systems, which contain prescription and medicines-related information about patients, is, of course, subject to the recognised confidentiality requirements. In 1997, the Caldicott Committee reported on issues relating to security and confidentiality of patient information[21] in the UK, and indicated that patient-based information systems used in the NHS should be designed in a secure way, with *privacy-enhancing technologies* incorporated within the application structure.

There are a number of guiding principles for safeguarding confidentiality of patient information in electronic systems:

(a) System databases should have appropriate internal security, and patient data should be anonymised within them.
(b) Consideration should be given to appropriate encryption when data are transferred outside the system.
(c) A user's level of access should be appropriate to their role.
(d) A system should indicate in some way that the user is viewing confidential information.
(e) Identifiable information relating to UK patients should not be processed outside of the UK.

A particular issue that has been debated is the way in which especially sensitive personal information is stored on an electronic system – for example, information on a person's HIV infection status, or a record of their treatment at sexually transmitted disease (STD) clinics. While it is necessary for this information to be recorded electronically and, as far as possible, taken into account by decision support functions, consideration should be given to limiting access to that information, or providing some form of "sealed envelope" functionality to prevent the information being viewed freely by all users.

Related to the matter of confidentiality is the issue of a patient's consent to having their information stored on an EP system. In many instances, a patient's consent is implied when a medication history is taken from a general practitioner's letter; the assumption is that the patient agreed to the referral. Indeed, in many scenarios, it has to be assumed that consent is implied; if consent had to be obtained explicitly at every stage of the patient care process, the work of a healthcare provider would soon become unmanageable. However, in situations where information – for example, a prescribing history – is elicited from a patient, or when other information is obtained from the patient (such as the medicines review scenario described in Chapter 6), with the intention of putting the information on the EP system, then explicit consent should be obtained from the patient to store the data for a nominated purpose. This is consistent with the requirements of the UK data protection legislation.

Ethical Issues

As EP systems will be operated by healthcare professionals, the ethical principles followed by healthcare professionals (which are made explicit in the codes of ethics published by professional bodies) are of significance when considering the use of EP systems. It is well established in many legal systems that a health professional has a "duty of care" for their patients – that the healthcare professional will ensure that the patient is treated according to recognised best practice, has the most appropriate treatment for their illness and that the patient's interests are best served. For this reason, healthcare professionals, as professionals, will want to be assured that an EP system will optimise the therapeutic decision-making process for the patient, will reduce any known risks associated with the prescribing process and will ensure that confidential patient information is stored and retrieved in a reliable and secure manner.

Furthermore, if an EP system has any specific operational shortcomings, either due to software bugs or data configuration issues, then health professionals will want these issues to be rectified by the software vendor, in the interests of the healthcare provider and the patient population. However, this may bring them into conflict with software vendors, whose prime motivations are commercial and political, and who may not wish to allocate resource to resolve outstanding issues as there is no extra revenue for doing so. In particular, this may lead to conflicts of interest for health professionals who are employed by software vendors.

Resource allocation is an ongoing issue in modern healthcare providers, due to increased burdens of healthcare requirements, and a finite budget to meet those requirements. While resource allocation is a reality for health professionals, they may be concerned at the potential for EP systems to impose government restrictions on prescribing practice, or to apply such restrictions in an unrealistic manner, without regard to the professional's clinical judgement.

Conclusion

EP systems have been implemented successfully in some healthcare economies and have been associated with various clinical and organisational benefits. Furthermore, there is a huge potential for greater adoption of EP systems, and introduction of progressively more complex functionality. However, the design, implementation and operation of EP systems necessarily takes place in a world where there are complex interactions of sociopolitical, psychological, legal and technical factors, affecting EP implementation. Given the potential impact of EP systems on a wide range of stakeholders, these issues should be explored in greater detail, both as part of multidisciplinary EP implementation projects, and also by specific experts in the issues involved.

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Chapter 2
History and Context of Electronic Prescribing in the US and UK

The Development of Information Technology in Healthcare

With the advent of solid state technology, where for the first time it was possible to build computers that were powerful enough to handle large volumes of data with optimal speed, but small enough to be of practical use in a working environment, organisations began to see the potential of computer-based systems to replace paper records of different sorts.

Within healthcare, the first major area of IT application was the use of electronic systems to facilitate the collection, storage and dissemination of discrete, patient-related data (either numeric, or coded with a recognised coding methodology) as a solution to specific healthcare activities. Consequently, over the last 20 years, the most well-developed IT applications in secondary care have been (a) pathology systems, for the management of test results and (b) pharmacy systems, for the labelling of dispensed items and for pharmacy stock control. Systems such as these were relatively straightforward to implement, as they had their hub in one particular department of the hospital (and this department therefore had control over the implementation), the benefits of such systems were substantial in comparison to the potential risks, and they presented no special problems concerning database and communications technology. Subsequent IT applications in secondary care included whole-hospital systems such as patient administration systems (PAS) and order communications, dealing with the messaging of orders in the broadest sense (e.g. radiology orders as well as pathology and pharmacy orders).

Correspondingly, in primary care, GP systems have been in use since the mid-1980s and, in recent years, have become quite elaborate, in terms of the functionality they offer. In addition to the ability to store clinical notes (usually with a problem/note hierarchy) and generate prescriptions, these systems are able to provide prescription pricing information, detailed medical information from reference sources such as the British National Formulary (BNF) or the Physicians Desk Reference, pathology order management and items of service/billing and claim management.

However, the issue facing all users of healthcare systems is that of their intraoperability. This has particularly been an issue in secondary care where a hospital has, historically, had a number of computer systems – a PAS, a pathology system, a

pharmacy system, a radiology system – offering reliable functionality, but operating in parallel, in a "silo" fashion, with no connectivity between them. This presents a number of problems: (a) duplication of effort in the design and configuration of functions that may be common to all systems (e.g. patient selection functions), (b) duplication of staff effort in data entry onto the systems and (c) introduction of risk due to all elements of a patient record not being visible to a user through a single system. One of the key goals of regional and national healthcare IT programmes, such as the English Connecting for Health IT programme is systems integration, in order to eradicate these problems. Nevertheless, a higher level of intraoperability, supported by appropriate coding methodologies, and a willingness of all stakeholders to work towards an integrated system are essential to realise this goal.

In any case, aside from the issues of silo development and intraoperability, there are some areas of secondary care that have not as yet been adequately catered for with IT applications. These are primarily clinical applications, most notably the so-called "electronic patient record" (EPR) and the broader term "electronic health record" (EHR). These areas have not been so well developed possibly because of (a) the complexity of algorithms required to perform the required clinical decision support on EPR data; (b) the lack of expertise available for the design of these systems by IT vendors and (c) the reliance of such systems on the availability of adequate technology for handling images (X-rays, MRI scans, CAT scans etc.) One of these clinical applications that is still in its infancy is electronic prescribing.

If hospital information services can be illustrated as a pyramid, EP systems constitute the pinnacle of the pyramid, and are built on the foundation of other more basic functionality (see Fig. 2.1).
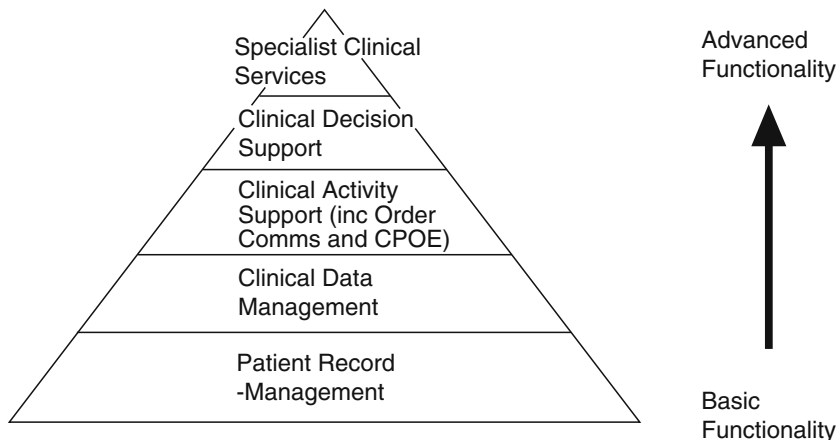

Fig. 2.1 Health informatics pyramid. Specialist clinical services are built on the foundation of basic health information functions

Development of EP Systems in the United States

Much of the available published information on EP implementations originates from the United States. Electronic systems for medicine prescribing and administration have been adopted more widely in the US, possibly due to (a) the need for costing of medication administration, in an insurance-based health system, and (b) the need for risk management to reduce clinical risk to a minimum, and to optimise audit trails in a highly litigious society. As a consequence, there are many proprietary EP, or CPOE systems, available in the United States.

In the late 1990s, US Government Agencies increasingly began to recognise the potential for electronic prescribing systems to reduce clinical risk in busy hospitals.

In 1999 and 2001, the US Institute of Medicine (IOM) produced two well-publicised reports,[1,2] which looked at how technology could be used to support and improve patient safety. The 2001 report, *Crossing the Quality Chasm*, recommended that all stakeholders – providers, purchasers, clinicians and patients – collaborate in the redesign of healthcare processes, towards the goals of evidence-based medicine, knowledge sharing and patient empowerment.[3]

Furthermore, in 2000, the commercial sector made a much-publicised call for an improvement to patient safety by the use of electronic systems. The Leapfrog Group – a coalition of major US companies, the Fortune 500 companies – have identified CPOE as one of the three changes that would most improve safety.[4] It is likely that many senior managers in the commercial sector see safety issues as a major cause of litigation and potential source of financial cost.

In the opening years of the twenty-first century, the US government began to make capital funding available for the implementation of new EP systems. For example, in 2001, the US Senate tabled the Medication Errors Reduction Act, to create a $1 billion federal grant programme to help healthcare providers purchase EP systems. Also, in 2003, the House of Representatives passed the Patient Safety Improvement Act, which aims to provide $50 million in grants over a 2-year period to organisations implementing information technology to improve patient safety.[5]

Subsequently, one of the key drivers for functional development of existing EP systems was the Medicare Modernization Act (MMA) 2003, which recognised the capacity of electronic systems to produce efficiencies in risk reduction and cost savings in the management of chronic diseases.[6] The Act required that Part D Medicare plans should support an "electronic prescription program" should a healthcare provider choose to use one. In the Act, there was also permission for third party organisations to offset costs of implementation of EP systems by healthcare providers.

Specifically, the Act required the US Government Department of Health and Human Services to facilitate standards of interoperability in different functional areas, which are compatible with, and which build upon, existing standards. These include:

(a) ANSI ASC X12N 270/271 – to deal with eligibility and benefits enquiries and responses between prescribers and insurance payors.

(b) National Council for Prescription Drug Programs (NCPDPs) SCRIPT 5.1 – to deal with the majority of transactions between prescribers and dispensers.
(c) NCPDP Telecommunication Standard 5.1 – to deal with eligibility and benefits enquiries and responses between dispensers and insurance payors.

It is well recognised that commercial EP systems in the US vary in the level of advanced functionality they provide, in terms of decision support, and it has been suggested that there should be further legislation to incentivise the standardisation of these advanced functions.

In the US, decision support applications have been used by clinicians at the point of prescribing for many years, and have been extensively evaluated in the medical literature – major reviews of the available studies were published in 1994[7] and 1998.[8] However, there was little published information on quantitative analysis of comprehensive EP systems until the late 1990s.

The most notable centre for EP use in the US is the Brigham and Women's Hospital, Boston.[9–11] The Brigham and Women's CPOE functionality was developed in the early 1990s as part of an in-house information system, the Brigham Integrated Computing System, which was designed to manage all aspects of the hospital's administrative and clinical processes. The initial system included formulary prescribing menus, default doses or dose selection, display of relevant laboratory results and limited sensitivity checking, drug interaction checking and laboratory test interaction checking. Further checking functions were added in an upgrade to the system in 1996.

Another early implementation of CPOE was the system at the Wishard Memorial Hospital, Indianapolis, Indiana,[12] which was implemented in the late 1980s, and documented in a study published in 1993. This system consisted of the Regenstrief Medical Records System mounted on a series of networked PCs through the wards and emergency department of the hospital. This system enabled electronic ordering and decision support on each ward and electronic transmission of orders to the pharmacies.

There have been published studies of other EP implementations in the US. Spencer et al.[13] describe the implementation of the Siemens Medical Solutions CPOE System at the University of North Carolina (UNC) Hospitals in 2002. The system was initially piloted on one general medicine floor at the hospitals in 2002 and was then further rolled out to a second medical floor, and a step-down critical care unit in 2003. The implementation was then studied by analysis of medication errors generated between February 2002 and May 2003.

Mekhjian et al.[14] have published their analysis of the implementation of an EP system at an academic medical centre. They found that major process changes following the implementation of an advanced CPOE system did not adversely affect hospital stay time or hospital stay cost, but had a beneficial effect on turnaround times for medicine supply and pathology test reporting and radiology test reporting.

Koppel et al.[15] describe the operation of a commercial EP system (TDS) at the University of Pennsylvania between 1997 and 2004, and, in particular, a qualitative and quantitative analysis of system use, conducted during 2002–2003.

Studies of these implementations have showed a number of benefits of EP, notably (a) reduction in medication error rate; (b) a reduction in transcription error rate (as would be expected); (c) a reduction in medicine supply turn-around times (due to electronic communication between the ward and the pharmacy); (d) a modest reduction in hospital stay time and (e) an improvement in radiology test reporting and laboratory test reporting times (due to fully electronic communication processes). However, these benefits may not be realisable to the same extent in other health economies due to differences in health service structure, clinical practice and medicine costing and reimbursement.

Two of the US studies, however, highlight the potential for EP systems to generate, or facilitate new types of medication error, an issue that will be examined in greater detail in a subsequent chapter (Chapter 4).

Development of EP Systems in the United Kingdom

The adoption of EP systems in the UK has been equally slow. In early 2007, it was reported that only three hospitals in England (the Wirral Hospitals, Burton on Trent and Winchester) had whole-hospital electronic prescribing systems.[16] This is broadly consistent with a survey of 188 hospitals conducted in the UK in 2000,[17] indicating that, at the time, 89.4% of hospitals surveyed had no EP system, 11% had an EP system but only 2% of hospitals had full electronic prescribing facilities. This suggests that the uptake of EP systems in UK centres has been minimal since 2000. The likely scenario is that local EP innovation has been slowed down, pending the availability of the full clinical IT solutions from the English Connecting for Health IT programme. In any case, the difficulties associated with EP implementations due to commercial and organisational factors have been commented on in the literature.[18,19]

UK hospitals have a good track-record of technology innovation over the past 20 or 30 years. Enterprise-wide PAS have become commonplace. Pharmacy systems in the UK came into routine use in the mid-1980s, following a change in the law requiring labels to be in typeface rather than handwritten. Pathology systems for test result processing and reporting have also been in use since the 1980s. However, as mentioned previously, these systems have largely developed in a separate "silo" fashion, as individual departmental systems. Consequently, one of the most significant tasks in any new healthcare software implementation is not necessarily establishing the technical platform (networks and servers), or configuring the software, but designing and testing the interfaces required between the new application and other hospital systems. A typical example of such an interface would be between, for example, a pathology system or pharmacy system and a hospital PAS, to provide a feed of patient demographic data to the departmental system. The use of "service oriented architecture" has the potential to surmount intraoperability issues within healthcare provider organisations. The business process rationale for using a service-oriented architecture will be discussed in Chapter 3.

The UK centres with the longest history of EP innovation are the Wirral Hospitals, in Cheshire, England, and the Burton Hospitals, Burton on Trent, Staffordshire, England.

The Wirral Hospitals began implementing their EP service as part of an integrated hospital information system (HIS) in 1992, and by 2002, they had achieved Level 4 EPR status.[20] The Wirral Hospitals subsequently installed an automated dispensing system (pharmacy robot) in 2001.

The Burton on Trent Trust has also been working with electronic medicines management systems since 1992.[21] Queen's Hospital, Burton, had a Meditech HISS (hospital information support system) already in place, and implemented the pharmacy module of the Meditech system in 1992. In 1995, the Trust was selected by the then NHS Information Management Group to be one of two sites to participate in the EPR programme. The chief criterion for this was that the Trust was already operating an integrated HISS and had commitment from all the major stakeholders in the implementation process – clinicians, hospital management and suppliers. The EPR programme included electronic prescribing as one of its subprojects and, when the EPR programme was complete in December 1996, three pilot wards in the elderly care directorate were using the EP system. The system was subsequently extended to two further care of the elderly wards, the admissions unit and the ophthalmology ward. The EP system at Burton offers integration with the hospital EPR system, easy to use medicine look-up lists and clear display of patient medication records (PMRs), modelled on the Trust's standard treatment card. The area that provided some difficulties for the team at Burton was the implementation of an appropriate level of decision support within the system. This is an important issue in EP design and will be discussed in a subsequent chapter.

Case Study 1

Shrewsbury & Telford NHS Trust

The eSCRIPT electronic transcribing system

The Shrewsbury and Telford NHS Trust is an acute healthcare provider in Shropshire, UK, which has developed eSCRIPT, an electronic system which enables prescriptions transcribed from the wards to be fulfilled in the pharmacy. Because the prescription history is captured electronically, a patient medication record (PMR) and legible discharge documentation can be generated for each patient.

The eSCRIPT system was developed in-house at the Trust with a Crystal database platform, a custom-designed user interface and links with the PAS and bed management systems. The rationale for developing the system was to streamline the discharge process, produce legible discharge prescriptions and

to support the work of ward-based clinical pharmacists. The system was initially piloted on a few wards (long-stay stroke/rehabilitation wards), before being rolled out across the hospital over a period of 18 months.

The system consists of a central server, networked with wireless workstations on the wards, mounted on Psion Netbook devices. The key benefit of the system is that it provides a PMR, supply record and discharge summary for a patient within the same system. The system is generally popular because a) the initial design process was led by the users (a benefit of an in-house system) and, b) key stakeholders (pharmacists, IM&T staff and clinical divisional leads) were engaged early on during the project.

While the system was tested at the outset using a variety of patient scenarios and use cases, a number of issues became apparent once the system became fully operational. These concerned the management of patient's own drugs (PODs) by the system, and the recording of POD use in long-term patients. Related to this was the development of an interface with the EDS pharmacy system, which is used by the Trust. So far, it has not been possible to produce a reliable interface, and it is still necessary to rekey information from eSCRIPT into the pharmacy system.

The system is administered by two senior pharmacists, and uses third party drug data from First DataBank Europe (FDBE) Ltd (Exeter, UK). FDBE send regular updates to the Trust, which are loaded onto the system by Trust IM&T staff, who then itemise any data changes for the attention of the system administrators. Based on FDBE data, the system provides decision support for drug interactions, sensitivities, drug-disease interactions, duplicate therapies and clinical trials management (Trust customised table). The training of new users of the system is an in-use process consisting of a combination of desk-based initial training, together with shadowing experienced users.

Future development of the system will involve enhancing the system to become a thoroughgoing electronic prescribing and medicine administration system. The Shrewsbury & Telford NHS Trust will consider this development, if there is no timely production of appropriate software from the Connecting for Health (CfH) programme. The likely scenario is that a prescribing and administration solution would be designed for initial use in a day case clinic setting (probably urology). Work will also need to be done to resolve the pharmacy system interface issue.

Fowlie et al.[22] have conducted an analysis of prescribing errors and medicine administration errors at Ayr Hospital, Scotland, following the introduction of an electronic prescribing and medicines administration system (Pharmakon). The system was evaluated in a 36-bed orthopaedic ward between February 1998 and July

1999. The authors compared rates of prescribing errors for inpatient and discharge prescriptions and rates of administration error for (a) the existing paper-based prescribing system, (b) electronic prescribing 1 month after implementation and (c) electronic prescribing 12 months after implementation. They found that the electronic prescribing system led to a significant reduction in the prescribing error rate for inpatient prescriptions but, interestingly, not for discharge prescriptions, and that the system led to a significant reduction in medication administration errors. The impact of these results on medication risk management will be discussed in detail in a later chapter.

Gray and Smith[23] have reported on the implementation of an electronic prescribing system on surgical wards at Southmead Hospital, Bristol. Southmead Hospital, which is now part of the North Bristol NHS Trust, embarked on an EPR project in 1997 using the Sunrise Clinical Manager software, which subsequently became iSOFT's iClinical Manager (iCM).[24] This established electronic order communications in the hospital for pathology tests, radiology procedures and selected clinic referrals. In January 2001, Southmead Hospital embarked on a two-year project to establish an electronic prescribing and electronic medicines administration system throughout the hospital, using the Sunrise/iCM system. However, during the course of the project, the scope was reviewed, for financial and strategic reasons, and the EP system was limited to pilot use in the surgical unit. The EP system was piloted between September and December 2002 on the surgical admissions ward, two general surgical wards and the associated theatres and recovery rooms.

The system had electronic drug administration functions and an interface with the Trust's pharmacy system. However, it did not have comprehensive decision support functions; sensitivity checking and duplicate therapy checking were available within the application but were not implemented, and no third party clinical rules engine was employed. The charting of anaesthetics and fluids was not included on the system.

Since the completion of the Southmead pilot, other NHS Trusts have piloted the iCM product for electronic medicines management applications, using enhancements arising from the Southmead project. One such pilot was at Hope Hospital, Salford,[25] where an EPR project was launched using the Sunrise/iCM software in 1999. The EPR system went live in mid-2000, and allowed storage of admission history and correspondence, together with electronic ordering of radiology tests. One of the most beneficial features of the system for electronic medicines management at Salford was the introduction of immediate discharge summaries (IDS). These were piloted in medical and care of the elderly wards in mid-2001, and rolled out to the whole hospital in 2002. This function enabled clinicians to assemble an electronic discharge summary for each patient, including drug ordering from picklists or pre-defined orders. The rationale for the IDS function was to streamline the hospital discharge process, which is a significant issue in the UK context.

Most recently, experience of implementation of electronic prescribing at the City Hospitals, Sunderland, has been reported.[26] EP has been implemented at Sunderland

using Meditech software, as used at the Burton Hospitals. In Sunderland, other modules of the Meditech software have been in use by pharmacists and nurses since 1992, but medical staff have had little experience of the system prior to the introduction of electronic prescribing and medicines administration. Consequently, adoption of the system by medical staff was therefore a major aspect of the change management required to roll out the EP system at Sunderland. EP functionality has been available at City Hospitals, Sunderland, since 2002.[27]

In their review of the implementation process for EP, Foot and Taylor[26] noted a number of benefits with the system. These included (a) a reduction in the overall prescribing process duration; (b) the ability of staff to access patient records from remote locations (leading to further time and logistical efficiencies) and (c) a clear audit trail of signatures for each prescription. The authors note, however, that, at the time of publication, systems to be deployed under the Connecting for Health programme do not have EP modules that are comparable to the functionality already implemented locally in Sunderland. This may be an issue for other centres for innovation for EP in the UK in future.

Case Study 2

The Winchester & Eastleigh NHS Trust

Two generations of Electronic Prescribing

The Winchester & Eastleigh NHS Trust, in the south of England, was the first hospital to implement electronic prescribing in the UK, and has been working with electronic prescribing functionality for almost 20 years. In the mid 1980s, as a result of a government initiative, the Winchester Trust received some regional funding to enable them to deploy advanced IT within the hospital. The Trust purchased the American TDS Hospital Information System (HIS), and invested time and resources to configure the system to a UK context.

The Trust Board took a strong line in implementing the technology at a time when there was considerably less experience with IT applications in acute clinical environments. The implementation project was managed by the IM&T department and various pharmacy and nursing personnel were seconded to the project as domain analysts. In addition, in-house analysts and trainers were provided by TDS. A programme of acceptance testing was conducted whereby users changed roles (prescribers became pharmacy users and vice versa etc), prior to installation.

The system was piloted on surgical wards, and rolled out across the whole hospital during 1989-1990. Problems with the implementation of the software centred around three areas a) certain aspects of the EP software - for example, non-scheduled intravenous fluid ordering did not function to suit working

practices in the UK, and were complicated b) hardware support for the mainframe had to be negotiated for 24/7 coverage instead of the usual 9 to 5 business hours and c) staff attitudes to the system at a time when computers were an unknown to most staff, and perhaps something to be worried about.

When launched, the system consisted of a mainframe with three static terminals on each 30 bed ward (2 terminals on smaller wards) and five terminals in the pharmacy, all connected by a token ring network. As technologies improved, mobile workstations were introduced and now the system operates with three mobile workstations on each ward as well as the static ones. The system is now supported by an Ethernet network.

For some time after initial roll-out, the system was not wholly popular with some hospital staff, partly because of the changes that it entailed, and partly because of the change management process. However, clinicians soon began to see the advantages of an electronic system – especially when they left the Trust to work elsewhere, and had to return to paper-based systems. The system has enabled the expansion of clinical pharmacy services on the wards, has considerably improved the workflow in the dispensary, and has also increased the efficiency of the pharmacy emergency on call system.

Over the years, various methodologies have been employed to train new users. Initially the approach was didactic, with formal training sessions. However, the training now consists of a talk and demonstration by a trainer, with training exercises on a training data environment, and then ward-based follow-up. A one-to-one training programme would be ideal but this would be impossible to implement, given the high turn-over of users.

In recent years, because of the increasing cost of support for the TDS system, together with the need to adopt CfH (Cerner) functionality for other hospital systems, the Trust has moved over to using the JAC Computer Services EP module (JAC Computer Services, Basildon, UK). The JAC system was implemented during 2006, as the interim "next generation" EP system, and the TDS system prescribing module was decommissioned in September 2006. The JAC EP system offers the advantage of an intuitive Windows-based system, medicines administration functionality that closely mimics the traditional drug chart, and which is therefore readily acceptable to all users, and third party data support from First DataBank Europe (FDBE) Ltd (Exeter, UK). The third party data platform is of particular importance because this enables the system to undertake comprehensive decision support on drug interactions, allergies and other clinical warnings. JAC send a monthly FDBE data update to Winchester.

Future plans for the system include the possible installation of the total parenteral nutrition (TPN) module, and the chemotherapy module, with the inclusion of HRG codes for oncology functions. With almost 20 years of EP experience in the Trust, electronic prescribing is now part of the culture at the Winchester and Eastleigh NHS Trust, and Trust personnel have built up considerable expertise in the practical use of EP systems.

An electronic prescribing system has been in use on a surgical ward at Charing Cross Hospital since 2003.[28] In addition to the clinician interface, this system has a novel medicine administration system involving an electronic dispensing cabinet ("magic cupboard") and an electronic drug trolley on the ward, to facilitate accurate medicines administration. It is therefore a "closed loop" system.

The system was evaluated fully between 2003 and 2006 for risk management capacity, time requirements, user acceptability, stock control and audit trailing. The system has been shown to have a positive effect on the rates of both medicine prescribing errors and medicine administration errors.

Nightingale et al.[29] have evaluated a rules-based electronic prescribing system, which was designed for use with pen-based portable PCs and has been used on the renal unit at the Queen Elizabeth Medical Centre, Birmingham. In 1996, the renal unit at the Queen Elizabeth Hospital and the Wolfson Computer Laboratory embarked on a project to develop a rules-based prescribing system, with the intention of improving prescribing safety on the renal unit. The system developed was based on a Windows user interface and, as well as patient demographic data and prescribing history, the system handled data such as laboratory results, diagnosis, allergies and renal function calculations (Cockcroft Gault). Since its design at the Wolfson Laboratory, the system has been adopted by healthcare IT vendor, McKesson, for further development.

The system was introduced into the renal unit in January 1998, and a study of its use was conducted between October 1998 and August 1999. The system was used with 1,646 patients in this study, with a total of 87,789 prescriptions. The study found that, of these 87,789 orders, 58 prescriptions were disallowed for clinical reasons by the system – these were allergies and serious drug interactions. The authors concluded that the system made a positive impact on safe and effective prescribing on the renal unit.

Development of EP Systems: A European Perspective

A survey of the use of electronic prescriptions in Europe, conducted in 2003,[30] indicated that automated solutions for electronic prescribing were not in widespread use in Europe and that the only two countries where electronic prescriptions were issued routinely were Denmark and Sweden. Pilot studies had taken place in the United Kingdom, and Germany had plans to implement electronic prescriptions. This study related primarily to electronic prescriptions in primary care and was concerned with the development of an EU-wide standard for dispensing and reimbursement of prescriptions. However, it is likely then that adoption of EP systems in secondary care in continental Europe has been equally slow.

There are few published reports of medicines management software applications used in hospitals in European countries. In a study of the implementation of hospital EP systems in Spain published in 2005, [31] responses from 47 Spanish hospitals

were analysed. Thirteen hospitals (27.7%) had EP systems and a further 15 (31.9%) were due to implement an EP system in the near future. Software used varied in its functionality but few of the applications implemented were able to be integrated with other systems to promote seamless pharmaceutical care. In a paper published in 2003,[32] Llopis Salvia et al. described the implementation of an EP system at the Hospital de la Ribera at Alzira, Valencia, Spain. The system offered integration with the whole HIS, computerised physician order entry and integration with pharmaceutical care activities.

Nielsen and Dybwik[33] have described the use of decision support software in Norway to alert intensive care unit clinicians to drug interactions. They used the internet-based decision support system, DRUID (www.druid.uio.no) to evaluate drug interactions of drugs prescribed for patients during the first 24 h of their intensive care stay. Using the system, they identified 274 potential drug interactions in 110 patients. However, while just over half of the interactions required extra precautions to be taken (e.g. dose reduction), there were very few serious interactions noted.

Integration of EP Systems with Pharmacy Systems

As mentioned previously, the use of pharmacy systems became widespread in UK hospitals from the mid-1980s. The core functionalities of pharmacy computer systems were initially (a) to provide a legible label for each medicine, ensuring that all relevant information is displayed, according to legal and best practice requirements; (b) to maintain a record of the medicines issued to a patient, and the label instructions for each issue and (c) to maintain a pharmacy stock control record of each pharmaceutical product, so that drug usage could be monitored.

However, as systems have developed, they have inevitably become more sophisticated. Many systems now have complex stock control algorithms to take into account contract purchasing and cost-centre billing. They have modules for specialist manufacturing, such as total parenteral nutrition, chemotherapy and central intravenous additives services (CIVAS). Many have interfaces with hand-held terminals to enable real-time stock control by pharmacy support staff on wards.

Because of their increasing sophistication, the scope of pharmacy systems in the UK has been expanding since 2000. There is an initiative to link pharmacy system reporting to the central NHS supply chain project, under the auspices of the NHS Purchasing and Supplies Agency (PASA). There is a need to link pharmacy systems with pharmaceutical wholesaler systems to enable e-procurement. In response to the increasing adoption of automated dispensing systems (pharmacy robots), pharmacy systems need to be interfaced to an automated dispensing system in many hospital pharmacies in the UK. Furthermore,

because of their expertise in software for managing medicines information, the key pharmacy system providers in the UK, JAC Computer Services and Ascribe, have been developing electronic prescribing modules for use in conjunction with their pharmacy systems. The most established example of this is the use of the JAC Computer Services EP module at the Royal Hampshire County Hospital, Winchester, UK. In 2006, the existing HIS prescribing functionality, which had been originally installed in 1989, was replaced by a second-generation EP system from JAC.[34] Thus, in the UK, despite the establishment of a national IT programme, some healthcare providers are implementing EP systems as a development of their hospital pharmacy system, rather than as a module of a wider EPR system.

This distinction is worth noting because, while there is a need to link an EP system with a pharmacy system, many implementers stress the distinction between an EP system and a pharmacy system. An EP system is concerned with the effective and safe prescribing of medicines to a patient, whereas a pharmacy system is concerned with the accurate stock-control, assembly and labelling of medicinal products. In essence, an EP system is patient-centred, whereas a pharmacy system will be product-centred. The interface between an EP system and a pharmacy system therefore needs to provide an appropriate link between the distinctive functions of the system, so that these functions are not, in any way, duplicated in both systems. The reason why the relationship between a prescribing system and a pharmacy system should be carefully considered is because some IT vendors, particularly those with little prescribing or pharmacy domain expertise in house, tend to view medication functionality as a homogenous whole, and do not recognise the detailed design issues that have to be addressed to provide suitably comprehensive functionality.

In 2001, the UK Audit Commission published its report entitled "A Spoonful of Sugar – Medicines Management in UK Hospitals."[35] This report looked at the "re-engineering" of healthcare business processes in UK hospitals, and in particular, highlighted the potential of automated dispensing systems (pharmacy robots) to reduce dispensing errors and free up staff time for more near-patient clinical activities. This led to many hospital pharmacies in the UK implementing a robotic system to automate some, if not all, of its dispensing and supply workload. When automated dispensing systems began to be implemented, there were concerns that these systems would lead to staff redundancies, due to the efficiencies that they would facilitate. However, in practice, while automated dispensing systems do lead to a reduction in dispensing errors, they do not generally allow reductions in staff; pharmacy staff are involved with other tasks, such as ward-based activities or maintaining the robot and other systems that are in place to handle the supply function.

Nevertheless, the increasing adoption of pharmacy robots in UK hospitals, interfaced with the department's pharmacy system, opens up the possibility of a seamless, closed loop process for the supply of medicines in hospitals, once EP systems are in place and fully integrated with pharmacy systems.

Development of Medicines Information Services and Their Integration with EP Systems

Hospital medicines information services (formerly referred to in the UK context as drug information services) were established in the UK, following the publication of the Noel Hall Report in 1970, which indicated that hospital pharmacists had an important advisory function concerning the medicines that they supplied.[36] During the 1970s, drug information services were established in the UK at regional and local level, staffed by hospital pharmacists, and often working closely with the hospital library. Medicines information services provide information about medicines to healthcare professionals and patients. Information may be provided in a proactive way – production of local guidelines and bulletins on new medicines and evidence-based medicine, the prescribing of medicines in a rational manner – or in a reactive way – responding to medicine-related enquires submitted by telephone, e-mail or in writing.

For many years, medicines information pharmacists answered medicines-related enquiries and provided information to hospital drug and therapeutics committees, largely based on evaluation of paper-based reference sources, mainly pharmaceutical industry information, the primary medical literature and national prescribing guidelines, such as the Drug & Therapeutics Bulletin and the Medicines Resource Centre (MeReC) Bulletin. These paper sources were supplemented by dial-up online services, such as the US National Library of Medicine Medline service on DataStar and microfiche based products, such as the UK pharmacy service compiled PharmLine and the Iowa Drug Information Service (IDIS).

However, during the 1990s, there was a shift towards universal availability of medical information in electronic form. This was brought about by two main factors: (a) the increasing use of the CD-ROM as a publication format by medical publishers and (b) the development and acceptance of the internet as a repository of medical information. This led to the trend of standard medical reference sources, such as the BNF, being made available on hospital intranet sites, for perusal in electronic format, and the development of specialist medicines information internet sites, such as UKMI/UKMICentral and druginfozone. In addition to being used for current awareness, these sites are used for the sharing of hospital-derived or compiled information lists (for example, stability information for fridge medicines left out of the fridge).

Because of the ready availability of medicines information in electronic form, from official and ephemeral sources alike, there is the possibility of comprehensive use of electronic medicines information, from networked local sources or internet sources, in future EP applications. This will be discussed in detail in Chapter 5.

EP Systems and Oncology Systems

The historical development of oncology and haematology prescribing systems represents a special case within the electronic prescribing initiative. Systems for electronic prescribing and dissemination of prescriptions for oncology and hae-

matology patients have already been developed, as part of departmental systems designed for oncology/haematology clinic management. Generally speaking, these systems have been designed to manage the entire patient pathway through an oncology referral, including diagnosis and disease scoring, patient scheduling (incorporating local regulatory requirements, such as the UK NHS 2-week wait rule), pathology test result monitoring, protocol-based prescribing, post-cycle toxicity monitoring, pharmacy preparative functions (worksheets and labels) and documentation management. Such systems are now well developed to meet the needs of current clinical practice and management reporting requirements and, as such, are much further ahead, in terms of available functionality, than EP systems for general medicine.

The reasons for this are as follows:

(a) Oncology/haematology treatment clinics represent a discrete, well-defined area of clinical practice, where there is very little overlap with other areas of medicine. Development of these systems has thus been on a "silo" basis, as with other healthcare software initiatives.
(b) Prescribing for oncology and haematology is distinct from other forms of prescribing as it is largely based on agreed protocols, to which certain well-defined adjustments can be made. Automated systems are therefore an obvious choice for the management of protocol-based prescribing.
(c) The drugs used in chemotherapy are often highly toxic and doses are critical. This is a major driver in the use of automated systems for risk management, to reduce risks that may be introduced by human calculation errors, or failure to heed monitoring results.
(d) The drugs used in chemotherapy usually require specialist compounding or assembly in the pharmacy department. An automated system helps to ensure that worksheets and labels conform to legal requirements and good manufacturing practice requirements.

A number of systems have been developed to meet oncology clinic management requirements and many of these have electronic prescribing and records management functions for chemotherapy and/or radiotherapy prescribing. The Inhealth Systems/Torex/iSOFT suite of applications for oncology, radiotherapy and palliative care management – OPMAS, RCAS and PCAS respectively – were developed and implemented at various sites in the UK between 1987 and 2004. Newer, comprehensive systems include ChemoCare from Clinisys, and MedOncology from Varian. Another system that has a large share in the US market and may become more popular in the UK is the IMPAQ system.

In 2005, the UK government announced its intention to bring forward the electronic prescribing initiative for oncology and cancer care. The rationale for this was that EP systems for oncology would help to resolve the issues of "post-code" prescribing of expensive chemotherapy agents and immunomodulators in oncology, and a perceived lack of information governance in oncology prescribing and cancer health outcomes. Consequently, the UK Connecting for Health programme – then the National Programme for IT – released a short to medium term specification for oncol-

ogy systems,[37] much of which has since been developed by the oncology specialist software vendors, such as Clinisys and Varian. However, it is not clear when oncology functionality will be developed for the proposed national solution, under the auspices of the UK Connecting for Health Programme. For this reason, CfH undertook a benchmarking process in 2006, in which it evaluated a number of existing oncology management solutions from specialist vendors. The Clinisys Chemocare system was given the highest rating in this benchmarking process. The benchmarking process raised awareness of oncology prescribing systems and it is likely that there will be various further implementations of specialist systems in UK NHS Trusts and Cancer Networks, in advance of any general EP systems in UK hospitals.

The Development of Consolidated Electronic Medicines Management Systems in Hospitals

Historically, hospitals have implemented a number of different systems for electronic medicines management on a discrete, departmental basis. Hospitals often seek interfaces between these different systems. Furthermore, one of the goals of regional or national healthcare IT programmes is to develop holistic solutions, which cover all aspects of a healthcare provider's business processes, and which may be rolled out uniformly across a number of hospitals. A suggested architecture for a consolidated EP system, which would address all aspects of a hospital's medicines management needs, is shown in Fig. 2.2.

The benefits that such an architecture might confer are discussed in Chapter 3.
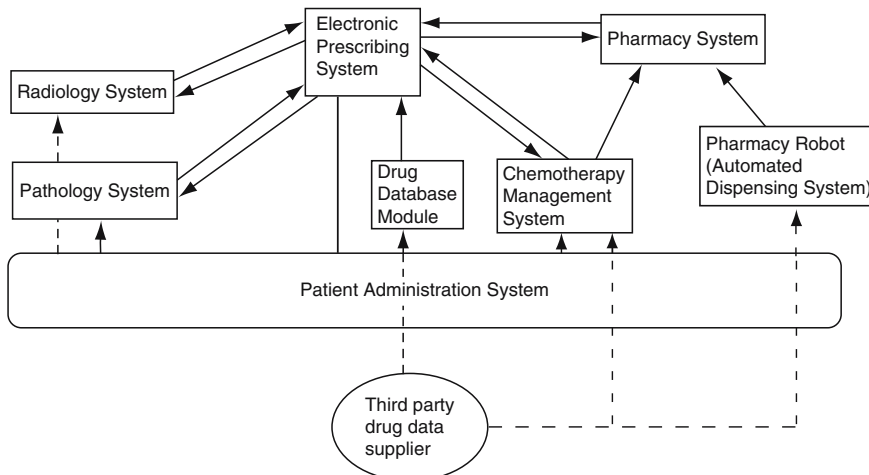

Fig. 2.2 E-prescribing architecture

Barriers to Implementation of EP Systems

There is a consensus on both sides of the Atlantic that the implementation of EP systems is a desirable development, and there are initiatives in both the US and the UK to bring about greater adoption of EP systems by healthcare providers. Nevertheless, it is apparent from a review of the historical development of EP systems that various factors play a part in EP system adoption and innovation – and that some of these factors can lead to barriers to system implementation in specific organisations, or in particular healthcare economies.

Some of these are human factors – social and psychological factors – and have been discussed in the previous chapter on the philosophical issues surrounding electronic prescribing. However, some of these are regulatory, financial and political factors, and will be considered here. A number of studies have examined the potential barriers to adoption of healthcare IT applications in general[38,39] and these factors are equally applicable to EP systems. These factors would include:

(a) High financial costs of installation of EP systems. In addition to the actual installation of the EP software and the technology platform (servers, network, desktop computers, palm PCs and PDAs), consideration needs to be given to time spent on site by IT vendor personnel for project management, configuration and testing purposes. If there is not a clear business model for benefits realisation, it may be hard for provider organisations to justify the high costs of an EP implementation.

(b) Lack of intraoperability with other systems. Intraoperability – the ability of an EP system to communicate effectively with other IT systems within a healthcare provider organisation – is an important deliverable for IT systems, and lack of intraoperability, either due to a lack of communication standards, or due to software inadequacies, is a major disincentive for investment in such systems, especially in those countries where regional or national healthcare IT programmes are pending.

(c) Security and privacy issues. Concerns of healthcare professionals and patients about the security of healthcare IT systems have been well-documented both in the professional literature and the popular press. Security has been a controversial issue in the development of the UK Connecting for Health healthcare IT programme, although some have commented that clinicians' concerns over confidentiality have simply been a means of resisting any interference with their professional interests.[40] Nevertheless, implementers need to consider the security of their systems, especially if wireless networks are in use.

(d) Legal issues. A wide variety of legal issues can influence the adoption of EP systems. These include:

  – The laws governing the prescription and supply of medicines. For example, for many years, the development of EP systems in the UK was impeded by the fact that UK law required a prescription to be signed by hand.
  – The laws concerning intellectual property and licensing. For example, there may be a problem with the operation of an EP system, if licenses and permissions to

use subsidiary software applications are not in place. In some countries, there may be special arrangements for deployment of platform software within health-care providers (for example, in the UK, the agreement between Microsoft® and the NHS concerning the use of MS applications within NHS Trusts).

– The laws concerning medical negligence. Fear of negligence proceedings in a highly litigious society may prove a disincentive to implementers of EP systems.

– The laws concerning antitrust. In the US, until recently, the anti-kickback legislation has prevented third parties, such as healthcare providers and insurance payors, from investing in EP software for associated physicians, thus slowing the adoption of EP systems.

– Many of these legal issues can be offset by initiatives by governments and government agencies to reform the relevant legislation or to provide new legal provisions, with the specific purpose of encouraging EP implementation, in the public interest.

(e) Failure of software vendors to produce acceptable systems, within agreed timescales. It is widely recognised that not all organisations in the healthcare IT market place are able to provide and install software that is fit for purpose for every application. This is especially the case with electronic prescribing, which is arguably one of the more innovative areas of healthcare IT. There may be a number of reasons for this. First, it is widely understood that the awarding of large contracts to healthcare IT vendors is based more on marketing and commercial factors, rather than on proven expertise and delivery track-record for all the deliverables under negotiation. Second, IT vendors may not have the relevant domain expertise available in-house, or may not have the political will to recruit and retain such expertise. Third, many international software suppliers will attempt to adapt software developed in one country, for use in another country. This may lead to a composite system, whose design is not adequate for either context, when the better course of action would have been to undertake a more lengthy, substantive redesign process, to produce a core product that can be appropriately configured to each healthcare market. Fourth, many IT companies offshore their design and development facilities, which may hamper the software production process, especially if there is substantial iterations in the testing process, or scope-creep in the software requirements.

Conclusion

To date, there has been a track record of innovation with EP systems in the US, the UK and mainland Europe. In the UK and the US, such an innovation has been stimulated by an increasing understanding of the benefits of EP systems. Often, the ease with which EP systems are accepted within local healthcare provider organisations depends on factors that are specific to those organisations. Some areas of

functionality – most notably, chemotherapy clinic management – are further advanced than EP in general. Furthermore, a number of factors have been identified as potential barriers to adoption of EP systems.

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Chapter 3
Organisation Benefits of Electronic Prescribing

The potential for IT systems and applications to facilitate changes in working practices by automating mundane, logical processes is now well recognised throughout the business world. Indeed, much commercial system design methodology now seeks to model data and business processes, using tools such as UML diagrams, in order to design software that is the "solution" to the business challenge, regardless of past practices and procedures. Thus the introduction of a new software solution can lead to an organisation meeting its business objectives more efficiently, with a paradigm shift – a radical change in working practices – for those who are involved in the business area.

Healthcare IT applications such as electronic patient records (EPRs), EP and order communications have led to a paradigm shift in working practices, and indeed professional role, for many healthcare professionals. For pharmacists, this has been described as a move away from product- and process-centred work, towards patient-centred work,[1] and will be discussed at length in a later chapter.

Principles of Business Process Redesign

Analysis and redesign of business processes is essentially part of the design phase of software production, and is therefore properly within the remit of software vendors. Nevertheless, implementers should be aware of the general principles of business analysis, business process modelling and business process redesign for a number of reasons:

(a) In practice, many healthcare software providers do not have adequate clinical domain expertise in-house, and will seek input from clinical professionals within the NHS when implementing a system at a particular site, via user groups and, in some cases, at the software design phase.

(b) Many modern Windows-based systems have a vast range of configuration options embedded within them. Furthermore, the more complex the processes being supported, the greater the potential for different configuration and installation options. For a system designed for commercial distribution, configuration

options are useful as they increase the number of customer sites where a system can be installed without major code changes and enhancements.

(c) An appreciation of the business processes being modelled, and the assumptions taken when designing the software to support those processes, provide implementers with a valuable insight into why the software was designed as it was.

Consequently, there are a number of important principles of business process redesign that need to be considered by implementers of EP systems and associated healthcare software applications.

First, within an enterprise or organisational unit, as many of the business processes as possible should be modelled in order to provide a solution that is holistic, and that covers the vast majority of business scenarios that might arise in the organisation. A single system covering a range of business processes will be more efficient and consistent in its operation because common server platforms, data platforms and application algorithms will be in use.

Given the range of different types of business scenario and use case that can occur across healthcare, it is difficult in practice to produce systems that are truly universal in their scope. It is primarily for this reason, as well as for reasons of system ownership, that traditionally in healthcare, systems have developed in a "silo" manner as individual departments and professional groups have sought to automate their processes in a "bottom up" approach. Consequently, many healthcare software vendors have taken a modular approach, where a patient administration system (PAS) can be supplemented with an order communications module, an electronic prescribing module etc. Furthermore, in any particular healthcare enterprise, there may be reasons why a system may not cover all business areas – for example, where a satellite hospital or remote unit does not have full connectivity or system availability for communications or infrastructure reasons.

Nevertheless, with regional or national healthcare IT projects, such as the English Connecting for Health programme, there are now opportunities for large, highly configurable systems to be deployed, which aim to address as many healthcare business processes as possible. Indeed, many software vendors are seeking to provide products based on "service-oriented architecture" where the structure of the system is based on the services it is intended to support, and processes that are common to all functions (e.g. terminology and decision support) are provided by single engines, which are integrated with the various service units within the system. While service-oriented architecture is of great benefit in supporting a large range of use cases in an efficient and consistent manner, it confers a uniformity on the system that may render it easier to interchange with another similar architecture, which has major commercial implications for software vendors[2] (Fig. 3.1).

Second, the scope of the business processes being supported must be clearly defined. Given the vast number of business processes and scenarios that are in operation in a healthcare setting, it is inevitable that some processes will not be able to be supported by a single system. This may be for infrastructure reasons, or because an alternative system, or a legacy system, is already in place, which the organisation does not wish to replace, or which is not easily replicated. In this situation,
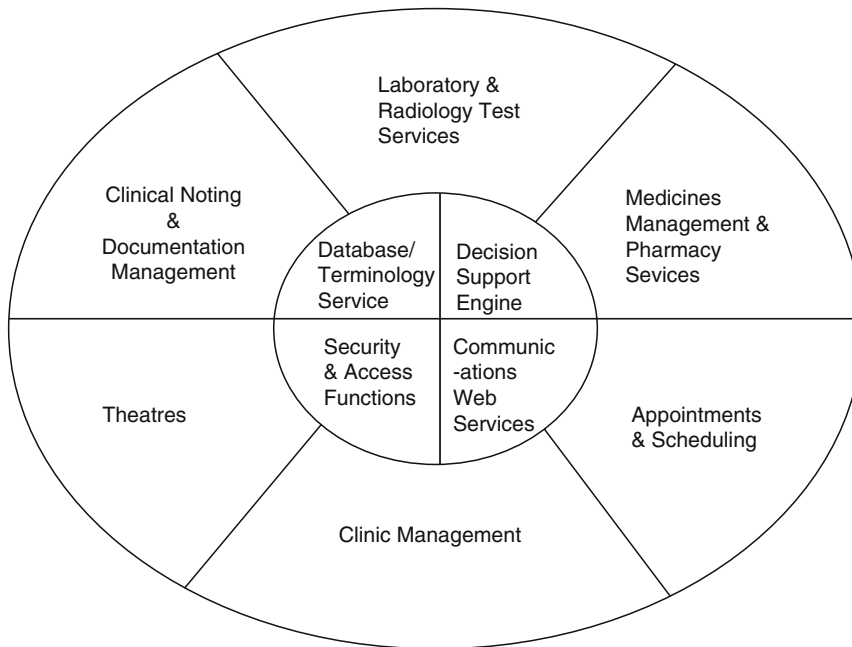
Fig. 3.1 Service-oriented architecture

it is important to define the scope of the new system clearly. It is also important to have a clear understanding of the type and capability of any interfaces that will be required with existing systems. This is important, given the way that, historically, systems in healthcare have developed in a "silo" manner (silo development). Furthermore, interface requirements are of particular significance in medicines management since, in order to provide full business process management, an EP system would need to interface with a PAS, a pharmacy system, and an automated dispensing system (pharmacy robot) via the pharmacy system. Issues surrounding interfaces of this type will be discussed in detail later in the chapter.

Third, the significance of business processes must be clearly understood in their context before a software solution can be designed to support them. Take, for example, the UK practice of 28-day dispensing, or "one stop" dispensing. It is important that an EP system has the functions to support 28-day dispensing (a 28-day supply flag for items, with a reorder after 21 days algorithm etc.), but it is essential to realise that the rationale for 28-day dispensing is to prevent duplicate dispensing and thus streamline the discharge process. This awareness ensures that all associated functionality – e.g. discharge functions – will be designed and linked in appropriately.

Fourth, and most significantly, it is essential when implementing a new system that business processes are not re-engineered to match the system design, or technological capability available, rather that the software is designed and configured to support current – and, most importantly, emerging – business processes. On one

hand, the appropriate technology must be available to ensure that an application can be deployed across an enterprise without any loss of performance; some early EP programs in the US failed because the technology used was not scaleable.[3] On the other hand, technology may fail to deliver benefits if it does not meet needs, or it requires that practice is altered to accommodate system use.[1] Indeed, experience from the US suggests that healthcare providers need a technology strategy to ensure that technology supports the organisation's goals, rather than fitting business processes around the available technology.[4] Appropriate use of electronic systems to support current and emerging business processes will be facilitated by highly configurable systems, use of service-oriented architecture and the involvement of clinical professionals and domain experts in their design.

Medicines Management in Hospitals: Existing Business Processes

However, prior to any discussion of the appropriate design of EP systems and their impact on hospital business processes, it would be beneficial to describe the way the prescribing and medicines supply process has taken place in hospitals to date.

Traditionally, in a hospital, medicines for inpatients have been prescribed on a medicine administration chart, commonly referred to as a drug chart, and sometimes called a "Kardex." An example of the layout of a drug chart is shown in Fig. 3.2.

The drug chart will have sections of the page allocated to prescriptions of:

1. Regular medicines. These are medicines that are given on a regular basis, at set administration times. An example of this would be Amoxicillin 500 mg capsules – one to be taken three times a day at 08.00, 14.00 and 22.00.
2. When required (PRN) medicines. These are medicines that are given only when required to treat acute symptoms, and are generally medicines such as analgesics, antiemetics and laxatives. They are not given at set administration times, but the time and date of each dose is recorded on the chart. An example of a PRN medicine would be Paracetamol 500 mg tablets – one or two to be taken every four to six hours as required for pain.
3. Once only (statim) medicines. These are medicines that are given as a single dose, with no instruction to repeat the dose. These medicines may be routinely given, for example, vaccines, or may be given in relation to a particular procedure that has been, or is about to be, performed. An example of a once only medicine would be diazepam, 10 mg, by intravenous injection (as a premedication before an operation).
4. Fluids. These are large volume infusions routinely given in hospital for the purpose of hydration or plasma replacement, in clinical situations where they are needed. A fluid is essentially a once only order, but it is given over a period of time, and the flow rate of the fluid is set using a burette on the intravenous giving set. An example would be sodium chloride infusion, 1 L of 0.9% solution, to be given over 6 h.

DOCUMENT REASONS IN CARE PLAN IF APPROPRIATE

ONCE ONLY DRUGS AND PREMEDICATION DRUGS

Approved Drug Name	Dose	Route	Prescriber Signature	Time to be Given	Date to be Given	Date and Time Given	Given by: Check by:	Pharmacy Supply

REGULAR PRESCRIPTIONS

Date:

			Regular Times / Other Times									
Approved Drug Name	**Dose**	**Route**	0600									
			1000									
Signature	**Date**	**Frequency:**	1200									
			1400									
Special Directions	Pharmacy Supply: / Pharmacy Supply:	Pharmacist Check	1800									
			2200									

VARIABLE TIMES/DOSES

Approved Drug Name	Dose	Route										
			Date									
Signature	Date	Pharmacy Supply	Time									
			Dose									
Special Directions	Pharmacist Check	Pharmacy Supply	Initial									
			Check									

RECORD OF ONCE ONLY STANDING ORDER DRUGS/FLUID GIVEN

Approved Drug Name	Dose	Route	Signature of Nurse/Midwife	Date	Time	Given by:	Check by:	Pharm supply

CONTINUOUS INTRAVENOUS/ SUBCUTANEOUS DRUG INFUSION THERAPY

Approved Drug Name	Diluent	Volume	Route									
			Date									
			Time									
Concentration (mg/ml etc.)	Flow Rate (ml/hr)		Supply / Rate									
Prescribers Signature	Date		Supply / Initial/ Check									
Special Directions	Pump Code:		Pharmacist Check / Volume infused									

Fig. 3.2 Medicine administration charts

5. Continuous infusions. These are intravenous infusions that are given at a fixed
   or variable rate to treat a specific disease. Unlike fluids, continuous infusions
   will be small volume (250 ml or less) and will consist of medicines with specific
   pharmacological activity. Furthermore, because of the potent effects of the drugs
   used, they are usually delivered by a syringe driver, which will maintain a more

accurate flow rate than can be achieved with the burette on a fluid giving set. An example of a continuous infusion would be isosorbide dinitrate, 50 mg in 50 ml infusion, given at a variable rate of between 2 and 4 mg/h for the treatment of ischaemic (angina) pain.

When prescribing a medicine, the prescriber writes the details on the drug chart, and the various boxes on each section in the drug chart prompts the clinician to include all relevant details for a particular order type. The prescription is then signed by the prescriber.

The drug chart is then used as the basis for medicine supply and medicine administration in the hospital. Medicines are supplied against the formulation details on the drug chart, either from ward stock, if a medicine is used regularly on a ward, or direct from the pharmacy. Pharmacists make prescription-related enquiries based on the details on the drug chart, and make any relevant additions or amendments on the chart (traditionally in green pen, in UK hospitals). Nursing staff then administer the medicine to the patient according to the detail on the drug chart. Each administration of a regular medicine is initialled by the nurse administering the medicine. The date, time and initials of the administering nurse are recorded for other prescription types. If a regular, or scheduled, prescription is not administered, an agreed missed dose code is placed in the administration box, instead of the nurse's initials. This indicates the reason why a dose is not administered – for example, the patient refused the medicine, the patient is "nil by mouth" or the medicine is not available. For fluids and intravenous medicines, there is the facility to record that an infusion was stopped because of a blockage in the giving set, or extravasation – where the intravenous cannula has come out of the patient's vein, and the drug is leaking into the surrounding tissues.

While a patient is an inpatient, all medication will be recorded on and administered on the drug chart, with the exception of anaesthetics and perioperative medication, and possibly some departmental investigations. However, when the patient is discharged, a discharge prescription is written (this is sometimes referred to as a "to take out/away" (TTO/TTA) prescription) and sent to the pharmacy to be prepared. The discharge prescription is usually completed on a separate form, in duplicate or triplicate, and includes the attending clinician's diagnosis, treatment and planned follow-up or care plan.

This prescription recording system has been used for many years. Nevertheless, in practical terms, there are many problems associated with it.

(a) Because prescriptions are handwritten – often in a hurry by busy clinicians – they may be illegible or incomplete. Alternatively, in patients with large numbers of medicines, there may be inadvertent duplications.

(b) Nursing staff may have to query prescriptions before they administer them, leading to inefficiencies in the medicine administration process.

(c) The drug chart can be lost. If there are two or more charts, they may become separated from each other.

(d) Medicine administration may be delayed when a drug chart is not on the ward for any reason – for example, when a patient is having an investigation in another department, and the chart has gone with him or her.

(e) The drug chart cannot easily be reviewed alongside results of tests and other monitoring investigations.

(f) The drug chart cannot be viewed remotely by a clinician or other health professional; the clinician has to attend the ward or department to view the patient chart.

(g) For a medicine that is not ward stock to be ordered from the pharmacy, either the chart must go to the pharmacy department (leading to the situation described in (d)) or a pharmacist must transcribe the prescription details onto a pharmacy order list (with the potential for transcription errors).

(h) The discharge prescription generation and fulfilment process represents a major workload for the pharmacy department in many UK hospitals. There are many inefficiencies throughout the process that lead to delays in patient discharge, difficulties with bed management and low staff morale.

Organisational Benefits of EP

Electronic prescribing systems can offer possible solutions to all of these problems with the current medicine supply process, and therefore, can promote efficiency in the medicine prescribing process and medicines administration process in hospital. As mentioned previously, a review of UK EP implementations has identified a number of key benefits with EP systems.[5] They are as follows:

(a) Availability of a fully electronic prescribing history.

(b) Improvement in legibility and completeness of prescriptions.

(c) Improvement in hospital business processes due to electronic dissemination of prescriptions.

(d) Improvement in the quality of prescribing due to the availability of electronic decision support tools at the point of prescribing.

(e) A comprehensive audit trail of prescribing decisions made.

(f) Reduction in the rate of medication-related errors.

All these benefits impact on the efficiency of the healthcare enterprise, as well as the optimum care and safety of the patient. EP systems have particular organisational benefits in the following areas:

1. Workflow management for clinical users of EP systems
2. Clinical system intraoperability
3. Improvement in hospital business processes due to electronic dissemination of prescriptions
4. Reduced use of paper and consumables
5. Facilitation of a seamless pharmaceutical supply chain
6. Contribution of workflow improvement to professional practice development

These issues will be discussed in detail from an organisational and ergonomic perspective.

Workflow Management for Clinical users of EP Systems

Clinical professionals of all disciplines face a twofold task in their daily practice in a healthcare environment. On one hand, they have a duty of care towards their patients, and an obligation to ensure that patients are treated in a way that fulfils legal requirements and ethical requirements, and most closely represents accepted best practice for their profession. On the other hand, there are operational pressures from the healthcare organisation to treat patients as quickly and efficiently as possible and to achieve statistical benchmarks and service-level targets. Furthermore, these two objectives can sometimes seem to be in opposition; best care of the patient by the practitioner may be at the expense of meeting organisational targets. However, there is a greater chance of both objectives being achieved if workflow for the practitioner – both the prescriber of a medicine and the person administering the medicine – is streamlined by the appropriate use of electronic systems.

For many healthcare systems, designed for use in a busy working environment, the design of the user interface is important. For an application such as electronic prescribing, where there is a need to present complex prescribing information in a way that enables appropriate professional decision making, and to input comprehensive medicine order information in a straightforward and timely manner, user interface design is critical.

Prescribing Workflow Design

The obvious benefit of an EP system is a legible and complete prescription, facilitated by the electronic display of that information. Thus, an EP system can ensure that, for every prescription, the following details will be included:

- Medicine
- Form/formulation
- Strength
- Dose
- Route
- Frequency
- Duration (if applicable)
- Any specific prescribing or administration instructions

The legibility and completeness of prescriptions is beneficial to the working practices of all system users involved in the prescribing, dispensing and administration of medicines. Two UK implementations of EP systems have commented on the positive impact of EP on the legibility and completeness of the prescribing record.[6,7] In an analysis of 2,180 prescriptions from the Wirral Trust, UK, for legibility and completeness, with reference to hospital standards for prescription writing, based on the British National Formulary, it was found that electronic prescribing

significantly improved the legibility and completeness of prescriptions compared with prescribing by hand ($p < 0.0001$). In a review of EP experience at the Wirral, presented at the British Pharmaceutical Conference in 1999,[8] Farrar indicated that the use of EP at the Wirral Hospitals had increased the number of complete and correct doses on medication charts from 17.7% to approaching 100%. However, the record of dose administration was not always complete; often once only prescriptions were completely and correctly prescribed, but no record was made of when they were administered.

The legibility and completeness of an electronic prescription are dependent on other factors. First, the legibility of prescription information on an electronic system in the clinical environment cannot be assumed; it will depend on (a) the design of the screens and forms used to display the data, (b) fonts and styles of text used and (c) graphics and colours used on the screens. The adoption of chart designs and form templates that were already in use in the hospital, as happened in Burton on Trent, UK,[9] will facilitate staff familiarisation with the system and, as well as having a positive effect on the reduction of prescribing errors and medicine administration errors, will increase staff confidence in the system and the efficiency with which the EP system is used.

Second, the completeness of the displayed prescribing history will depend on the completeness of the prescription data captured in the first place. To facilitate adequate prescribing data capture, the database structure should have sufficient granularity, and the medicines data should be sufficiently comprehensive to handle a wide range of complex prescribing scenarios. This is because, in general terms, many prescriptions generated in secondary care are more complex and varied than those in primary care.

For example, a secondary care EP system would need to include:

(a) A comprehensive range of routes (including routes to support enteral feeding)
(b) A comprehensive range of formulation types
(c) Reducing or increasing dose regimens (e.g. prednisolone, reducing dose)
(d) Loading doses and associated maintenance doses of the same drug (e.g. gentamicin)
(e) Alternate routes of administration for the same drug dose (e.g. metoclopramide, 10 mg po/pr/im)
(f) Complex administration instructions (e.g. co-trimoxazole, 960 mg, on Monday, Wednesday and Friday)

The provision of adequate functionality to allow the capture of complex drug orders is important because, in two reports [8,10] it was found that errors of omission increased after EP implementation, because prescribers found themselves unable to enter certain types of prescription because of the design of the system and the configuration of the drug data.

In addition to the clear display of a prescribing history for a patient, another important issue in facilitating an efficient workflow for the user is the ease of operation of the system. For any EP system, there is a balance between the completeness of data capture during the prescribing process, and ease and usability of the system for

the prescriber. A system might have a 12-stage prescribing process to enable the clinician to prescribe a complex regimen, but this may not be acceptable for a busy clinician using the system. One way of addressing this issue might be to use pre-defined orders (PDOs) for commonly used prescriptions (e.g. furosemide, 40 mg tablets – one to be taken each morning), so that the clinician can select a complete medication order in a single process. This approach was used in the pilot at Southmead Hospital, Bristol, UK,[6] to speed up the prescribing process and to incorporate implicit decision support, in the form of prescribing guidance. However, use of PDOs may lead to different kinds of error due to incorrect selection of a PDO, or errors within a PDO being propagated inadvertently through large numbers of patient records.

In addition to the number of operations required to generate an electronic medicine order, in terms of defining the order details – medicine, form, strength, dose, route, frequency etc. – consideration needs to be given to the number of confirmation boxes ("double dares") and warning messages that appear during the workflow for different types of prescribing. It is well recognised that, if a system presents an excessive number of clinical warnings in any particular workflow, especially warnings that are irrelevant to the specific prescribing scenario, the user will begin to ignore the warnings (so-called "warning fatigue").

The need for confirmation boxes may be reduced by the appropriate use of control default options and highlighting, but the risk management implications of these developments need to be considered carefully. Furthermore, because of the increasing granularity of data – both coded data from patient records, and drug data within decision support systems – decision support data providers are now looking at aggregated querying techniques to single warning messages that are more intuitive to the particular prescribing scenario. The issues surrounding warning fatigue will be examined in more detail in the decision support section in Chapter 5.

Medicines Administration Workflow Design

Just as the prescribing workflow of an EP system can affect the efficiency with which clinicians prescribe medicine, so the medicine administration workflow of an EP system can streamline the process of medicines administration in a hospital environment. As with the prescribing workflow, the medicine administration workflow is highly dependent on the user interface and the screen layout.

Some systems have been designed to capture the prescribing history electronically but, rather than providing a real-time on-screen medicines administration system, they have instead produced computer-generated charts based on the electronic prescribing record. There is then the facility to reprint, or overprint, these computer-generated charts, following on from changes to the electronic prescribing history. While such a system avoids the complexities of an electronic medicine administration

function, it is fundamentally flawed because the administration system is not part of the system, in real time.

A paper-output EP system has the following problems:

(a) For acute medical wards, where there will be a high turnover of patients, and a high turnover of prescribed medication per patient, it will be impossible to maintain a current set of computer-generated charts for each patient.
(b) It is difficult to define a series of trigger events for chart reprinting that fit all situations.
(c) A number of problems with paper charts – e.g. loss or damage to the chart – still apply.

For these reasons, it is now well recognised that an EP system must include electronic medicine administration functionality (electronic drug administration or electronic nurse administration) to provide a satisfactory medicines management system. To present the complexities of all prescription types in a concise manner, some EP systems have chosen to design a medicines administration screen that, to a greater or lesser extent, mimics the traditional drug chart or Kardex, with sections for each of the prescription types – regular, when required, once only, fluid and continuous infusions. The different order types may be displayed on different tabs on screen, so that the nurse can view all active orders according to order type. Scheduled orders, due at a particular time, would then display distinctively – for example, highlighted in red. The order would then revert to the standard background once the administration had been recorded (or alternatively shown in, for example, green for a set period of time after the administration had been recorded, to indicate that it was a current administration that had recently been done). For regular medicines, there would be a facility to input a user code for the person administering the medicine; for other order types, there should be a facility to record a user code, a date and time of administration and a dose, where a variable dose is required. With all scheduled order types, there should be the facility to record a missed-dose code.

Alternatively, all the orders scheduled to be given at any given time could be displayed on one administration screen, regardless of order type. The disadvantage of this, however, is that they cannot be immediately viewed alongside the whole record of prescribed medication.

Electronic medicine administration has the advantage that it can force users to conform to a general process for medicines administration. However, the underlying rules used by an electronic medicine administration system are potentially complex and would need to be carefully considered, in relation to the established policies and professional practices within a hospital or healthcare provider organisation.

Among others, the following issues would need to be considered:

(a) What would be an appropriate time window for highlighting a scheduled prescription as due for administration? For example, with a regular medicine, the system might highlight it in red for an hour either side of the scheduled administration time.

(b) What would be an appropriate time window for allowing a scheduled prescription to be administered? For example, with a regular medicine, the system might enable recording of an administration (cells active and highlighted) for an hour either side of the scheduled administration time.

(c) Should once only medicines and fluids display as being administrable as soon as they are electronically signed by the prescriber? If they are not administered, how long should they persist on the administration profile?

(d) Should "lock out" functions exist for when required medicines? For example, the system might disable the prescribing of paracetamol-based analgesics more frequently than every 4 hours and at doses of more than eight tablets in 24 h.

Other issues that would need to be considered in detail would be the design of administration functions for continuous infusions and controlled drugs, the configuration of missed dose codes and the provision of an on-hold and off-hold facility for items that have been prescribed, but which need to be withheld pending other events, for example pathology test results. The latter function is useful in a number of situations involving elective treatments – for example chemotherapy.

Facilitation of a Seamless Pharmaceutical Supply Chain

Many of the inefficiencies of existing manual prescribing and medicine supply processes in hospitals surround the way in which prescriptions written on the wards are filled with actual medicines from the hospital pharmacy department. Consequently, a direct link between each ward and the pharmacy department, either as different workstations in a networked EP system, or as an interface between an EP hub and a pharmacy system, represents the means for automating order transfer between wards and the pharmacy, and a valuable tool for reducing inefficiency in the pharmacy requisition process. This is shown in the architecture diagram in Chapter 2 (Fig. 2.2).

A conspicuous benefit from a UK perspective is the potential for EP to streamline the discharge process.[6] However, while systems offer a seamless transmission from the ward to the pharmacy, or real-time display of prescribing information in the pharmacy, the total business processes of handing pharmacy supply of discharge prescriptions (TTOs) should be considered. Implementers will need to assess how an EP system can be configured to their established procedures and, alternatively, how their procedures may need to be modified following the introduction of an EP system. An EP system should be able to provide a comprehensive supporting information for each discharge prescription to enable a clinical pharmacist to undertake an initial clinical evaluation (diagnosis, tests performed, care plan etc.). It should also provide distinct functions for clinically checking a TTO as a whole, as opposed to individual items on the inpatient prescribing record. Consideration should also be given to how the system might facilitate workflow management within the pharmacy. It is important that all of these factors are considered

because they will all contribute to any benefits in terms of staff time efficiency and streamlining of the discharge process.

In addition to the way that an EP system can streamline medicine ordering and supply within a hospital, it has been suggested that EP systems can help to facilitate a seamless pharmaceutical supply chain from manufacturer to patient. For over 20 years, hospital pharmacists in many countries have been using departmental pharmacy systems for procurement and stock control of medicines. More recently, automated dispensing systems (pharmacy robots) have been introduced to increase the accuracy of the dispensing process. Furthermore, with the availability of web-based intranets and the associated security technology, together with the growth of e-commerce and the regulatory framework to support it, many pharmaceutical wholesalers are looking to promote e-procurement of medicines by hospitals. Moreover, many hospital pharmacies are seeking to implement e-procurement, with the stock movement and control efficiencies that it can provide.

Consequently, there now exists the means for a seamless pharmaceutical supply chain from the pharmaceutical industry to pharmaceutical wholesalers, and then via central procurement agencies and hospital pharmacies to the patient.

To this end, the baseline specification for the English Connecting for Health electronic prescribing programme has proposed a number of functionalities that are intended to streamline the medicines supply chain. These would include:

(a) The electronic link from the ward to the pharmacy for placing orders
(b) Interface with hospital pharmacy systems
(c) Automatic escalations for overdue medicines
(d) Support for newer stock control methodologies such as 28-day dispensing and patient's own drugs (PODs)
(e) Supply chain tracking in real time (viewable by patient)
(f) Medicine costs to be displayed throughout the supply chain

While many of these requirements may seem straightforward, there are various implications of providing these functions. First, as many implementers have already found out, the interface of an EP system to an (existing) pharmacy system constitutes a major technical task, in terms of interface building and data configuration. Furthermore, provision of price information for medicines is problematic, both in terms of appropriate adjustments for actual and notional costs, and maintaining the data in real time, throughout the system, at each point of the supply chain. Second, supply chain tracking, which includes the wholesaler would require involvement of wholesaler systems staff and would link the electronic prescribing programme with the e-procurement agenda within the NHS, with the complexities that would involve. Third, provision of supply chain information to patients, as the end-user, would potentially increase the number of disputes between the pharmacy department and wards concerning throughput issues.

It is highly desirable that an EP system should support the various stock control methodologies currently used in hospital pharmacy – 28-day dispensing, use of PODs etc. However, as with clinical pharmacy tools, this represents an area that is unique to hospital pharmacy, and pharmacy managers should have an active role in the design of these functions.

Reduced Use of Paper and Consumables

Traditionally, hospital records have been used and stored in a paper format. As well as the clinical notes pages, the records include proforma results pages for radiology and other departmental investigations and mount sheets for pathology result slips. The records for one patient will have different sections in the clinical notes for each specialty and admission, together with outpatient appointments. As a consequence, the records for a patient who has had a long history of chronic disease and/or multiple acute referrals to clinicians of different specialities may fill several folders and occupy up to 50 cm of shelf-space in A4 format. The difficulties associated with the storage and retrieval of such records have driven the developments in PASs and clinical coding over the last 30 years. Specifically, hospital inpatient prescribing records have been recorded on a drug chart, or Kardex, as discussed previously. During any one admission, a patient may have a number of different charts, some of which might be overflow charts with only one or two entries on, prior to the aggregation of the patient's current prescription on a single new chart.

The introduction of electronic prescribing and medicine administration will therefore reduce the amount of consumables used by a health provider – charts, paper, pens etc. Depending on the size of the healthcare provider, the resulting savings may be significant. Nevertheless, while these savings may represent a clear, unambiguous and relatively easily measurable benefit of introducing an EP system, they are insignificant compared to the costs of wasted staff time due to inefficient paper-based systems and processes, and the possible costs of litigation when errors are made, as a result of these inadequate processes. However, unlike savings on paper and consumables, costs for staff time and potential litigation are more difficult to calculate, and it will be tempting for health providers not to attempt to quantify them.

Clinical System Intraoperability

The ability of different clinical systems to interact with each other in an integrated manner is a key factor in the streamlining of healthcare business processes within a hospital or healthcare provider. This is especially the case, given the disparate nature of many business processes within a healthcare enterprise, and the silo development of individual departmental systems in the past.

In a number of UK EP implementations, authors have commented on the ability of an EP system to provide a complete and comprehensive prescribing history, which is interfaced with the hospital EPR system.[6,9,11] This reduces the number of lost or absent medication records, facilitates remote electronic prescribing and enables the easy production of hard copy discharge prescriptions and other supporting information from different locations. There is therefore the potential for transferability of the prescribing history to and from different systems. For example, this enables electronic prescriptions to be routed to the hospital pharmacy departmental system, to streamline the medicine supply process, as discussed previously. This

would also enable pathology test orders to be triggered from within the EP system, and sent to the pathology system, and for pathology test results to be posted to the EP system.

As mentioned previously, a comprehensive prescribing history within an EP system is important for ensuring evidence-based working practices and user confidence in the system. However, when the system is designed to provide an optimally comprehensive prescribing record, there are complications associated with the actual transfer of high-granularity prescription data between systems. While transfer of data may be relatively uncomplicated within a system in a physical or wireless networked environment, or through interfaces with other systems in the same hospital location, there are issues associated with transferring data to external systems. There is, for example, currently no model in the UK for transferring medicines data from hospital EP systems – where they exist – to GP systems or community pharmacy systems in primary care.

This is a key driver for regional or national healthcare IT programmes, such as the English Connecting for Health programme, where prescription information is transferred to a central spine, from which it may be retrieved by other healthcare providers as the need arises. Apart from technical issues concerning architecture and hardware, standards for interoperability are required for data formats and messaging. With healthcare application data entities and structures, the international messaging standards are the Health Level 7 (HL7) formats, which are based on XML conventions. For data relating to medicines, the standard terminology is SNOMED CT, from which comes the terms for the UK dictionary of medicines and devices (dm + d).[12] These will be discussed in more detail in the chapter on data support for EP applications. However, at the present time, there is still work to be done on the definition of messages to allow transfer of prescription information between systems at the level of complexity required to support secondary care EP, and also on the ability of applications to receive these messages.

Improvement in Hospital Business Processes due to Electronic Dissemination of Prescriptions

As mentioned previously, clinical practice in healthcare provider organisations is undertaken in the context of a health economy and practitioners are under pressure to achieve health outcome targets and service-level agreements. These pressures exist irrespective of whether the health economy is insurance-driven, as in the US and many countries in continental Europe, or based on central government funding, as with the UK National Health Service. Consequently, healthcare managers in any context are receptive to the use of electronic systems to facilitate greater efficiencies in the use of healthcare resources in a provider organisation.

A number of studies have postulated organisational efficiencies as benefits of using an EP system. However, more than perhaps any other EP system benefit area, organisational

benefits cited for EP systems are most dependent on the political and socioeconomic contexts in which they are demonstrated.

Furthermore, organisational benefits of EP systems are also dependent on the structure and objectives of the study in which they were demonstrated. Organisational efficiency benefits cited in studies include:

(a) Reduced medication ordering turn-around times
(b) Reduced hospital stay times
(c) Streamlining of the hospital discharge process (an important issue in the UK context)
(d) Reduced pathology test and radiology test reporting times
(e) Reduced number of pathology orders generated
(f) Improved patient record documentation

Some studies have indicated that EP has a beneficial effect on medication ordering turn-around times, which is not surprising as many systems facilitate the seamless transmission of prescription data from a prescribing workstation on the ward to a pharmacy system in the pharmacy. One US study has identified a 64% average reduction in medication ordering turn-around time following implementation of an EP system.[13] It has been suggested that EP systems can have a positive effect on the total hospital stay time,[14] but this is harder to demonstrate conclusively and may not be applicable to the UK context.

Nevertheless, two of the UK reports indicate that EP is a useful tool for the clinical pharmacist, and helps to streamline the pharmacist's work in terms of the prescription review process, thus allowing them to spend more time on near-patient clinical activities.[9,11]

One important factor in the streamlining of hospital prescribing processes is the ability of the electronic prescribing record to be viewed remotely in a number of different locations.

Contribution of Workflow Improvement to Professional Practice Development

Organisational benefits – and in particular, improvement of medicine prescribing, administration and supply workflows within a hospital or healthcare provider organisation – have potentially profound implications for the practice of clinical professionals. Because of these efficiencies, healthcare professionals can be confident that time-consuming routine processes can be automated with accuracy, and their time can be released to enable them to engage in more patient-centred activities, which require intuitive input that only a human being can provide. These tasks might include detailed history taking, medicines review, health education, involvement in specialist clinics and patient support groups, clinical research and, of course, evaluating resources and technology that could be used to facilitate further service developments. The staff time that can be released to healthcare professionals

following the introduction of an EP system to deal with the routine tasks and processes of hospital prescribing can be significant; one UK study indicated that, in hospitals where there was an EP system, pharmacists could spend up to 70% of their time on activities relating to pharmaceutical care, rather than the prescribing and supply processes.[15]

Nevertheless, in addition to releasing the time of healthcare professionals to focus on other clinical activities, EP systems provide an infrastructure to support these clinical activities, and to support new and emerging services that can be provided by healthcare professionals. The ways in which EP systems can support professional practice are explored in detail in a subsequent chapter.

Conclusion

In many organisations where IT has been used to automate business processes, implementers have sought benefits in terms of organisational efficiency and cost-effectiveness. Such benefits have been observed where EP systems have been implemented in hospitals, although the benefits observed may be specific to the healthcare context in which they were observed, and may not be reproducible in other health economies. Implementers should consider how existing business processes may be automated, and the extent to which automation may allow new business processes, and support changes in professional roles for, and service development by, health professionals. To gain the maximum organisational benefits from EP systems, it is essential that system designers take into account the comments, views and aspirations of clinical users.

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Chapter 4
EP Systems as a Risk Management Tool

The practice of medicine is an inherently risky activity. It is to be hoped that many therapeutic interventions are beneficial when used in the appropriate clinical situation. However, the majority of medical treatment interventions – and indeed some diagnostic or monitoring interventions – carry with them an element of risk. An important aspect of the healthcare professional's job is risk management – to evaluate the risks associated with any particular therapeutic or diagnostic intervention and to follow working practices that reduce the risks involved. The clinical professional evaluates risk on the basis of documented experience, together with clinical judgement, arising from his or her own professional experience.

Electronic systems cannot completely eradicate risk in medicine since, by definition, they operate heuristically using defined and discrete datasets and logical algorithms, and their ability to be intuitive is limited. Nor can electronic systems address the human elements of the communication of risk information to, and the assimilation of risk information by, individual patients. Although electronic systems can provide some information support for this, this aspect of risk assessment remains primarily in the domain of the face-to-face consultation between patient and professional, and rightly so. Nevertheless, there is a reasonable body of evidence to suggest that electronic prescribing systems can reduce prescribing risks that are associated with, or may be influenced by, prescribing procedures.

This chapter will discuss the ways in which EP systems can influence risks associated with the prescribing, supply and medicines administration process. Firstly, however, it is necessary to review the potential risks associated with the medicines management process, and the general principles of how these risks can be managed, before examining specific aspects of risk reduction with EP systems.

Principles of Risk Management in Therapeutics

The medical risks associated with pharmacological therapeutics may be divided into two broad categories:

(a) The risks associated with choosing the correct medicine, in the correct formulation and at the correct dose for a particular patient.

(b) The risks associated with ensuring that, once the correct medicine has been chosen for the patient, the correct medicine is then supplied to the patient and that the patient is concordant with treatment.[1]

Figure 4.1 shows the medicines management cycle, a flow diagram for the treatment of a patient with medicines.

As can be seen, the cyclical element to this process is that, depending on the response of a patient to a medicine, the patient may be reassessed, or even rediagnosed, and the prescribing cycle starts again, with new medicine(s) prescribed instead of, or in addition to, the original prescription.

There are risks associated with each stage in the cycle, and they are as follows:

- *Diagnosis*. There may be a risk of misdiagnosis, depending on the complexity of the disease and the probability of atypical presentations. This risk could be reduced with computer decision support tools or by seeking a specialist second opinion.
- *Assessment*. Disease assessment may be complicated by the use of different scoring or disease activity tools in certain therapeutic areas and this may lead to an inappropriate assessment of a patient's disease. Again, electronic decision support tools may facilitate the appropriate use and interpretation of disease assessment schemas.
- *Care plan.* Lack of clinical guidelines, or guideline interpretation, may mean that individual healthcare providers may not have robust care plans to help clinicians manage different patient groups. In this situation, individual treatment
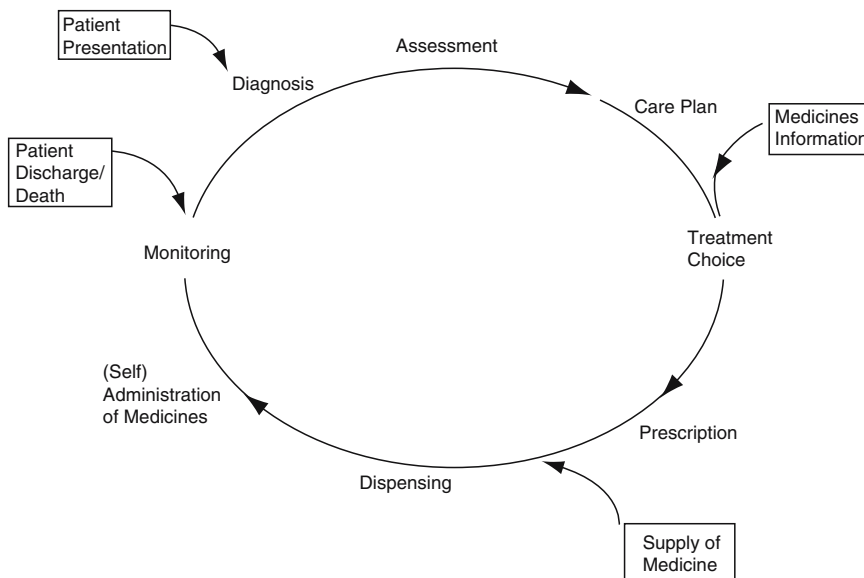
Fig. 4.1 The medicines management cycle

decisions made by clinicians may differ from best practice evidence, thus introducing risks to the patient.

- *Choice of medicine*. Due to the plethora of pharmacological treatments available, together with their respective efficacy profiles, their contraindications and their licensed uses, the choice of medicine for a patient represents a huge area of risk in the prescribing process. This risk may be compounded by the promotional messages of the pharmaceutical industry, which may not be consonant with established guidance from national prescribing bodies and medical royal colleges. The use of decision support tools in EP has considerable potential to reduce the risks associated with medicine selection, and much research has been conducted into the use of decision support systems to support rational choices of medical treatment. This will be reviewed later in the chapter.

- *Prescribing.* The prescription written by the prescriber should clearly state the medicine, the formulation, the dose, the route, the frequency and any other special instructions concerning the use of the medicine. When prescriptions are handwritten on hospital drug charts, it is easy for some aspects of the prescription to be unclear or omitted. What often happens in practice in this situation is that the pharmacist will either contact the prescriber to clarify the exact instructions, or may themselves add the necessary additional instructions, if they are satisfied with the prescriber's intention. However, there are risks associated with both of these practices. Furthermore, there is the risk that items may be erroneously omitted or duplicated when a drug chart is rewritten, which can happen at least once during a patient's hospital stay (more often if they are in an acute medical setting, and taking a large number of frequently changing medicines). Once the prescription is written on the chart, the item has to be obtained either from the pharmacy (often via the hospital's portering system) or selected from the ward stock. Hospital pharmacy staff will be familiar with the perennial problem of lost drug charts or medicines. Electronic prescribing systems have a pivotal role in managing these risks. They can contribute significantly to the completeness and accuracy of prescribing by providing a structured prescribing record for each patient, where all of the prescription data elements are present, together with what might be prescribed as "forcing functions",[2] which ensure that prescribers complete all required entries in the electronic prescription form. Furthermore, an EP system with an electronic link to the pharmacy, as discussed in Chapter 3, is able to reduce the risk of the medicine not being present in the clinical area when the patient needs it.

- *Dispensing*. The risks associated with the dispensing of the medicine are concerning incorrect product selection and incorrect product labelling. Historically, these risks have existed because the entry of prescriptions onto the pharmacy system and the dispensing and labelling of medicines have been manual processes, and have been subject to the human error that can arise in repetitive processes. There is also the risk that treatment cannot go ahead due to medicine supply failure, i.e. the medicine cannot be sourced from the pharmaceutical wholesaler, and an alternative prescription is not facilitated in a timely manner.

Where they are being implemented, EP systems are increasingly being interfaced with pharmacy systems and pharmacy robots, thus reducing potential risks in the dispensing process. The issues associated with using EP functionality to manage the supply chain were discussed in some detail in Chapter 3.

- *Medicine administration.* Traditionally, medicines for hospital inpatients have been administered to each patient from a drug trolley on the ward, according to the instructions on the drug chart (see Chapter 3). The procedure is that the nurse will sign the relevant box on the patient's drug chart to signify that the drug has been given, or put a missed-dose code, to show a reason for non-administration, in the box. For Schedule 2 or 3 controlled drugs (see Chapter 1), a double check is required before the dose is administered. There are many risks that can arise from the medicine administration process in this form: (a) the incorrect medicine can be supplied from the drug trolley; (b) the correct medicine can be supplied but incorrect details recorded on the drug chart and (c) the patient may receive a time-critical medication late, due to delays in the drug round procedure. The increasing trend towards self-administration of medicines in hospitals may reduce these various sources of error, as patients who are able to self-administer will be familiar with their own regimens. However, EP systems may reduce the risks associated with the medicines administration process, by providing electronic medicines administration, thus making a "closed-loop" process (i.e. the whole medicine supply process is controlled electronically), as discussed in Chapter 3. This will reduce risks by providing a clear electronic drug chart and by providing prompts to ensure that each medicine administration event is recorded in a timely fashion.
- *Monitoring.* In hospital practice, where patients may be critically ill, or who may be having various changes to their medication, monitoring of response to therapy is especially important. EP systems are able to alert clinicians to routine time-dependent monitoring requirements, and can be designed to manage corollary orders, i.e. orders that are raised only in association with other orders. For example, when a patient who is taking potassium-sparing diuretics is then prescribed an ACE inhibitor for heart failure or high blood pressure, their plasma potassium level should be monitored, as the two medicines have an additive effect on potassium levels.

There are a number of general principles of risk management that emerge from a study of the medication management process:

(a) Human error, or operator error where the process is being facilitated by electronic systems, is a major risk element in the prescribing process, since, at various points in the medicines management cycle, human actions and decisions are required. The potential for human error increases when tasks are repetitive or inherently boring. EP systems have the potential to automate tasks in the prescribing process that are repetitive, iterative or which are complex, but predictable, thus minimising human error in these areas.

(b) Medication errors are often multifactorial in their causation. To give a simplistic example: a patient is prescribed Amitriptyline 10 mg tablets, and the directions are 1–2 at night. The hyphen on the drug chart becomes illegible, and the patient

is given 12 (twelve) amitriptyline 10 mg tablets in error. In this situation, there are three potential factors which gave rise to this incident. Firstly, the prescriber's instructions were not completely unambiguous; secondly, the pharmacist did not clarify the directions and thirdly, the nurse administered the dose without querying it. Situations of this nature commonly arise in busy clinical environments and the likelihood of such errors increases with workload, if systems are not in place to monitor the medicines management process. Furthermore, if just one of these factors had been addressed, the incident would not have happened. This phenomenon has been described in medicines risk studies as the so-called "Swiss cheese effect"[3] – i.e. the skewer can pass right through the middle of the cheese, if all the holes line up. Furthermore, at a statistical level, a number of different types of error may contribute to the overall medication error rate in a hospital. These are the sort of statistics that are assessed in qualitative studies of EP systems, which will be reviewed in the remainder of this chapter.

(c) As a general rule, the incidence of medication errors may be reduced by having standard operating procedures (SOPs) in place, which anticipate likely causes of errors, and which reduce any variations in working practice arising from exceptional circumstances. These should closely reflect, and aim to standardise, normative working practice. Each step may be straightforward and even self-explanatory, but documentation of the procedure helps members of staff to follow it, so that it becomes instinctive for them. An example of this is the checking of a patient's hospital number as well as their name, prior to administering drugs. The recent mandating of SOPs in community pharmacy in the UK was with the intention of reducing errors due to variations in practice and high prescription volumes.

Reduction in Medication Error Rates With EP Systems: Experience From US Implementations

The potential for an electronic prescribing system to reduce medication errors in hospitals is a key benefit of using the system, given the financial cost of medication errors, both in terms of patient morbidity/mortality and in terms of costs to the healthcare system. For this reason, considerable research has been conducted into the extent to which EP systems can reduce medication errors. Many of the demonstrated benefits in the area of risk reduction for electronic prescribing systems (CPOE systems) themselves are in the prescribing, dispensing and medicine administration stages of the medicine management cycle. The decision support tools associated with EP systems are likely to have risk management benefits in the diagnosis, assessment, care planning, treatment choice and monitoring stages of the medicine management cycle, and will be discussed in the next section.

Much of the available quantitative research on risk reduction has originated in the United States, for reasons outlined in Chapter 2. In US studies, reduction in medication errors following the introduction of EP systems is well documented. In a key US study from the Brigham and Womens' Hospital, Boston, MA, Bates et al.[4] compared

computerised physician order entry (CPOE), with CPOE plus a team intervention approach, in the prevention of non-intercepted serious medication errors. They found that, with both interventions, during the implementation period, there was a reduction of non-intercepted serious medication errors by 55%, from 10.7 events per 1,000 patient-days to 4.86 events per 1,000 patient-days ($p = 0.1$). Also, there was a reduction of preventable adverse drug events (ADEs) by 17% (from 4.69 to 3.88 events per 1,000 patient-days), and a reduction of non-intercepted potential adverse drug events (ADEs) by 84% (from 5.99 to 0.98 events per 1,000 patient-days). There was found to be no additional benefit of CPOE plus the team intervention over CPOE alone. The error rate reduction figures of 55% and 84% in this study are substantial, and look impressive, but it must be borne in mind that these figures are for *potential* (non-intercepted) errors, rather than *actual* errors, and it is not clear how many of these potential errors would have become actual errors in practice. The reduction figure for preventable adverse events, 17%, is considerably smaller.

In a follow-up study, Bates et al.[5] looked at medication errors detected in all patients admitted to three medical wards for a 7–10 week period in four different years (four points in the implementation process). This study took a broader approach than their previous study, in that it looked across the EP implementation period, and that it looked at the effect of CPOE on all error types, not just serious errors. Data were collected at four points in the implementation period:

(a) Period 1 (1992) – At baseline, before EP implementation
(b) Period 2 (1993) – EP system implemented
(c) Period 3 (1995) – Allergy checking improved
(d) Period 4 (1997) – Drug interaction checking and potassium ordering improved

The ADEs were assessed by pharmacists in a structured manner. The study showed that the overall non-missed dose medication error rate decreased by 81%, from 142 ADEs per 1,000 patient-days to 26.6 ADEs per 1,000 patient-days ($p < 0.0001$). Also, the rate of non-intercepted serious medication errors was reduced by 86% from baseline to Period 3 in the implementation process. However, as discussed, since non-intercepted medication errors are by definition those which are not readily detected under normal circumstances, it is difficult to ascertain whether this reduction was as a result of introducing the EP system. Furthermore, this study also showed that the non-missed dose error rate actually increased from Period 1 to Period 2, despite the overall decrease. The study also showed that the missed dose error rate increased between baseline and Period 3, and that the intercepted potential ADE rate increased between the baseline interval and Period 2. Again, however, the rise in this latter parameter may not be significant since potential errors may not immediately translate into actual errors.

A US baseline analysis of medication errors,[6] involving pharmacist evaluation of 1,111 prescribing errors over a week period, indicated that a significant proportion of these (64.4%) could be prevented by EP implementation, and that a further proportion (22.4%) could possibly be prevented, depending on EP system design.

A particular issue with US data on risk reduction with EP systems is concerning the transcription process. In the US, it is standard practice for hospital staff to produce a drug chart from the physician's clerking notes, and this process is a significant source of medication error in the US setting; some 11% of errors are as a result of the transcription process. Bates et al.[4] (1998)indicated that the rate of non-intercepted errors arising from the transcription process was reduced considerably by 84%, from 1.3 events per 1,000 patient-days to 0.2 events per 1,000 patient-days. Nebeker et al.[7] also commented that the introduction of CPOE, combined with an electronic medication record, had the potential to obviate the need to transcribe orders, and therefore eliminate transcriptions errors. Such a reduction might be expected if an automated system is being used for electronic dissemination of prescriptions to the hospital pharmacy.

Reduction in Medication Error Rates With EP Systems: Experience From UK Implementations

Many United Kingdom centres have not published detailed quantitative studies on risk reductions following EP implementation. Furthermore, it is recognised that, since the healthcare system is different in the UK, the risk profile will be different from the US context. Nevertheless, the incidence of medication errors in the UK has been documented. An analysis of medication errors as part of an assessment of a pharmacy intervention scheme[8] indicated baseline incidence rates of 10.1% for medicine administration errors, 6.3% for non-formulary prescribing and 4.6% for transcription errors. All of these could be reduced by implementation of an EP; again, the transcription error rate could be largely eradicated.

Reductions of errors associated with the prescribing process itself have been noted for some UK EP implementations. Farrar[9] has indicated an increase in the number of complete and correct doses on drug charts, following the introduction of EP. In research information available from the Wirral Trust[10] 2,180 prescriptions for 267 patients were analysed for legibility and completeness, with reference to hospital standards for prescription writing, based on the British National Formulary. One thousand two hundred and seventeen prescriptions generated prior to computerisation and 963 prescriptions generated after computerisation were assessed; electronic prescribing significantly improved the legibility and completeness of prescriptions, compared to prescribing by hand ($p < 0.0001$).

In a review of EP experience at Wirral, presented at the British Pharmaceutical Conference in 1999, Farrar[9] indicated that the use of EP at the Wirral Hospitals had increased the number of complete and correct doses on drug charts from 17.7% to approaching 100%. However, the record of medicine administration was not always complete; often once only medicines were completely and correctly prescribed, but no record was made of when they were administered.

These improvements in prescription accuracy and legibility and completeness of prescriptions may be attributed to a number of factors: the availability of a comprehensive

drug dataset to support prescribing, and a structured prescribing workflow, and also to the availability of implicit or explicit electronic decision support tools at the point of prescribing. These factors are discussed elsewhere in the book.

In their EP implementation in Ayrshire, Scotland, UK, Fowlie et al.[11] noted a significant reduction in inpatient prescribing errors, and medication administration errors, but a non-significant reduction in discharge prescribing errors, following the introduction of an EP system. Their main findings were as follows:

1. The electronic prescribing system led to a significant reduction in the prescribing error rate for inpatient prescriptions but, interestingly, not for discharge prescriptions. The inpatient prescribing error rate fell from 7.4% prior to EP implementation, to 7% one month after implementation and then to 4.7% 12 months after implementation ($p < 0.001$). The decrease in prescribing errors with discharge prescriptions, from 7.5% prior to implementation, to 5.9% 12 months after implementation, with an initial increase in error rate to 7.7% after the first month of EP, did not achieve significance.
2. The electronic prescribing system led to a significant reduction in medication administration errors, from 9% prior to implementation, to 6% one month after implementation, and then 5.4% 12 months after implementation ($p < 0.001$). However, medication administration errors involving intravenous drugs and controlled drugs were omitted from these figures, which could affect the overall medication administration error rate.

The observation that the inpatient prescribing error rate was reduced significantly, but the discharge prescribing error rate was not, may reflect the fact that the discharge prescribing process is innately more structured than the inpatient prescribing process, and therefore the potential for error reduction is greater with the inpatient prescribing process. These authors also showed a significant reduction in medicines administration errors, but indicated that the administration of controlled drugs and intravenous drugs was excluded from this assessment. Inclusion of these groups of medicines, and also implementation of the system in an acute medical area, could both adversely affect the outcome concerning medicines administration errors, due to more complex medicines administration scenarios. Consideration should be given to the design of controlled drug prescribing and administration functions and also to design of functions for prescribing and administration of continuous infusions and other complex intravenous drug regimens. The latter is particularly complicated, in terms of developing clear user interfaces that support all possible prescribing scenarios, and poor design in this area will lead to the introduction of new errors, resulting in critical incidents.

Shulman and colleagues[12] compared the use of a commercial EP system, without decision support functions, with handwritten prescriptions on an intensive care unit at University College Hospital, London, UK. The study found a moderate reduction of medication errors with the EP system. The medication error rate was 6.7% (69 errors on 1,036 prescriptions) for handwritten prescriptions and 4.8% (117 errors on 2,429 prescriptions) for EP generated prescriptions ($p < 0.04$). In addition, there was evidence that error rates with the EP system decreased gradually following its

implementation, due to increasing staff familiarity with the system. When both non-intercepted and intercepted errors were combined, patient outcome scores improved under the EP system. However, the three most serious errors that were identified in this study were with the EP system. While it is clear that EP systems can reduce routine errors, they can lead to facilitation of errors, depending on their design.

Charing Cross Hospital, London, UK, has implemented a commercial EP system (ServeRx, MDG Medical, Israel), which deals with all aspects of medicines management in the hospital environment, including electronic medicines administration, with patient identification using bar code technology, and automated dispensing.[13] The system therefore provides a so-called "closed-loop" process, in that it automates all aspects of the medicines management process. The system had a positive effect on both medicine prescribing errors and medicine administration errors. The prescribing error rate fell from 3.8% (across 2,450 medicine orders) before EP system implementation to 2% (across 2,353 orders) after implementation ($p < 0.001$). Non-intravenous medicine administration errors were reduced from 7% (across 1,473 non i/v orders) before the implementation to 4.3% (across 1,139 orders) after implementation of the system. However, while the system reduced nurse time spent on the medicine administration process, it increased time spent by physicians ordering medicines, and also the time spent by pharmacy staff in providing the ward pharmacy service. The impact of EP systems on the time management of health professionals, and therefore on their patterns of professional practice, is discussed fully in Chapter 6.

In a study conducted at the Sunderland Hospitals, Beard and Candlish[14] note that current UK hospital "Kardex" systems are probably unacceptable from a risk perspective, and may exceed the UK Health & Safety Executive's threshold of 1 in 10,000 medication errors per year, although there is no specific evidence to show this. The authors indicated that international research had shown that an automated unit-dose drug distribution system was most likely the safest hospital system. On the basis of this research, together with information on error rates at the Sunderland Hospitals, the authors concluded that if such a system were installed at Sunderland, the system was likely to pay for its investment, in terms of harm reduction, within 2–3 years, and that it would be a positive enhancement to clinical governance. Based on published data and in the context of the Sunderland Hospitals, the authors calculated the risk reduction figures as in Table 4.1.

However, the authors noted that, while greater risk reductions could be obtained with systems of increasing complexity, there was a trade-off against the cost of the system. While a unit dose medicines administration system would be the most effective way of reducing error rates, it would be a considerably bigger investment (Fig. 4.2).

However, the problem with this analysis is that, it does not take into account the firstly, proportion of different types of medication errors that might occur in a specific hospital and, secondly, the way that different systems may introduce new, unrecognised error types depending on their configuration. This latter issue will be addressed in the next section.

Automated systems have the potential to reduce errors and manage risk at the supply end of the medicines use process. The UK Audit Commission's "Spoonful of Sugar" report[15] published in 2001, highlighted the potential of pharmacy automation

Table 4.1 Risk reduction and cost benefit figures with different elements of electronic medicines management, as modelled at the Sunderland Hospitals

	Electronic prescribing (CPOE only)	Transcription	Dispensing	Medicines administration
Risk reduction	56%	6%	4% (base line rate at Sunderland – approx 0.05%)	34%
Cost benefit of risk reduction (harm reduction)	£120k pa	£7k pa	£5k pa	£84k pa
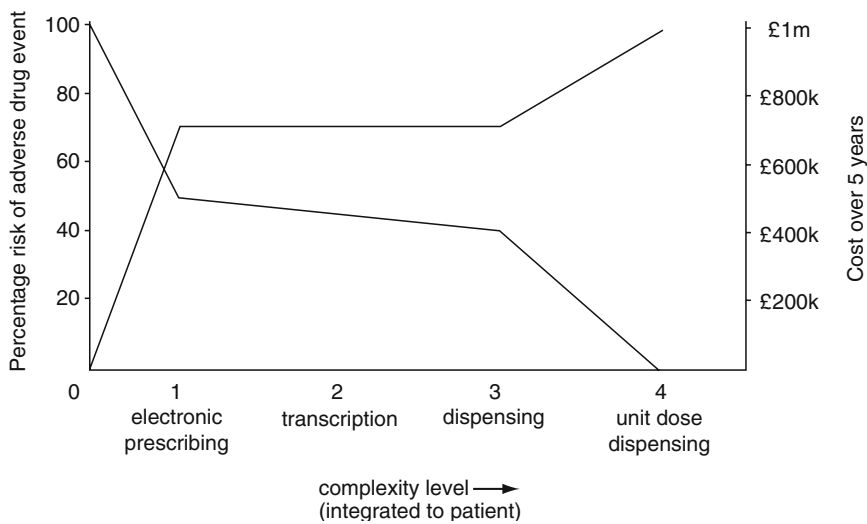
Fig. 4.2 Graph of complexity level of EP system against error reduction and financial cost Reproduced by kind permission of the Birchley Hall Press

to reduce dispensing error rates. Following on from that report, many hospital pharmacy departments constructed business cases to install automated dispensing systems (pharmacy robots) and to re-engineer pharmacy services. The operational aspects of these, and their relationship with EP systems, have been discussed in Chapter 3. A further study by Beard and Candlish at Sunderland[16] examined the extent to which an EP system could reduce the incidence of dispensing errors. An important general factor is that, because traditional dispensing is a manual process, error rates will to some extent be dependent on the number of staff present in a dispensary, and so dispensing error figures should be adjusted to take this into account, and be expressed as errors per member of staff. The authors found that the use of the EP system for inpatient medicine ordering led to a dispensing error rate of 0.0029 errors per person, compared to 0.0045–0.0057 errors per person in other areas of the hospital. One of the pharmacies in the Trust uses bar code product selection, which achieves a slightly lower dispensing error rate of 0.0022 errors per person.

Due to the high ratio of staff to prescriptions, and the highly controlled environment, the lowest dispensing error rate was in the Trust's chemotherapy manufacturing facility, where the authors calculated an error rate of zero.

Bar code technology has also been used by EP systems in order to reduce errors in the medication administration process on the ward. The patient's wristband bar code is scanned prior to a medicine administration event to confirm patient identity, and the bar code on the medicine is scanned to confirm the identity of the medicine to be administered. Medicines administration with the assistance of bar codes to identify either the patient or the drug may contribute to reductions in levels of medicine administration errors at the point of administration. In the Charing Cross study,[13] the EP system process forced nurses to use the bar code system for patient identification, and the percentage of patients who were not definitively identified prior to medicines administration decreased from 82.6% before EP system implementation to 18.9% after system implementation.

The limitations with use of bar codes are the availability, configuration and scalability of appropriate hardware, and also the fact that there is a proportion of medicines that do not have a correct bar code identifier. The use of bar codes may also be limited by harmonisation issues and obsolescence, due to development of RFID (radio frequency identification) technology.[17] In addition, use of bar codes for reduction of medicine administration errors relies on use of original packs (with bar codes) at ward level in a hospital.

Increases in Medication Errors Due To the Introduction of EP Systems

An important finding in some US studies is that the implementation of an EP system can actually increase the number of medication errors reported, at least at the outset. In the first of these studies, the Bates (1999) study,[5] an increase in error rate was noted during the initial stages of the study, as noted earlier. The increase in error rate was attributed to the EP system's functionality for dealing with potassium orders, which was only finalised later in the implementation process. In the second study, an observational review of a CPOE implementation at the University of North Carolina Hospitals,[18] the increase in medication error rate was attributed to (a) increased ability to identify errors due to enhanced data capture on an electronic system, (b) errors generated by staff unfamiliar with a new system or (c) error detection bias (due to either pre-conceived ideas about EP by users, or evaluators keen to report errors in a new system).

More worryingly, it has been suggested in some studies that the very design of EP systems could facilitate errors, leading to hitherto uncharacterised errors. Koppel et al.[19] did a study of medication errors generated by a commercial EP system that had been in operation in a US hospital for 7 years. They found that the EP system facilitated 22 error types, which fell into two groups: (a) errors generated by the

fragmentation of data by the system and lack of integration between the different components of the system and (b) errors arising from the human–machine interface.

Nebeker et al.[7] commented on how a high rate of ADEs could occur even at a hospital where there was a high level of IT usage, to support hospital processes. The study looked at ADEs across the electronic prescribing process, by performing a prospective daily review of the electronic medical record for a random sample of all admissions over a 20-week period at a US hospital. The study showed that, of 937 admissions, there were significant ADEs in 483 admissions. 99% of the ADEs identified resulted in serious harm to the patient and 27% of the ADEs were due to medication. The study observed that ADE rates were still relatively high after CPOE introduction, if decision support systems were not present as an integral part of the system. The role of decision support systems in reducing prescribing risk with electronic systems is discussed in detail in the next section.

This phenomenon has also been noted in the UK. As mentioned previously in this chapter, an initial increase in prescribing error rate following implementation of EP (leading to an eventual reduction in error rate), was demonstrated at the Ayrshire and Arran Trust, Scotland,[11] for discharge prescriptions, and this observation was responsible for the reduction of prescribing error rate for discharge prescriptions not reaching overall statistical significance. This effect was also noted in the comparative study of an EP system with handwritten prescriptions in the intensive care unit context,[12] where the three major errors occurred with the EP system. The authors concluded that clinicians should not become complacent about the use of automated systems to eradicate errors.

It is recommended that high volume, longitudinal studies are conducted on future EP implementations, specifically in order to further evaluate this phenomenon, and to determine what factors can lead to a rise in prescribing error rate following the introduction of an EP system.

Reduction of Medication Errors Due To the Availability of Electronic Decision Support Tools At the Point of Prescribing

In the study by Nebeker,[7] documenting 937 hospital admissions, it was found that 483 admissions had significant ADEs associated with them and that 27% of these were associated with medication. Of the medication-related ADEs, 61% were associated with prescribing errors and 25% with monitoring errors and the authors concluded that EP with decision support (DS) features would have a major impact on these error rates, by reducing inappropriate prescribing at the outset and by providing suitable monitoring tools when certain drugs are prescribed (e.g. digoxin, lithium, theophylline). Indeed, the consensus among electronic prescribing specialists is that decision support tools should be an integral part of EP systems, as they have the potential to "add value" to the system as a clinical tool. The above data suggest that DS functions are particularly valuable in reducing selection errors and inappro-

priate selection at the medicine ordering stage of the medicines management cycle, and thus reduce risks associated with prescribing errors.

Clinical decision support facilities may be classified into *active* decision support or *passive* decision support. Active decision support functions provide a clinical alert to the user automatically as part of the workflow of the system, without the user having to actively seek the clinical information. Active decision support mechanisms are built into the EP system software. Passive decision support functions, however, are stand-alone medicines information reference sources mounted on the Internet, an intranet or a local server, and accessible via a "hot key" or quick link by a clinical user, when the user is actively seeking information to resolve a clinical problem.

Active clinical decision support warnings and information would include some or all of the following:

(a) Sensitivity checking
(b) Drug interactions
(c) Duplicate therapy/drug doubling
(d) Precautions/contraindications
(e) Dose checking
(f) Formulary status
(g) Monitoring warnings

The key issue with proactive DS functions is that they must be sufficiently comprehensive to be of clinical value, but designed in such a way that they are not intrusive to the clinical user, which might lead to important warnings being disregarded by the user. This is a delicate balance and requires considerable thought if the rules are going to be configured within the EP application – for this reason, some implementers have chosen not to support DS functions at all, rather than implement them in a partial manner or without full evaluation; this is the reason why the EP project at Southmead Hospital, Bristol, did not implement any DS functions.[20] In the past, for example, there have been some systems that have limited the number of drug interaction warnings to two or three per drug, or limited the number of allergens for sensitivity checking to two per patient. Limitations of this nature are clearly not acceptable if an EP system is to provide comprehensive DS functions.

However, with a comprehensive DS tool, based on a drug database from a third party data supplier, these issues can be addressed by the mode of implementation of the DS functions in the EP application; with, for example, the use of graded drug interactions, where the system can be configured so that only the most clinically significant drug interactions are displayed to clinical users, or flagging of absolute contraindications only. The advantages and disadvantages of using a third party data supplier to enable DS functions will be discussed in Chapter 5.

Another question to be addressed in the provision of DS is whether there is any type of prescription that should be completely disallowed by a DS function on the EP system. There are some prescriptions that are absolutely dangerous and that should (and could) be prevented automatically by an EP system (for example, intrathecal use of vincristine, daily dosing of methotrexate). The EP system used on the renal unit at the Queen Elizabeth Medical Centre, Birmingham, UK[21] disallowed some orders

because of sensitivities and serious drug interactions. However, careful consideration should be given to the issue of disallowing prescriptions because of relative contraindications; if too many prescription types are automatically disallowed, clinicians may choose to handwrite prescriptions, thus defeating the object of an EP system and compromising the completeness of the electronic prescribing record.

Some authors have indicated that use of an EP system made it easier to monitor prescribing habits within a hospital.[9] It is possible to control choice of formulary medicines over non-formulary medicines by the system either (a) guiding prescribers towards formulary medicines or (b) disallowing prescription of non-formulary medicines. However, again, implementers should consider the implications of a rigid system of prescription control. Furthermore, there is some evidence (albeit in a US primary care setting) to suggest that EP systems do not have a major impact on the balance of formulary and non-formulary prescribing[22].

If systems provide integral application algorithms for calculations (e.g. renal function, hepatic function, body surface area), rather than using a third-party "black box," then clinical users will need to establish whether these are user configurable and how they will be validated and maintained.

While provision of active DS within a system is associated with various implementation issues, the provision of passive DS – links to intranet-based information sources such as WeBNF and eMIMS – are straightforward technically, but may pose licensing issues. Again, the data sources available for passive decision support will be discussed in detail in Chapter 5.

Due to the significance of clinical DS functions in assisting prescribing and the widespread use of such systems (usually PDA mounted databases) to support paper (non-CPOE) prescribing, DS applications have been in use in the US for some years. Furthermore, due to their potentially pivotal role in preventing medication errors, DS systems have been subject to a great deal of quantitative research in the US medical literature.

Hunt et al.[23] performed a systematic review on 68 controlled studies of prescribing DS systems. The effect of a DS system on physician performance was assessed in 65 of the studies and, in 43 of these studies (66%), a benefit to the physician was demonstrated. A majority of studies demonstrated benefits to the physician for drug dosing systems, preventive care systems and other medical care applications. Physician benefits were not adequately demonstrable for diagnostic DS tools, but the sample size in this review consisted of only five studies. The authors also concluded that further work would be required to assess the impact of DS systems on health outcomes, rather than physician performance.

Evans et al.[24] evaluated the use of an application to assist prescribers in the selection of antibiotics. The study compared 545 patients where the antibiotics DS system was used, with a control group of 1,136 patients. The application was found to have the following benefits:

- Reduction in number of orders for drugs for which patients had known sensitivities (from 146 orders to 35 ($p < 0.01$))
- Reduction of excessive drug doses (from 405 orders to 87 ($p < 0.01$)

- Prevention of antibiotic-susceptibility mismatches (reduction from 206 events to 12 ($p < 0.01$)
- Reduction in the mean number of days of excessive drug doses (from 5.9 days to 2.7 ($p < 0.002$)
- Reduction in the number of ADEs caused by antibiotics (from 28 events to 4 ($p < 0.02$))

The system therefore facilitated improved patient care, and more cost-effective use of antibiotics. However, the authors noted that, despite these positive results, the antibiotic regimen suggested by the computer was only followed exactly in 46% of orders. The implication is that physicians were not following the computer recommendation blindly, but were using the application to augment their clinical judgement in a beneficial way, as should happen with clinical decision support.

Teich et al.[25] conducted a time series analysis of an EP system where, as new medication orders were entered, the system displayed drug usage guidelines, including dose and frequency information. The EP system led to various positive changes in prescribing practice. These included (a) an increase in the percentage of orders for the formulary recommended drug in a particular drug class; (b) a decrease in the percentage of orders for a drug with doses that exceeded the recommended maximum dose for that drug and (c) an increase in the use of the approved frequency of administration for a drug.

In the US, the Joint Clinical Decision Support Workgroup (JCDSWG) has published recommendations for EP system DS function development.[26] The group recognised that the benefits of DS functions used in EP systems had not been fully realised, and that further development of DS systems was required. They reported recommendations and action plans in three general domains:

- Advances in system capabilities (DS knowledge base, database elements, usability and performance).
- Standardisation and centralisation of vocabularies and knowledge structures, so that standard DS routines do not need to be adapted by software vendors and healthcare providers.
- Financial and legal incentives to promote adoption of DS within EP systems.

However, research by Wang et al.[27] has shown that, on average, available EP systems in the US fulfill only half of these recommendations. It is this lack of advanced functionality that will need to be addressed before EP systems can have a positive effect on financial cost and health outcomes in chronic diseases in the US; this is one of the issues that was addressed by the Medicare Modernisation Act 2003. In response to these publications, Miller et al.,[28] highlighted the ability of large academic medical centres to implement complex EP systems, but that smaller, rural healthcare providers do not have the expertise or financial resources to implement such systems. Furthermore, Miller et al. claim that, while the DS functions of well-established EP systems at centres of excellence are often maintained in house, the third party drug database used in

commercial EP systems that would be implemented elsewhere may not be of such high quality. This claim will be examined in more detail in Chapter 5 on data support. Miller and colleagues argue for the development of US-wide drug database and terminology standards to support DS, and indicated that EP systems would not be implemented widely across the US, in rural areas as well as major conurbations, until that happened.

Problems With Evaluating Risk Reduction Aspects of EP Systems

With many of the quantitative studies described here, whose purpose is to perform a statistical analysis on error rates and other risk issues in the medicines management process, and to evaluate an EP system as an intervention in the process, there are potential confounding factors. These may include the following:

(a) The subjectivity of reviewers in the evaluation of ADEs and medication errors in these studies
(b) The lack of parallel studies between units with EP and those without EP in the same hospital
(c) The extent to which the study period represents the full implementation schedule of the EP system. If certain functions of an EP system are not available, this may have a profound effect on the error rates detected by a quantitative study
(d) Error detection bias in error reporting, due to the vigilance of researchers and users when evaluating a new system
(e) The extent to which the benefits reported are specific to the working practices of the sites studied

The extent to which these confounding factors associated with research methodology or system design affect benefits needs to be evaluated in more detail.

For these reasons, it has been suggested[29] that there should be a formal methodology for validation of EP software, analogous to the process of licensing a new medicine. However, while a prospective, controlled study is the "gold standard" in clinical medicine, and especially therapeutics, to demonstrate associations and causal links, such studies are much harder to design to assess clinical informatics interventions.

In his discussion of the methodologies for evaluation of EP systems, Trent Rosenbloom[30] describes a number of issues in the design of clinical informatics studies, including (a) the isolation of specific system variables to be tested, (b) the choice of the most appropriate units of study (individual patient, ward, consultant list or hospital) to be exposed to the system variable under study conditions and (c) ensuring that the study groups remain distinct during the time that systems or workflows are tested, and that there is no inadvertent crossover of subjects.

Conclusion

There is now a large body of research evidence to suggest that EP systems reduce risks associated with the prescribing, administration and supply of medicines. Nevertheless, the risk reductions achieved are dependent on the design of an EP system, and the definitions and methodologies of the quantitative studies used to evaluate them. It is also recognised that EP systems can introduce new and hitherto uncharacterised risks to the medicines management process. There is a need for ongoing research to fully elucidate the recognised risk reductions with current EP implementations and to formally evaluate newly implemented EP systems.

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Chapter 5
Data Support for Electronic Medicines Management

It is clear from the operational requirements of EP systems that these systems require high quality data inputs from a number of sources. The supporting data for EP systems and other medication management systems fall into four main categories:

1. *Patient data.* For example, demographic data such as patient's name, address, date of birth, next of kin, religion, etc. These data are usually imported to an EP system from a patient administration system (PAS) and do not give rise to any design issues specific to EP systems, except possibly at the integration level. For this reason, patient data support will not be considered in any detail in this chapter.

2. *Drug data.* For example, medicine name, form, strength, route of administration, synonyms, dose, storage conditions, etc. This basic dataset would be required for each prescribed item for a patient. In addition to this indicative information, it is expected that EP systems would provide referential information on prescribed medicines – for example, standard information on contraindications, precautions, side-effects and drug interactions. The accuracy and validation of these data are essential, and issues relating to the implementation of drug data will be discussed at length in this chapter. Some EP systems use their own drug databases, produced in-house from previous implementations; others will use a drug database supplied by a third party data supplier. The source of the drug data has various implications which will be discussed in some detail later in the chapter.

3. *Disease and monitoring data.* For example, diagnostic tools, disease classifications, rating scores and monitoring scales. This type of information is not specifically related to medicines, but it is required in the prescribing process (see Chapter 4, Fig. 4.1), to support disease monitoring, epidemiological reporting and some decision support functions – for example, cancer epidemiology reporting from an oncology system. These data are often readily available in algorithms that are easily codable, but conventions for disease assessment and monitoring can and do change over time, according to guideline, health service and professional body recommendations. It is important therefore that these ancillary data are not hard coded into an EP system, but are set up as data tables, so that they can be changed when necessary.
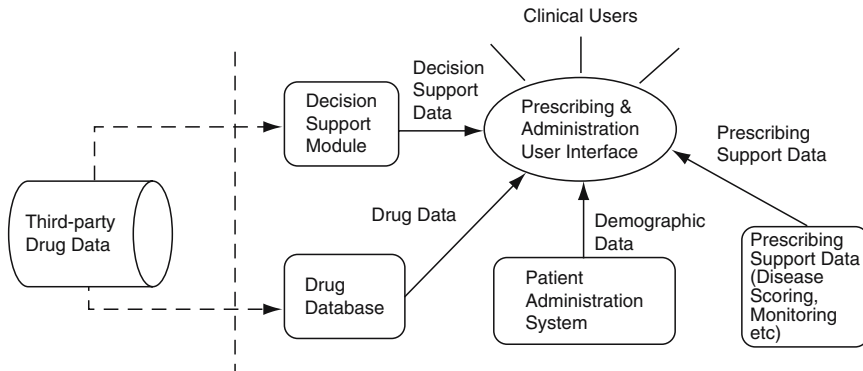
Fig. 5.1 EP data architecture

4. *Decision support (DS) warnings*. In addition to the data items described in the first three categories above, which are instantiated in individual patient prescribing records within the EP system, there is a requirement that an EP system provides a system of clinical warnings and alerts for clinical decision support at the point of prescribing. This would include, for example, warnings for drug interactions, sensitivities, duplicate therapies, contraindications and precautions. The warning messages themselves are non-patient-specific, in that the same type of message might be used for various different drug interactions for different patients. Consequently, DS functions on EP systems need data tables to store the various clinical alert messages that would be required, and an indexing and querying system to generate the appropriate clinical warnings at the relevant point of the workflow. The data configuration issues relating to DS functions will be discussed in detail later in the chapter. The data architecture of an EP system might be as shown in Fig. 5.1.

In order to gain an appreciation of some of the issues that must be considered in structuring of data support for an EP system, it is helpful for the reader to have a broad understanding of how medicines information reference sources and clinical data coding conventions have developed to the present day. This chapter will examine some of the clinical coding systems and terminologies that have developed, before focusing specifically on the drug data requirements for EP systems and drug data related issues.

Coding Systems for EP Concepts

As discussed previously, in addition to the data specifically relating to medicines and their properties, EP systems require data schemas to describe details of diagnosis, contraindications and side-effects, in order to provide the most comprehensive functionality.

The discipline of health informatics has developed to analyse and systematise health and disease related information and, with time, a number of clinical coding systems have evolved to describe health and medicine concepts in a machine-readable manner.[1] Many of the coding systems have their historical origins in the need to classify and enumerate medical events for public health purposes. Many of these have relevance to EP systems and are discussed below.

The International Classification of Diseases (ICD) is a multiple axis disease classification schema which is published and administered by the World Health Organisation. It is now in its tenth revision (ICD 10). This schema has its origins in the work of William Farr, the first medical statistician for the General Register Office of England and Wales, in the mid-nineteenth century. He saw the need for a classification system for diseases to enable mortality statistics to be collected on an ongoing basis. Initially the schema was designed to record causes of death, but was subsequently developed to list diseases and disorders causing considerable morbidity. Nevertheless, the classification continued to be used for the pragmatic purpose of collecting epidemiological data, and it is still used by WHO for making international comparisons of health statistics. The schema is therefore a practical classification, rather than a theoretical one, and it may require adjustments to allow finer levels of detail to be expressed in certain applications. ICD 10 coding is often used as the coding system for diseases and diagnoses assigned to patients in electronic medical records, and would be the point of reference for EP decision support tools giving contraindication/precaution checking or drug–disease interaction checking, based on patient record information. ICD 10 codes are of particular concern in EP applications where there is a clear requirement for production of reports or statistical returns. An example of this would be oncology systems for the management of oncology and haematology clinics, where there is a major political need to report epidemiological data. In the UK, this is facilitated by the agreed National Cancer Data Set, which was established to eliminate reporting inconsistencies between different UK Cancer Registries.[2]

Diagnosis related groups (DRGs) were developed in the US by the Healthcare Finance Administration as a means of assigning a cost of treatment to a patient's diagnosis. They were developed to enable calculation of Medicaid reimbursement costs. DRGs are based upon ICD Clinical Modification (ICD-CM) codes in ICD 9 or ICD 10. Appropriate ICD codes are refined by placing them in diagnostic categories and then grouping them into subgroups that reflect consumption of resources, criteria for treatment and potential complications. Thus patients are assigned a DRG from a relatively small number of DRG codes. DRGs are used routinely in the US and have been adapted in other countries where a reimbursement algorithm has been required. They are designed for hospital inpatients and do not provide a suitable means of assessing the costs of chronic disease care. Availability of a DRG designation for a patient, together with actual medicine cost data from an EP system may permit a variance analysis of projected costs and actual costs of inpatient treatment within the US context.

Read Codes (subsequently called Clinical Terms) were developed in the UK to enable clinicians (mainly in general practice) to code events in the electronic patient record, and thus enable statistical auditing of the patient care process in primary care. Read Codes have latterly been owned and administered by the UK government. Read Codes have changed considerably both in their terminology and in their structure during their lifespan. Version 1 of the Read Codes was a strictly hierarchical schema. In version 2, the structure was changed so that they more closely approximated ICD 9 disease codes and OCPS 4 procedure codes. Version 3 of the Read Codes was, in contrast with version1, a compositional schema, where each term could be augmented by qualifier terms.

Read codes have been used extensively to code for diagnosis, problems and medicine prescribing in GP systems in the UK. However, they have not been used routinely in secondary care applications, largely because they were developed for primary care use. A key issue in the use of Read Codes has been the increasing potential for lack of concept control with combination terms, in the latter versions. However, many primary care (GP) systems map prescribed medicines to their respective Read Codes, and Read Codes may therefore have a role in facilitating communication between primary care and secondary care systems in the UK.

The Systematised Nomenclature of Medicine (SNOMED) is administered by the College of American Pathologists, and was derived from classifications of tumour and pathology nomenclature used by the College. SNOMED is designed to be a comprehensive, computer processable terminology to support all medical concepts. SNOMED is in use in over 40 countries. Principally, it is a hierarchical, multiple axis schema, but it also allows composition of complex terms from simple terms, so is partly compositional, and it has the facility of cross-referencing between terms in the schema. SNOMED International (SNOMED III) incorporates almost all ICD 9 terms, so reports can be generated in ICD 9 format.

In 1999, the College of American Pathologists and the UK National Health Service announced their plan to converge SNOMED and Clinical Terms (Read Codes) version 3 into a single terminology. The stated intention was to avoid duplication of effort and to create a universal, international terminology to support electronic patient records. The first version of the combined terminology – SNOMED Clinical Terms – was released in 2002, and it has been adopted as the standard terminology for UK Connecting for Health healthcare applications.[3] Third-party drug data suppliers are working to map their datasets to international terminologies such as SNOMED-CT, in order to provide intraoperability with other systems in the area of more advanced decision support, for example contraindications, dose/indication checking and drug–disease interactions.

An important area of data standardisation is the development of HL7 (Health Level 7), which is an XML-based terminology,[4] designed for the purpose of modelling healthcare processes, and producing a common terminology for all concepts in health care, to provide an industry standard for intraoperability across all healthcare applications. Many healthcare IT systems are marketed as "HL7 compliant". However, development of the message formats to enable extensive and comprehensive description of healthcare processes is an ongoing and gradual

process. This is because (a) HL7 message formats are being designed to model all healthcare scenarios, not just those involving pharmacy and therapeutics, (b) there is a need for consistency in the consensus-forming process and (c) major semantic assumptions need to be made and understood by the international HL7 community, at each stage of the HL7 design process in different domains. Recently, there have been initiatives to make closer links between SNOMED-CT concepts and HL7 message formats, in order to achieve greater semantic intraoperability in healthcare applications.[5] Specifically in the area of pharmaceuticals, the Dictionary of Medicines and Devices (dm+d) has been developed to describe concepts associated with the use of specific medicines and devices for the diagnosis and treatment of patients.[6] The dm+d is integrated with SNOMED Clinical Terms and would enable applications dealing with medicines – such as hospital EP systems, and hospital and community pharmacy systems – to exchange information with a common terminology. The dm+d is the medicines terminology for the UK Connecting for Health programme, and will enable intraoperability of systems in the UK NHS IT initiative. The first part of the dm+d work was the Primary Care Drug Dictionary, which was launched by the UK Prescription Pricing Authority in 2003. The first version of the full dm+d, for medicines used in primary care and secondary care, together with some prescribable devices, was released in 2004.

In order to support all aspects of the prescribing, supply and administration of medicines, the dm+d is structured into a number of related concepts as shown in Fig. 5.2.

The dm+d data structure enables EP systems to differentiate at the data level between the concepts of medicine prescribing, administration and supply, which is important to provide rich functionality at each stage in the medicines management process. It will enable users to identify prescribed medicines of the EP system clearly and unambiguously, which will impact on the risk management aspects of
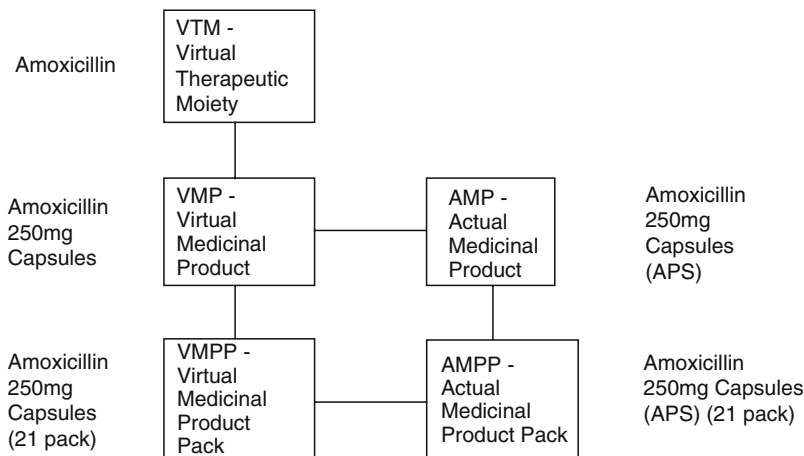
Fig. 5.2 dm+d structure

EP system use. dm+d will also provide a common platform for analysis of prescribing data in both primary and secondary care in the UK, something that cannot be done at present. This will have important implications for commissioning and care management.

The Development of Medicines Information Reference Sources

Prior to a discussion of drug data sources for EP systems, it would be beneficial for the non-clinical reader to be aware of the types of medicines information that a prescriber might need to know, and the established reference sources that are available for prescribers and clinical professionals.

Historically, sources of drug information have consisted of:

(a) Medical and pharmaceutical primary literature from hardcopy journal publications
(b) Secondary literature, such as recognised pharmaceutical compendia and reference books

The primary literature consists of clinical trial reports, reviews of specific therapeutic issues, case studies and anecdotal reports. The secondary literature consists of drug information compiled from primary sources. This might include recognised reference books, addressing specific clinical issues, such as Stockley's "Drug Interactions", or Briggs' "Drugs In Pregnancy". The secondary literature also comprises of recognised pharmaceutical compendia. A compendium is a book, with a section or monograph, on each listed medicinal product or drug substance. Some of the compendia provide standards for manufacturing and quality control purposes (for example, the British Pharmacopeia and the European Pharmacopeia) and are of little value for prescribers and clinical professionals. Others contain more evaluated clinical information (for example, the Martindale Extra Pharmacopeia) or provide treatment guidelines for rapid reference (for example, the British National Formulary (BNF) or the Monthly Index of Medical Specialities (MIMS)).

Since hardware technology has allowed substantial indexed databases to be compiled, stored and retrieved electronically, medical publishers and medical information providers have sought to provide their information sources to end-users in an electronic format. Initially, these electronic products were abstract database services such as the US National Library of Health Medline database, or the Exerpta Medica EMBASE, provided by hosted data services accessed by modem connection – for example, DataStar and Dialog – which enabled remote users to search proprietary databases and information sources. Recently, with the development of the Internet, many of these database services have become available via Web browsers, which have made access far more straightforward and has simplified searching techniques, enabling a higher degree of end-user access.

Also, with the introduction of optical disk technology over the last 20 years, many of the biomedical databases have been "packaged" and sold as CD-ROM products for single and multiuser use, to enable fast and secure local searching. Many of the pharmaceutical compendia – for example, the British National Formulary or the Martindale Extra Pharmacopeia – are also now available in electronic format, on CD-ROM for single-user or network access.

It should be noted that there are many different databases of medicine-related information that are produced by commercial vendors, professional societies and public bodies, in different countries. Examples of some of these are tabulated in Table 5.1.

In addition to information about medicines produced and compiled by healthcare professional bodies, health providers and the publishing industry, a prime source of information on medicines is from the manufacturers of those medicines. A number of key documents on licensed medicines are produced by the pharmaceutical industry and regulatory agencies in Europe. These include:

1. *The Summary of Product Characteristics (SmPC)*. This is the definitive document on a marketed medicine for use by healthcare professionals. It provides a full listing of available data on a medicine in medical terminology.
2. *The Patient Information Leaflet (PIL)*. This is the approved information on a medicine that is available to a patient. The PIL is usually written in plain English, with non-technical language. The PIL is included in each medicine pack and, in countries where original pack dispensing is not universal, such as the UK, there is a legal and ethical requirement for the pharmacist to include a copy of the PIL in the dispensed pack.
3. *The European Public Assessment Document (EPAD)*. This is the document produced by a pharmaceutical company, under the auspices of the European regulatory system, giving a summary of the information supporting the product license application for a medicine.

It is often thought that information provided by the pharmaceutical industry is inferior to that available from independently published sources. However, the required content of the standard medicines documents, the SmPC and the PIL, is now highly

Table 5.1 Examples of electronic medicines information reference sources (abstracting services)

Database	Geographical emphasis	Specialty
MedLine	US/UK	Medical research and clinical medicine
EMBASE (Excerpta Medica)	Europe	Clinical medicine
TOXBASE	UK	Drug toxicity and side effects
TICTAC	UK	Medicines identification database
IDIS (Iowa Drug Information Service)	US	Clinical medicine and medicines information
PharmLine	UK	Clinical use of drugs/pharmacy practice research

controlled and regulated, and therefore these documents form a reliable source of definitive information on a medicine. Furthermore, since the introduction of the structured SmPC format some years ago, much of the information available to health professionals from the pharmaceutical industry in the UK and Europe is presented in a structured way, which could be incorporated into electronic systems. The SmPCs and PILs for UK authorisations are available online in the Electronic Medicines Compendium (EMC).

There is therefore a wealth of information available in various electronic formats concerning the pharmacology and clinical use of medicines. For example, compendial information, such as the British National Formulary (BNF) or the Physicians' Desk Reference (PDR), is available in Internet or CD-ROM form, and therefore links could be made to these reference sources (mounted either on a local network or on the Internet) from an EP system. Indeed, many EP systems have implemented controls to link passively to standard electronic medicines reference sources, in order that these reference sources may be used as passive decision support tools, although there may be issues concerning licensing in a multi-user situation, or with performance if the reference source is mounted on a remote server. Links to the BNF and local clinical guidelines in this manner are a requirement of the UK Connecting for Health baseline specification for electronic prescribing.[7]

Moreover, medicines information reference sources encoded as XML are particularly suitable for access by EP systems. For example, there is an initiative in the UK to produce PILs in XML format (X-PILs) to enable PILs to be easily adapted to different formats, to enable access by people who are blind or partially sighted.[8]

Sources of Drug Databases, and Their Implementation Within EP Systems

However, aside from the licensing and permissions issues involved, many of the available drug data sources that are electronic versions of paper-based references are not used as direct sources of the active drug data that are used in the prescribing workflow of an EP system.

Although electronic versions of hard-copy medicines reference sources constitute high quality sources of medicines data, they are not suitable for use within EP applications for a number of reasons. Firstly, they are compiled for referential purposes, not to support automatic retrieval. This is to say that they are designed for use by a human evaluator and do not have the detailed linkages to support information retrieval by an EP system. Secondly, the data are not structured or defined in an appropriately granular manner for use in an electronic system to support complex prescribing. Thirdly, the data are often not linked with appropriate coding systems to allow intraoperability with other systems and to support a variety of advanced functions.

For these reasons, many EP systems use drug databases that are structured to support the functions of the system. The standard data items – drug name, form,

strength, synonyms, possible routes, units of prescribing, administration and supply, etc. – are all incorporated into data tables within a standard database platform, such as Microsoft® SQL Server. The database tables are structured so as to provide appropriate granularity to permit a range of detailed functionalities (for example, complex prescribing and medicines administration) and are linked in such a way as to provide consistent retrieval of information on medicines and prescribing concepts by the EP system, together with the possibility of incorporating mappings to other drug coding systems (e.g. SNOMED CT, dm+d, Read 2).

The actual drug data used for an EP implementation may be compiled in one of three ways:

(a) The drug database is built for the implementation, by personnel at the hospital site implementing the system. This approach has been taken with certain order communications systems that have been adapted for the application of prescribing. However, the build process is time consuming and laborious and it is highly unlikely that the dataset will have the internal consistency of a commercially produced system. Furthermore, the implementing site has the burden of maintaining the system to reflect new products, changes in dose, etc. It may be possible to take this approach with an EP or medicines management system with a limited scope of operation, or to support a pilot or prototype study, but it is not feasible for a whole-hospital EP system.

(b) The drug database is adapted from a software vendor's reference database, or a database from another implementation. However, with system providers' in-house databases, there may not be a systematic validation process in place, and the quality of the maintenance process will depend on the expertise and management structures in place within the software provider's organisation. Often, with databases built by software houses, where developers may be working both on the software code and the data tables, there may be the temptation to provide some data-related functionality via hard-coded software changes, and thus the boundary between the data and the software can become indistinct. Furthermore, if a database from one EP implementation is used to support a new implementation, it may introduce data that are inappropriate to a different healthcare setting, and errors in the database are perpetuated. Furthermore, if the database has been compiled by a healthcare provider, there may be legal issues surrounding the ownership of the data.

(c) The drug database is structured around, and the data imported from, a third party data supplier dataset. The use of a third party dataset has the advantage that it is more likely to be of a higher quality than a database built by a software vendor or healthcare provider. Third party drug data providers are commercial organisations whose business is to produce databases to support EP systems and other medicines management software, and will have considerable expertise – both clinical and information science – available to them. The dataset of a third party data supplier should be consistent and accurate, with established business processes in place for the compilation and validation of their data. Furthermore, some of these organisations will have external validation, according to quality standards

such as ISO 9001. The use of a third party dataset removes the responsibility of maintenance from the EP system vendor or the healthcare provider (although some data configuration by the software vendor may be required). Also, with a third party data supplier, the legal responsibility for the internal quality of the drug data lies with the data supplier. The major disadvantage with using a third party dataset is the cost of using the data. Typically, a third party data supplier will charge a software vendor for the basic cost of supplying the data, together with an additional charge based on the number and size of sites where the system using the data is in use. These costs are factored into the total contract between the software vendor and healthcare provider, but it still increases the total cost of the implementation. Furthermore, the process of implementing a third-party dataset into a system that has not previously been supported by one will constitute a major technical task, which may deter some EP system providers and their users from migrating to a third party data supplier.

Currently, the most prominent of third party data providers for the provision of drug data to EP and medicine management system suppliers are First Databank, Inc. and First Databank Europe Ltd, owned by the Hearst Corporation, and Multum, part of the Cerner Corporation. Other sources of drug data include the MicroMedex product range (Thomson, Inc.), although these products are designed more for use with stand-alone hand-held devices.

In the US, some authors have in the past questioned the quality of data from third party data suppliers.[9] However, as commercial organisations whose principal business is supplying medicines data, third party data suppliers review their quality maintenance systems on a continual basis, and are often looking to introduce more advanced functionality. It should be noted too that, in the US, the major centres of excellence for EP systems have the resources and in-house expertise to produce institutional drug databases.[9] However, other smaller healthcare providers do not have the means to produce their own drug reference files and it could be argued that more widespread adoption of EP systems in the US cannot take place without the adoption of third party data sources. Indeed, many of the hospitals in the UK with operational EP systems use data from First Databank Europe Ltd (Exeter).[10,11,12] Indeed, adoption of a third-party decision support data provider has been listed as a requirement in the UK Connecting for Health e-prescribing specification.[13]

Requirements of Drug Databases for Supporting EP Systems

The electronic drug dataset forms a key data component of an EP system – this will provide all of the data relating to medicines. In addition to this, other coding and classification systems will be required to support other data elements within an EP system – for example, information relating to indications, contraindications, diagnosis, side effects and monitoring.

However, with EP drug data concepts, there are various potential issues that software designers and implementers should be aware of. Depending on how the

EP system database is structured, these issues have the potential to introduce anomalies in the operational use of an EP system. This section reviews some of these issues.

Medicine Nomenclature

Each chemical entity that is used as a medicine ingredient will have an approved name. In the past, all medicines in the UK were routinely named according to their British Approved Name (BAN). However, in 2005, drug nomenclature in the UK was changed to the revised International Nomenclature (rINN).[14] This change required third party data suppliers and owners of proprietary databases and medicines information products to change all drug ingredient names from BANs to rINNs on their databases. Common examples of BANs and their corresponding rINNs are shown in Table 5.2.

This change has brought UK medicine nomenclature more into line with that of Europe and the United States. However, the old nomenclature (BANs) still exists in historical records, and there is an argument for retaining the BAN as a synonym (see below) in the database to enable retrieval of historic records. This consideration would also apply to any future, specific or general changes of nomenclature.

Designers also need to consider the relationship between a generic name of a product and the ingredients in the product. Many medicinal products consist of two or more medicine ingredients and, in the UK, many established and most commonly used combination products have an approved combination name. For example, tablets containing a combination of paracetamol 500 mg and codeine 8 mg are called Co-codamol 8/500 tablets. However, many combinations do not have an approved combination name. For example, the antacid combination of sodium alginate 500 mg and potassium bicarbonate 100 mg per 5 ml has the brand name, Gaviscon Advance®. In addition, many ingredients of combination products are not available as single entity products; with the above example, sodium alginate is not available in preparations without an acid neutraliser, such as sodium or potassium bicarbonate. There is therefore a need to differentiate the concepts of ingredient and approved name, and to provide the necessary mapping between ingredients and approved name, for each medicinal product. This is important not only for ensuring that medicine descriptors are accurate, but also to ensure that the correct decision support warnings for sensitivities, duplicate therapy and drug interactions are flagged for each product.

Table 5.2 Some examples of British Approved Names (BANs) and their corresponding International Names (rINNs)

Drug type	BAN	rINN
Antibiotic	Amoxycillin	Amoxicillin
Diuretic	Frusemide	Furosemide
Antihistamine	Chlorpheniramine	Chlorphenamine
Anticholinergic (centrally acting)	Benzhexol	Trihexyphenidyl

Synonyms

In drug database terms, a synonym is an alternative name. Regardless of alternative nomenclatures, as discussed above, some drug entities have alternative names that are not branded product names. For example, gonadorelin is also known as gonadotrophin-releasing hormone, GnRH or LH-RH. Given the dm+d hierarchy, it is recognised that brand names of drug entities cannot be regarded as synonyms, since the approved name is a VMP concept, whereas the brand name is an AMP concept. Appropriate synonyms would need to be mapped to each approved name in the database. The use of abbreviations (for example, ISMO for isosorbide mononitrate) is not considered best practice and these should not be listed as synonyms.

Product Mapping

In the UK, general medical practitioners use systems that enable them to prescribe a product by name at the AMP concept level. Thus the prescription generated states "Amoxicillin 250 mg/5 ml SF Liquid – 100 ml – One 5 ml spoonful three times a day". It is clear to the pharmacist exactly what product needs to be supplied against the prescription and, indeed, with the UK system, this is necessary so that the pharmacist can claim the appropriate reimbursement for dispensing the product.

However, hospital doctors usually prescribe at the VTM concept level. A hospital prescriber would write "Amoxicillin 250 mg po (by mouth) three times a day", and would not specify the actual product in many cases. Hospital EP systems therefore face the challenge of translating the prescriber's VTM prescription to an AMP dispensed item. This process is achieved through two mechanisms within an EP system:

(a) By the mapping of VTM, VMP and AMP terms within the EP system database.
(b) By structuring the prescribing workflow of the EP system so that it forces the prescriber to be as specific as possible with the details of the order. This has to be balanced against the number of steps in the workflow that the prescriber has to complete.

Pharmaceutical Forms

In primary care, a relatively small number of pharmaceutical forms are used – for the most part, these are: tablets, capsules, inhalers, oral liquids, creams, ointments and lotions. Secondary care prescribing, however, includes a wider range of forms – for example, implant, bone cement, or impregnated stent. It is important that all possible pharmaceutical forms are included in an EP system database, using standard

nomenclature. However, care must be taken that route of administration concepts are not combined with form concepts within the data – for example, "subcutaneous injection". Also, proprietary terms for certain pharmaceutical forms – for example, "Spansule®", should be avoided, in favour of a generic concept (in this example, "inhalation capsule"). Consideration should also be given to how two different forms of the same medicine, supplied in the same pack would be expressed by the system – for example, Canesten Combi®, an antifungal product that contains a clotrimazole pessary and a clotrimazole cream.

Routes of Administration

As with pharmaceutical form, a much wider variety of routes of administration are used in secondary care, than in primary care, and it is important that all the routes of administration that are likely to be used are reflected in the database. The EP system must be able to support the following route-related issues:

(a) The system must be able to express the same product being given by different routes, either concurrently or sequentially.
(b) The system must be able to express alternative routes – for example: metoclopramide 10 mg injection – to be given intramuscularly *or* subcutaneously.

Dose Information Management

Consideration should be given to the way in which doses are expressed within EP systems. While the standard SI unit for a drug dose is milligrams, and the abbreviation "mg" is used, the recommendation is that drug doses are expressed as mg as far as possible and that, where other SI units are used, they are not abbreviated. Examples of this would be (a) Digoxin 125 microgram tablets and (b) Alfacalcidol 250 nanogram capsules.

EP systems need to differentiate between dose units, administration units and supply units. In order to operate a medicines administration module, an EP system needs to map the dose expression to the administration expression. Thus, for Flucloxacillin 500 mg capsules, a dose of "1 g three times a day" would translate to an administration instruction of "two capsules three times a day". The supply units are important if there is a direct feed to a pharmacy system and supplies are being made automatically. Unit doses such as tablets and capsules can also be supplied in the quantities that they are administered in, and this will enable electronic unit dose dispensing in countries where it is the norm. However, for many products, the supply unit cannot be directly equated to the dose and administration unit. For example, in order to fill a prescription for "Salbutamol 100 microgram Inhaler – two puffs to be inhaled four times a day", the smallest unit that can be supplied is a 200 dose inhaler. Also, antibiotic liquids would be supplied in quantities of 100 ml,

because they have to be reconstituted and, because of their shelf life, it is not practical to use them for another patient, in the same way as some other liquids. In any case, many topical products, such as creams and ointments, consist of a definite supply quantity (100 g tube), but with indeterminate dose and administration quantities (one application), so that the number of dose/administration aliquots making up the supply quantity cannot be calculated.

Admixtures

In addition to medicines that are fixed dose combination products throughout their product life, consideration should be given to those products that are essentially mixtures, originating from two separate products. In some cases, where the two individual products are mixed together at the point of medicines administration (for example, an intravenous admixture, such as the commonly used mixture of the antibiotics, cefuroxime and metronidazole), it is probably best for the two products to remain listed as separate entities at the database level, and for the EP system to have functionality to combine more than one medicine on the same order, so that the prescriber can specify the mixture, as opposed to the individual products, at the point of prescribing. In other cases, where the product is supplied as a mixture of two active agents (for example, extemporaneous products such as Coal Tar in Betnovate® 0.1% Ointment) it is better to list the mixture as a product in its own right on the database. This is especially the case if one of the ingredients is not routinely administered therapeutically to the patient as a separate product (Coal Tar Solution BP in the above extemporaneous example).

Some admixtures will have two or more variable ingredients. An example of this would be Total Parenteral Nutrition (TPN) – intravenous feeding solutions. These will have a nitrogen/protein component, a carbohydrate/energy component and a number of vitamins and minerals as trace elements, and the constituents would vary according to the patient's clinical and nutritional requirements. Sometimes a finite number of fixed regimens will be used – especially if a hospital routinely buys in TPN regimens from commercial providers, and in this case, the specific fixed combination regimens could be listed as single entities on the database. However, if there is continuous variability with TPN requirements, it would be appropriate to have the fluid and trace element formulations listed separately in the database, and to have TPN compounding functionality within the EP software for the pharmacy user to formulate custom regimens. However, TPN functionality represents an advanced functional area in EP systems.

Non-indexed Products

While there are a wide variety of medicines, pharmaceutical forms and routes of administration used in hospital prescribing that are not used in community prescribing, there are also a large number of products usually prescribed and supplied by

pharmacies in primary care, that might not be prescribed and supplied by pharmacies, in the usual way in hospitals. These would include items such as non-medicated dressings, colostomy products and dietary products. In some healthcare contexts, it may be appropriate for these non-acute products to be included on a hospital EP system for accounting purposes. Nevertheless, in other situations, they may be considered out of scope of the hospital EP system.

However, all of these products would be included in an update from a third party data supplier. There is therefore a need to designate a proportion of a data update as "non-indexed". This may be done either by (a) assigning non-indexed products to some sort of dump file, away from the main database structure or (b) by leaving them in the main data structure, but rendering them invisible to the end user. The former method may lead to retrieval problems if a non-indexed product needs to be retrieved from the dump file and placed within the active database. The latter method provides a consistent data structure but, depending on other factors, the performance of the drug database may be affected by large numbers of invisible records.

Third party datasets resolve many of the structure and consistency issues described here, according to their established rules, and through mapping to the various terminologies that are in use. For example, First Databank Europe's MDDF Product Set groups the relevant products (AMP concept) for each generic (VMP concept) term, within its dataset. So, for "Atenolol 50 mg tablets", the Product Set would include all of the Atenolol 50 mg tablet presentations from different manufacturers.

Many of the terminology-related issues here are subject to ongoing standardisation initiatives at European and international level – for example, ISO TC 215. Nevertheless, these standardisation initiatives often involve a considerable number of stakeholders, and a balloting process, and so they are necessarily slow, and not optimally responsive to new developments or drastic changes in professional practice. Furthermore, the process of standard development is often dominated by system vendors, who have a vested interest to ensure that the standard is closest to the functionality provided by their own system. Standards are often, therefore, compromises and may embody ambiguities which will find their way into EP systems datasets.[15]

Data for Decision Support Tools

In addition to the drug database, third party data suppliers will often provide data and messaging for clinical decision support (DS) functions. Typically, these will include sensitivities, drug interactions, drug–disease interactions, duplicate therapy warnings and precautions. When a medicine is prescribed for a patient, the EP system will query the other patient- and medicine-related data, and return any clinical warnings about the prescribing of that medicine, in relation to other medicines prescribed and other patient factors.

Take, for example, a system for sensitivity or allergy checking. Using an EP system, a patient is prescribed the antibiotic, amoxicillin, for a chest infection. However, it has been recorded in the patient's electronic record that they are allergic

to penicillin, and amoxicillin belongs to the penicillin group of antibiotics. In order to perform an allergy check, the EP system needs to run a query, or use a query tool or decision support engine, which registers the allergy information in the patient data, and the drug name, which is associated with the drug data, and gives a warning message to the user, as a result of this match.

In order to support DS functions, the structuring of the DS ruleset and the indexing of drug and patient data should be done in such a way as to ensure consistent retrieval. Using the above example, if a patient is allergic to penicillin, then the system should also show an allergy warning if pivmecillinam is prescribed, even though it is slightly different in structure to other penicillin antibiotics. Again, using the above example, the system should consistently recognise known cross-sensitivities. Therefore, if a patient is allergic to penicillin, then an appropriate warning should flag up if the patient is prescribed a cefalosporin antibiotic, for which there is a 10–20% probability of cross-reactivity with penicillins.

The accuracy and reliability of clinical alerts is a key consideration in the implementation of DS tools. In the past, various implementers have chosen not to introduce any DS functions in their EP system at all, rather than set up a DS system that does not have an adequate data platform or appropriate granularity in the data.[16] Another issue is that many DS tools on proprietary systems may display large numbers of warnings that may be of questionable clinical significance. A common example of this is the display of reciprocal warnings with drug interactions (the user is warned that there is an interaction between aspirin and warfarin, and also between warfarin and aspirin). The risk issues associated with warning fatigue are discussed at length in Chapter 4. However, the display of excessive warnings may be an indicator that the indexing methodology is not sufficiently refined, and improving the indexing methodology may well rationalise the querying process, and thus improve the performance of the system.

While accuracy of clinical warnings and appropriate inclusion of warnings in the prescribing workflow is a key consideration for risk management and implementation of best practice within the organisation, research has shown that the end user is primarily concerned with speed of response, i.e. the performance of the system.[17] Implementers need to consider how DS data is structured within an EP system database and transmission of queries between different parts of the system, as these factors affect the speed of operation.

Some implementers have attempted to build basic decision support functions from first principles within EP applications, in particular those applications that are designed for general order communications, rather than medicine prescribing and administration specifically. This approach, however, is very laborious, in the same way as building a custom drug database. Furthermore, the resulting DS system is unlikely to be comprehensive or fully consistent in its operation. On the other hand, implementation of a third-party DS system into an EP system may be a difficult task from a technical perspective. For this reason, some third party drug data suppliers provide the DS ruleset as a "toolkit" which serves as a "black box" so that developers do not have to produce complex querying routines to support the DS functions. All they need to do is route the queries into the toolkit, and a DS warning response will emerge from the toolkit for display at the front end.

Legal Issues with EP Data

It is an important principle in systems analysis that the function of the software and the accuracy and integrity of the data handled by the software cannot be considered in isolation. This is certainly the case with clinical systems, which seek to facilitate the patient care process by automation, because the correct outcome is dependent on both the software and the data, and errors made by the system could cause harm to the patient. With an EP system, it is of no value to have a well-constructed work-flow for the prescribing and administration of medicines, if the drug data used to formulate the prescriptions generated are full of errors and inconsistencies.

As mentioned previously, there are essentially two approaches to setting up a drug database to support an EP/medicines management application – to build a database specifically for the application or to implement a third party drug database. There are legal implications, however, with both of these approaches. If a drug database is built for a specific application by a software vendor, then the software supplier is the legal owner of the data and they structure, implement and deploy the data as they wish. However, there is a requirement for the software vendor to maintain that database, and ensure that it is fit for purpose on an ongoing basis. The software supplier is legally liable for any clinical errors arising from use of the software when the data are inadequate. For this reason, the supplier should have robust procedures for the maintenance of the clinical data and should have clinically qualified personnel involved in the processing of the data. Some software vendors use a reference dataset that has been built by one particular healthcare provider, as the basis for further implementations. As mentioned previously, this can cause problems due to perpetuation of errors, and use of a dataset designed for one organisation within another organisation. From a legal perspective, the originating healthcare provider is the legal owner of the dataset, even if the software vendor is subcontracted to maintain the site databases, which could lead to difficulties in the event of a dispute between the healthcare provider and the software vendor.

Third party data providers bear legal responsibility for drug data that they provide, as long as the data are implemented within client systems according to their recommended specifications.

Conclusion

Availability of high quality data – relating to the patient, the medicines and the prescribing process – is essential for the correct operation of EP software. A variety of formal coding and classification schemes exist to manage the data that may be required in EP systems. There are numerous sources of medicines information data, but only some of these are available electronically and structured in a suitable way to support EP applications. Furthermore, issues arise with the way such data are implemented within an EP system. Many systems use a drug data source from a

third party data supplier to resolve some of these issues. A major issue in data support for EP systems is the development of common data standards and conventions, as this is the key to interoperability of these systems.

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Chapter 6
Electronic Medicines Management: Support for Professional Practice

The changing role of the various professions in the NHS provides implementers of EP systems with the challenge of how professional roles are recognised and regulated within an EP system. This will be discussed further in Chapter 7, concerning the use of EP systems by non-medical prescribers. However, if systems are to be accepted by users, designers and implementers will also need to consider how EP systems will support, or can be configured to support, the needs of healthcare professionals in their everyday practice.

Modernisation of Healthcare Working Practices

As mentioned in Chapter 1, EP systems have the potential to revolutionise the working lives of healthcare professionals by facilitating changes in working practices. Because EP systems enable routine processing and dissemination of prescription information in an automated way then, depending on software design and hardware availability, systems can be used to support new and different ways of working.

Of the healthcare professionals that are principal stakeholders in the implementation of electronic prescribing, medical and nursing staff have traditionally had the most contact with patients in hospitals. On the contrary, pharmacists have in the past been departmentally-based, at a distance from patients, since historically, their role has revolved around the dispensing and supply of medicines.

However, over the last 30 years, there has been a paradigm shift in hospital pharmacy practice. This has been especially the case in the UK, but the same trend has been present in other countries. There has been a decline in the importance of the manufacturing and formulation aspects of the hospital pharmacist's role, and a corresponding increase in the significance of the pharmacist as an advisor in medicine use, working closely with patients and staff at ward level, to ensure the safe and effective use of medicines.

This paradigm shift in pharmacy practice has been stimulated by a number of factors:

(a) The increasing complexity (and cost) of new therapeutic advances, and the range of therapeutic interventions available, necessitating an increased reliance on clinical evidence in therapeutic practice. These changes in clinical pharmacology have been supported by the growth of the medicines (drug) information services over the last 30 years, and the adoption of electronic medicines reference sources by these services.

(b) The increasing expectations of patients concerning information about the benefits and risks of their treatment, together with the availability of information on medicines from other sources (e.g. the Internet). These changes have increased the significance of the pharmacist as an expert on medicines, providing high-quality medicines information. Moreover, patient expectations have been positively encouraged by the UK Labour government with its emphasis on consumer choice and effective healthcare driven by the "empowered patient".

(c) The loss of so-called Crown Immunity in UK NHS hospitals in the early 1990s. From this time onwards, hospitals were no longer exempt from the Medicines Act 1968 legislation governing the manufacturing activities of the pharmaceutical industry and so, instead of controlling their own manufacturing activities, hospital pharmacy based manufacturing units were required to obtain a manufacturer's license and be subject to regulatory inspections in exactly the same way as the pharmaceutical industry. This has curtailed manufacturing activities in UK hospitals.

The emphasis on near-patient clinical activities has increased in recent years for US hospital pharmacists too, and many forms of innovative clinical pharmacy activity are documented in the American hospital pharmacy literature.

The nursing profession also has undergone a paradigm shift, from being traditionally a labour-intensive vocational occupation, subservient to medicine, to being a degree-educated profession, with an increasing amount of clinical autonomy, and political significance. In many countries, nurses have recognised clinical specialties, manage specific clinic services, are active in health promotion and health education and have prescribing responsibilities (the specific implications of which will be discussed further in Chapter 7). With these new roles, nurses have gained a new political significance in many health economies, not least in the UK NHS, where the nursing professional bodies have been at the forefront of promoting new roles and responsibilities for nurses, and the nursing profession has had an increasing impact on the provision of routine healthcare and health screening, and provision of health education to the public.

Hospital doctors have faced a number of challenges in recent years, which have had profound implications for their professional practice. Firstly, the armamentarium of diagnostic and therapeutic techniques available to a clinician in his specialty is steadily expanding, both in terms of cost and technological complexity. There is therefore a need for physicians to keep up to date with new technologies and new procedures. Secondly, while there is an increasing number of effective medical interventions, in many countries, in particular the UK and Australia, there is a shortage of doctors. This is exacerbated by the political pressures to reduce the

contracted working hours of doctors, for reasons of patient safety, and changes to medical career planning. As a result of this, there is increasing willingness within health provider organisations to delegate routine tasks that have traditionally been performed by junior doctors, to other healthcare professionals. While there is good rationale for this, in terms of appropriate use of "skill mix", some physicians feel that patient care is compromised, and that their professional identity is threatened. Moreover, some studies have suggested that the continuing professional development needs of those health professionals engaged in providing new services have not been fully understood and addressed.[1]

EP Systems: Support for Professional Practice

It is clear that, in twenty-first century healthcare systems, health professionals are facing various professional and political challenges, and that professional roles are changing. Nevertheless, healthcare professionals are still committed to providing optimum patient care, according to best standards of practice, and in the light of an adequate evidence base. On this basis, there is a clear potential for electronic prescribing systems to support and enhance clinical practice, both in terms of optimising current practice, and supporting and developing new roles and services. A number of papers have discussed the capacity of EP systems to support and enhance professional practice, within the health professions.

Pharmacy-led evaluations of EP systems have recognised the potential of EP systems to support ward-based clinical pharmacy activities and interventions. Marriott et al.[2] undertook a study in the UK comparing the number and type of pharmacist interventions at Queens Hospital, Burton on Trent (BH), where a fully integrated patient data and prescribing management system has been implemented, as discussed previously,[3] and at Good Hope Hospital, Sutton Coldfield (GHH), where a traditional paper-based system was in place. Over a period of 2 months in 2003, a larger number of clinical interventions were made at BH – 2,512 interventions (equivalent to 0.2 interventions per finished consultant episode (FCE)) compared to 763 interventions (0.05 interventions per FCE) at GHH. Furthermore, the types of intervention were different between the two hospitals. Thirteen per cent of the pharmacist interventions at GHH, the paper-based hospital, were concerning drug interactions, use of non-formulary medicines, route changes and prescription legibility, but there were no interventions of this type at BH, the hospital with the EP system,. However, at BH, 26% of interventions were concerning medicines information and patient monitoring, whereas there were no interventions of this type at GHH.

Since the workload and case-mix of the two hospitals was similar, and the patient demographic profile similar, the authors concluded that the EP system facilitated more clinical pharmacy interventions. Considering also the different profile of interventions between the two hospitals, there may be three factors involved:

(a) The EP system, with its decision support tools, automates the prescribing proc-
     ess, and therefore eliminates errors associated with choice of drug, prescription
     legibility, etc.
(b) Because various types of intervention relating to the actual prescribing and sup-
     ply procedure are reduced, pharmacists have more working time available to
     devote to near-patient clinical activities – monitoring new treatments, assessing
     side effects and providing advice to other healthcare professionals – which will
     in turn give rise to other types of intervention.
(c) The EP system presents a larger amount of clinical data in a systematic manner
     and therefore facilitates the identification of hitherto unrecognised intervention
     issues by clinical pharmacists.

Traditionally, data on pharmacist interventions has been collected to justify the
existence of clinical pharmacy services. However, clinical pharmacy services are
now well established and there is a need to take the evidence-base a step further
to see how clinical pharmacy interventions actually affect clinical governance and
patient care. However, this requires a robust data-capture procedure, and paper-
based monitoring systems have usually been too laborious and haphazard to pro-
vide a validated and benchmarked dataset on pharmacist interventions. A project
has been conducted in five NHS Hospital Trusts in Wales, UK[4] where a personal
digital assistant (PDA) database has been used to report pharmacist interven-
tions. Pharmacists across the Trusts entered intervention data over a 2-week
pilot period, resulting in the collection of data on 1,531 interventions, from
38 hospital wards. The PDA clinical intervention system was a quick and
convenient way to collect intervention data. Furthermore, the dataset was use-
ful for identifying inconsistencies between different Trusts at the enterprise
level, and comparing the practice of pharmacists in different clinical special-
ties. An EP system would provide the potential for the clinical intervention
record, logging interventions by all professionals, to be held alongside, and
integrated with, the prescribing record. The introduction of tools to specifi-
cally support the work of clinical pharmacists is an important aspect of EP
system design; the UK Connecting for Health e-prescribing programme is
looking to design a pharmaceutical care record as part of the CfH e-prescribing
functionality.

American hospital pharmacists have long recognised the potential of electronic
prescribing and computerised decision support systems to support clinical prac-
tice in pharmacy. In her discussion on the potential for computerised physician
order entry (CPOE) to enhance pharmacy practice, Shane[5] indicated that, in
2002, a number of health providers in the US had already implemented central-
ised and decentralised automation to increase the efficiency of the prescribing
process and medicine supply process, and therefore enable pharmacists to con-
centrate more on pharmaceutical care. Indeed, since financial pressures faced by
health providers would focus managers' attentions on pharmacist headcount
once CPOE was implemented, there was a pressing need for the pharmacist's
role to be redefined.

Shane indicated that US health system pharmacists had traditionally focussed their attentions on medication management during acute disease – during a patient's hospital stay – and that lack of time and information had precluded any attempt to manage a patient's chronic disease medication requirements on a long-term basis. However, EP systems can now make chronic disease management possible, and this will have implications for the role of the pharmacist, and the pharmacist's required professional competencies, and therefore continuing professional development needs.

This requirement represents a particular economic burden in the US, where there are large and disparate ethnic groups of people with chronic diseases, many of whom are not receptive to health education messages, are poor and are reliant on State medical insurance (Medicaid/Medicare). Nevertheless, those with chronic diseases undoubtedly represent an equally significant challenge to the health economies of the UK, continental Europe, and Australia. EP systems have the potential to address issues relating to chronic care, and change the professional practice of healthcare professionals accordingly.

As discussed previously, the nursing profession has undergone significant changes. Nursing has historically been a vocational occupation, subservient to medicine. Increasingly, though, nurses take on a variety of enhanced professional roles, and have increasing clinical autonomy. In many countries, nurses have recognised clinical specialties, manage specific clinic services and have prescribing responsibilities (which will be discussed further in the following chapter). While it has been recognised that nurses are a key stakeholder in the implementation of an EP system,[6,7] and their attitudes to the introduction of an EP system can be influential in its acceptance, there is little documentation on the role of electronic systems in helping nurses develop their professional roles.

It is recognised, however, that EP systems can benefit nurses in their routine duties. The introduction of the closed-loop process electronic prescribing system at a London Hospital,[8] where medicines administration working practices were revised following the introduction of bar code patient identification and automated ward dispensing cabinets ("magic cupboards"), caused the medicine administration round time to be decreased from 50 to 40 min. There was a corresponding increase in nursing time spent on medication related issues outside of drug administration rounds, but this might reflect appropriate redeployment of skills as a result of automation. In a systematic review of the impact of electronic health records on time spent on documentation by nurses and physicians,[9] it was found that the use of bedside terminals and desktop PCs at the nurses' station reduced nurse documentation time by 24.5% and 23.5%, respectively, during the course of a shift. However, this decrease in nursing time was offset by a considerable increase in physician time per shift, when physicians used desktop PCs for CPOE.

The main area of interface for nursing staff with an EP system is the medicines administration functionality. It is important, therefore, that this part of the EP system is designed to be as user-friendly as possible for nursing staff doing their

drug administration round on a busy ward. A key element of this is that the medicines administration screen looks as much like a traditional drug chart as possible.[10] Another important element is that the medicines administration screen is designed in such a way that all of the drug administration instructions and annotations are clear, unambiguous and easy to read.

Nurse specialists will have involvement in activities such as clinic management, medicines review and clinical audit; all of these could be facilitated by specialist advanced functionality within EP systems. These are discussed in detail in later sections of this chapter. The role that EP systems can play to help support nurses in supplementary and independent prescribing roles is discussed fully in Chapter 7.

The potential impact of EP systems on physician practice has been extensively discussed in the literature. Many of the benefits of electronic systems to physicians concern the use of decision support systems to assist with the prescribing process, and the ability of CPOE systems to reduce medication errors within hospitals.[11,12] Both of these benefits should reduce the likelihood of a doctor facing litigation as a result of a medication error, and automate the routine processes of therapeutics, in order that clinicians can concentrate on the intuitive, human aspects of medicine. EP systems have also been shown to reduce financial costs and hospital stay time[13,14] which would be a benefit to clinicians with responsibility for budget management in their clinical area. However, as noted previously, it is likely that these organisational benefits are specific to the healthcare context in which they were elucidated.

Nevertheless, not all changes facilitated by EP systems are positive. Some studies point to the way in which CPOE increases physician prescribing time,[9,13] due to the design of the prescribing workflow. Also, it has been noted that decision support systems may not always be effective because they do not fit appropriately into the prescribing workflow, or do not flag up latent physician monitoring needs.[15]

Nevertheless, the electronic capture of the prescribing history by an EP system, together with the possibility of interfaces between the EP system and other systems and devices opens up a range of potential applications that might benefit medical practice. These might include automated data downloading for clinical audit and management reporting, remote clinics and the use of hand-held devices for domiciliary visits, clinical trial data collection and prescribing support.

It has been suggested that EP systems can change the dynamics of a patient's consultation with a prescriber (doctor or other healthcare professional).[16] Historically, the prescriber has "led" the consultation, imparting information to the patient, who has been in a passive role. With a comprehensive EP system, where the system can be used to retrieve medicines information, as well as prescribe the medicine, however, there is the potential for the prescriber and the patient to view the same screen. The prescriber can therefore talk the patient through the benefits and risks of the medicine to be prescribed, and the rationale for prescribing, using medicines information material retrieved from the EP system, or hospital intranet, while at the same time setting up the prescription for the patient. This is illustrated in Fig. 6.1.
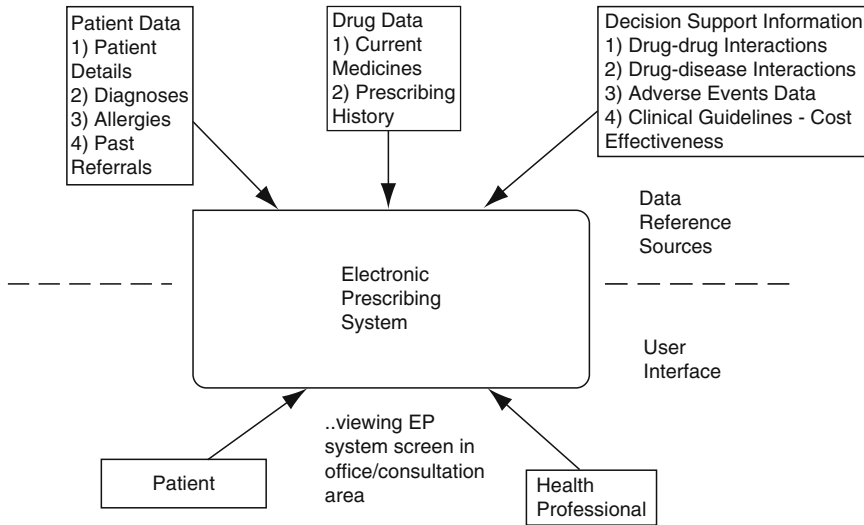
Fig. 6.1 Prescriber–patient dynamics with EP systems

The remainder of this chapter will discuss some of the specific ways in which electronic prescribing systems support clinical professional activities.

Audit Logs in EP Systems

The audit logs within an electronic system represent a major tool for data gathering to support professional practice, and manage operational issues within a healthcare provider organisation. Three published studies of UK EP implementations have highlighted the usefulness of the audit trail that an EP system can provide.[17,18,19]

The underlying audit functions of an EP application keep a log of all operations performed on the software, with a record of the operator, date and time of each operation. Thus, for any prescription, the user and time details are stored relating to initial creation of the prescription, subsequent amendments to the prescription, acknowledgement of clinical warnings, doses administered, and other significant points in the life of the prescription. Here, the term "audit" is used in a specific IT-related context, as opposed to clinical audit, a separate issue which will be discussed in detail in the next section.

Audit logs are a useful feature of an EP system as they may be used to:

(a) Investigate critical incidents relating to errors in prescribing and medicines administration, and to identify "near miss" situations, where a change of procedure would be beneficial

(b) Provide management information on the prescribing process and to resolve specific disputes concerning supply and administration of medicines
(c) Provide information on EP system user behaviour, which may be beneficial for future developments and enhancements of the system, as well as for guiding planners of user training and professional development

They may even be useful in providing evidence of malpractice; at the Wirral hospitals,[17] a nurse was arrested for unauthorised prescribing using a doctor's log-in details, because the doctor was not present at the hospital at the time the unauthorised prescribing took place, as evidenced by the system audit log.

A key consideration with audit trails in EP is that the database is designed with appropriate audit logging tables in it at the outset, in order to provide a sufficiently comprehensive dataset to support audit trails, and the extent to which the audit logging and reporting functions can be configured to each hospital site.

Other issues relate to user permissions. Firstly, a hospital implementing EP will need to determine how the database of users, their roles and access permissions can be maintained, given the fact that there is often an extensive and high-turnover pool of users (locums, bank staff, etc.), and that role-based access is an important deliverable for interoperable systems, which is a goal for implementers where there is a regional or national healthcare IT programme. Secondly, implementers will need to consider how user training and overall system design could address the standard problem of a user operating the system (deliberately or inadvertently) with another user's log-in.

Use of EP Systems for Clinical Audit

Over the last 20 years, medicine has become increasingly an evidence-based activity and now software applications are able to collect information on clinical activities within a hospital in an increasingly efficient manner. It is now relatively straightforward for a manager or clinician to obtain management reports of procedures undertaken or medicines administered in a hospital, with numbers and details of each event. These reports are used as the basis for clinical audit, whereby clinicians and managers review the information concerning a drug or procedure, to determine the activity level and cost of the intervention, and an estimation of whether the intervention is being done in accordance with local or national clinical guidelines, or accepted best practice for the profession concerned.

In many health environments, there are financial pressures limiting allocation of health resources, and practitioners are under pressure to justify their professional practice, in the eyes of patients and other stakeholders, and also to demonstrate that their interventions have an objective benefit to patient care. Thus, for many healthcare professionals, clinical audit is a useful tool and has profound political significance.

Traditionally, the data for clinical audits has been obtained by a variety of means. For analysis of hospitals admissions, a specific report would be generated

from the patient administration system (PAS), based on a search for the coded data entity for the diagnosis or admission type from the patient records. For a review of surgery performed within a hospital, an electronic health record would be queried on the basis of the OPCS procedure codes associated with each patient record. For some, very specific audits of clinical services, data have been collected manually using questionnaire or observational techniques.

Audits of medicine use generally seek to answer questions that managers and clinicians might have about cost-effective and appropriate use of medicines, across the whole population of patients who are admitted to hospital. Audits may be conducted to evaluate the following scenarios:

(a) For a relatively expensive medicine, for example, the 5HT3 antagonist antiemetic, ondansetron, an audit of drug use could address the following questions:

- How many dose units are being used, and of which formulation? (tablet or injection)
- Where the drug is being used, is it being used according to the manufacturer's recommended dosage schedule, or in line with any existing clinical guidelines within the hospital?

The results of such an audit may be used to establish a guideline for use of the drug in the hospital, if such a guideline is not already in existence.

(b) The extent to which patients commenced on intravenous antibiotics are transferred to equivalent oral antibiotics after 2 days of intravenous dosing. The transfer to oral antibiotics after a short i/v course is recommended in order to minimise treatment costs, to prevent the emergence of resistant pathogens and reduce the risks associated with intravenous therapy. A clinical audit of the route of antibiotic administration would monitor compliance to local clinical guidelines, identify exceptional cases and determine whether there are any consistent features of exceptional cases that could be remedied.

To conduct audits of medicines use, there have, in the past, been two basic approaches. Firstly, a standard starting point has been a product/formulation use report from the pharmacy system, as this would provide a reasonably accurate picture of medicines being issued from the pharmacy, and would be relatively easy to obtain from a pharmacy system. Such reports could be used as the basis of product use comparisons between different wards and specialties. However, the number of packs or dose units issued by the pharmacy, as evidenced by reports from the pharmacy computer system, does not necessarily correspond to actual administration of dose units to patients. Discrepancies may be caused by:

(a) The use of when required (prn) medicines, such as analgesics and antiemetics, where the consumption by the patient is variable and where there may be little correlation to the number of dose units issued by the pharmacy.

(b) The use of ward stock. A stock supply to a ward, issued by the pharmacy, might be used on a variety of patients, depending on the ward's pattern of admissions.

(c) The administration of a single dose of a medicine to a patient, as an emergency measure, where the medicine given was borrowed from another ward or department outside of pharmacy opening hours, and therefore would not be reflected in the pharmacy issues to that ward. This issue would also occur with the use of patient's own drugs (PODs) within the hospital, a practice that is common in the UK, as a means of reducing hospital expenditure on patient's long-term medicines that are unlikely to be changed during the course of an acute admission.

In order to surmount the problem of the relationship between doses issued by the pharmacy and doses actually administered to the patient, a second approach to clinical audit is therefore for ward-based staff to record the number of actual dose units of a medicine administered to a patient. This approach has the advantage that it would gather an accurate record of all medicine doses administered to a patient – be they when required (prn), single doses, or from stock packs. However, with the traditional system of using paper drug charts for recording administration of medicines, the record of all dose units administered would need to be transcribed manually to audit documentation. By this method, recording administration events for all patients on a ward just for one drug formulation would be a laborious process. Such a manual recording process is far too labor intensive to produce the variety of ad hoc reports of medicine use that may be needed in a routine operational environment.

In addition, there are specific problems arising from the manual transcription or rekeying of medicines administration data from paper drug charts:

(a) Due to the legibility of charts, it may not be clear what dose was administered and on what date.
(b) If details of administration are being recorded in the audit, the prescriber's administration instructions on the chart may be sufficiently ambiguous that it is not clear how exactly the medicine has been administered on each occasion.
(c) If a prescriber has specified multiple routes for a medicine (e.g. metoclopramide 10 mg im/pr/po prn) in a single prescription, it may not be clear from the administration record which route was used for which administration event.
(d) When manually transcribing administration events, inconsistencies in the data may be introduced due to assumptions made by different transcribers.

EP systems with full medicines administration functionality offer the possibility of comprehensive querying functions for conducting clinical audits. Such a system is able to capture data on dose units administered to a patient, at the point of administration, thus providing a detailed accurate record of medicine consumption for a ward, specialty or subgroup of patients.

Furthermore, if an EP system is interfaced with the pharmacy system, it is theoretically possible to reconcile the stock issued from the pharmacy with the doses actually administered to patients, and to analyse the variance. An accurate usage review will be harder to perform for items that are not issued for a specific patient (stock items). However, usage reviews for drugs issued to specific patients would

be helpful for monitoring wastage of mid-price, mid-volume items, and for analysing patterns of use of prn drugs.

There are, however, a number of issues that may affect the ability of an EP system to facilitate comprehensive clinical audits/drug use reviews:

1. There may be problems with mapping data on products issued by the pharmacy with records of doses administered at ward level. This may be due to inconsistencies in pack sizes for the same product, or anomalies in PIP codes or EAN codes assigned. This may also be because the pharmacy system and the EP system may have different ways of handling the drug data.
2. There will be a proportion of prescriptions where the administration instructions will be in a freetext format, because they are more descriptive. These prescriptions cannot be retrieved in the same way as prescriptions with coded administration instructions in an audit process.
3. It has been observed with some EP systems[17] that once only (stat) medicines may be administered in an emergency situation, but may not be subsequently recorded on the system. This may lead to an artificially low record of drug use in an audit.
4. Consideration would need to be given to the practicalities of extracting and collating drug usage data for audit purposes. Reporting software, such as Crystal reports, is useful for extracting data from an application database, in order to facilitate flexible reporting, but a certain level of IT competence is necessary to set up the reports required. Furthermore, there may be issues with collating the data if a report is compiled from two physically distinct databases – for example, the EP system database and the pharmacy system database. If the data elements are compatible, it may be possible to import the required data from the two databases into temporary tables, so that the reporting software can query the combined dataset. Alternatively, the reporting tool would need to be run against each separate database and the reconciliation of data from the two sources performed further down the process.

EP Systems and Patient-Centred Medicines Reviews

In addition to clinical audit and drug use review, which seek to answer questions about the general use of medicines across a population, for management and budgetary purposes, an area that is of increasing interest to many healthcare professionals is the performance of patient-focused, structured medicine reviews. With such a review, the patient is interviewed by the healthcare professional, so that the healthcare professional can obtain a full prescribing history for that patient and can identify any issues relating to side-effects or compliance. The reviewer then may make recommendations to the prescriber concerning possible dose adjustments or discontinuations of medicines.

Questions that a structured medicines review may seek to answer are as follows:

(a) Whether a prescribed medicine is appropriately indicated for a patient
(b) Whether medicines are being prescribed at the correct dose and frequency for the indication
(c) Whether there are significant side effects with any medicine
(d) Whether there are any significant drug interactions or drug sensitivities that may be giving rise to side effects
(e) Whether what is referred to as "polypharmacy" (the accumulation of therapy due to inappropriate overuse of drugs or inappropriate treatment of side effects) can be reduced

Structured medicines reviews have grown in their importance during recent years, and their significance is subject to some controversy. While it has been claimed that medicines reviews can improve health outcomes, some studies have failed to demonstrate the cost-effectiveness of pharmacist-performed medicine reviews.[20]

The role of the medicine review came to the fore in the UK NHS following the publication of the UK government National Service Framework for the Elderly[21] in 2001, which recommended that every patient over 70 years of age on four or more regular medicines should receive a medication review every 6 months. More recently, a structured medicines review, the medicines use review (MUR) has been introduced as a new service in the English community pharmacy contract, and is now a feature of community (retail) pharmacy in the UK, although implementation has by no means been widespread.

Hospital pharmacists have traditionally provided feedback to prescribers about appropriate use of medicines in a reactive manner; however, in the UK, comprehensive medicines reviews in hospitals, in a proactive manner, are still not being carried out consistently across a range of specialties and geographical locations[22].

Since EP systems will have a clear and accurate record of the medicines prescribed for a patient, together with proactive and reactive decision support tools, EP systems have the potential to support healthcare professionals in conducting patient centred, structured medicines reviews.

An EP system might have medicine review functionality as part of the pharmacy workflow, or alternatively, as a separate module within the application. The outline functional flow for medicines reviews might be as follows:

(a) The reviewer selects the patient record for review. There is a facility for the patient's consent to the review to be recorded.
(b) The system will then display the profile of currently prescribed medicines for that patient.
(c) The system would then guide the reviewer through a structured review process. For each prescribed medicine on the profile, the system would advise the reviewer of any significant clinical checks (drug interactions, drug–disease interactions, sensitivities, duplicate therapies), and would direct the reviewer to

any appropriate care plans or clinical guidelines for treatment. The likely scenario is that these decision support tools used in the medicines review process would be driven from the same decision support database used by the EP system for proactive decision support at the point of prescribing.

(d) For each medicine, the system would also prompt the reviewer to ask the patient relevant questions for each medication. Responses from the patient would then be entered into the system.

(e) The information from the review would then populate a predefined medicine review form, which may be a healthcare provider standard format document. The system would prompt the reviewer with suggested recommendations to the prescriber, either to be included on the medicine review form as they stand, or to be overridden by the reviewer on the basis of their clinical experience.

(f) The completed medicine review form would then be routed to the prescriber and would be displayed for action by the prescriber when the patient's record is next accessed.

It is anticipated that the medicine use review functionality would be operated by the reviewer on a wireless laptop PC or palm PC, so that they can conduct the review interview with the patient at their bedside on the ward, or in an outpatient clinic situation. As with medicine administration functions, a PDA would not be adequate for this application due to the small screen size.

One of the problems that has been noted in the use of medicine reviews so far, especially in the community situation, is the effective communication of medicine review information from reviewers (usually pharmacists) to prescribers. One of the advantages of an EP system facilitated medicines review process in hospitals is that it is possible for the review process to be designed and implemented in consultation with, and taking into account the needs of, both prescribers and reviewers. In this way, the process will be acceptable and relevant to all stakeholders, and is more likely to be used effectively. Furthermore, the recommendations of the medicines review are available directly to the prescriber in electronic form, thus reducing the possibility of the review not being available to the prescriber. Future, more sophisticated systems might offer functionality to link medicine review recommendations to prescribing routines. Then, if the prescriber accepts the recommendations of a review, by clicking on the relevant parts of the review form, new or amended prescriptions are automatically generated, which must then be authorised by the prescriber.

An EP system can therefore facilitate a closed-loop process for medicines review, whereby a review is initiated with an accurate prescribing history for a patient, and conducted in a structured and consistent manner, with inputs from the system's decision support tools. Specific and well-defined recommendations are then made to the prescriber and, if the prescriber chooses to accept the reviewer's recommendations, the recommendations are then implemented by the EP system in an accurate and consistent manner. The process can then be repeated with future reviews in an iterative manner (Fig. 6.2).

It is clear that, due to the use of decision support tools at the point of prescribing, electronic prescribing will lead to more rational prescribing at the outset,[12] which will
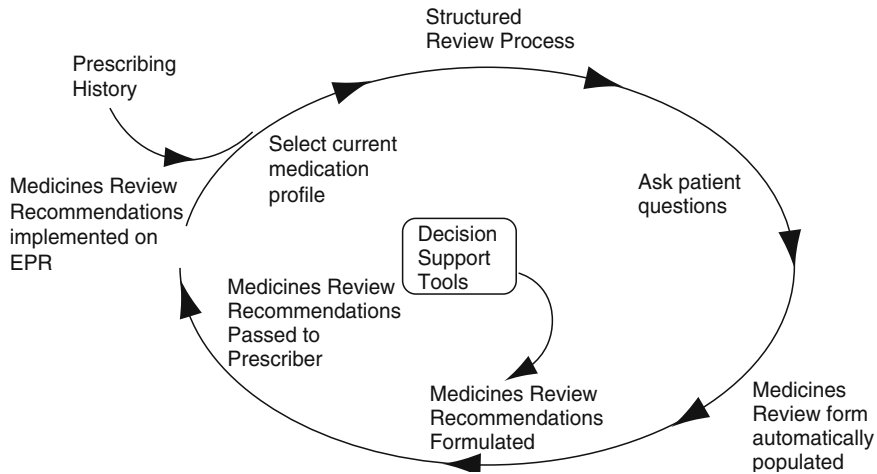
Fig. 6.2 Closed loop medicines review process

obviate some of the issues that present in medicines reviews at the current time. However, the extent to which electronic prescribing affects subsequent medicine reviews has not yet been fully elucidated. In any case, there is an important role for healthcare professionals in conducting patient-centred medicine reviews, in order to identify ongoing issues with side-effects, compliance and other aspects of pharmaceutical care (e.g. inhaler technique). The "closed-loop" review process, which can be supported by an EP system, will support health professionals as they develop this part of their professional practice and may improve patient outcomes relating to these reviews, thus clarifying the controversy concerning the efficacy of medicine reviews.

Involvement of EP Systems in Clinical Research

Clinical research represents an important aspect of medicine use in hospitals and an important element in the professional development of healthcare professionals. This is true for all healthcare professionals, but especially the case for the medical profession. In order to advance within a specialty, or to gain a higher degree (e.g. MD), doctors are required to undertake some clinical research in their specialist field.

Because of their ability to capture clinical data at the point of care, EP systems have the potential to be of value to health professionals involved with therapeutics-related clinical research.

The EP system could be used to perform the following tasks:

(a) Identification of a cohort of patients being treated with a particular therapeutic intervention (either an individual medicine, a particular dose of an individual

medicine, or a recognised regimen of several agents). The demographics of the patient and the duration of the therapeutic intervention may also be taken into account.

(b) Generate the necessary documentation for an ethics committee submission, and maintain a record of ethics committee approval.

(c) Flag up patients fitting the trial criteria to the investigator, as potential clinical trial patients.

(d) Maintain a consent record for each patient in the cohort, and an ethics committee approval record for the cohort.

(e) Flag up a warning to other prescribers accessing the patient's record in the EP system that the patient is enrolled in a clinical trial.

(f) Assign trial medication to each patient, with a "sealed envelope" de-blinding function, if it becomes necessary to identify whether the patient is taking active or placebo medication.

The patient data could then be exported to a database or clinical trial management application for subsequent processing. Alternatively the data could be maintained within the EP system, as part of a specific clinical trial module. Once the patient data is in a database designed for the clinical trial, either within the EP system or elsewhere, observational data could then be downloaded for each patient from PDAs used by healthcare staff attending the patient.

It has been demonstrated that handheld devices, such as PDAs, are an effective and accurate means of gathering observational data for clinical trial patients at the point of care.[23] EP systems have the potential to screen potential candidates for therapeutic clinical trials in an equally effective and accurate manner. This has the potential to improve the quality of the trial database, as well as streamline the data collection process.

EP Systems: Support for Continuing Professional Development

All healthcare professionals have a duty of care to their patients, in law, and therefore have an ethical responsibility to provide patient care according to the most current clinical evidence, and in line with accepted best practice for their profession. In all developed countries, there is increasing emphasis on the professional regulation of healthcare professionals, together with an awareness of a greater risk of litigation if negligence can be demonstrated. For these reasons, continuing professional development (CPD), where health professionals are required to keep abreast of the latest clinical and professional developments in their profession, has assumed greater significance for the health professions. The CPD process should be firmly rooted in the realities of practice and many adult educationalists will advocate the use of a reflective cycle type approach, which enables the practitioner to take an aspect of their current practice, learn something from it, and bring that learning to bear on future practice. There are requirements for health professionals to undertake a certain number of hours of CPD or a certain number of "CPD events"

per year. In some cases, completion of a structured CPD record is a prerequisite for professional reaccreditation, so that the health professional can continue in professional practice.

An EP system will contain a wealth of healthcare practice-related information – patient prescribing histories, care pathways and clinical guidelines, decision support information and disease monitoring information. Consequently, such systems have the potential to support CPD for healthcare professionals in a variety of ways, which might include a specific CPD module for clinical multiple choice questionnaires (MCQ), an integral CPD record, or links to professional body CPD Web sites, and use of the system to provide case histories or simulations.

A key consideration in the design of CPD support functions for an EP system is that CPD events should arise from practice and that the learning gained from the CPD is then reapplied to practice. It is important therefore that there is a facility for CPD functionality to be launched from any screen on the EP system that a healthcare professional is working from, in a way that does not impede their workflow.

The potential role of the EP system in the training of non-medical prescribers will be discussed at length in Chapter 7. However, EP systems are able to facilitate the development of prescribing skills and knowledge in all professional groups involved with medicine prescribing. As mentioned earlier, EP systems could be configured so that non-medical prescribers benefit from more active prescribing decision support during the prescribing process. Care management plans (CMPs) and care pathways can be an invaluable source of prescribing information for both the independent prescribers who set them up, and the dependent prescribers who work from them.

In addition to this, the active clinical decision support that an EP system provides (drug interactions, sensitivities, precautions and contraindications) is a potentially rich source of guidance to less experienced prescribers, as long as it is implemented in such a way that warnings are clear, relevant and do not excessively impede the prescribing workflow.

There is the potential for EP systems to provide simulation training for less experienced prescribers. Such simulation might be active or passive. With passive simulated prescribing training, a particular workstation – preferably not in a clinical area – would be switched to draw patient data from a training database, to allow a user to practice their prescribing, using the EP software, but against dummy patients. The training database would need to be clearly identifiable as a non-live database.

A further advance would be the development of an active prescribing simulation module, whereby the EP system would automatically present the trainee prescriber with a specific patient and a clinical scenario, and the prescriber would then prescribe for the patient using the EP system. The system would then simulate a response – or lack of response – to treatment by the patient, in terms of clinical observations and test results fed back, etc. The prescriber would then review the therapeutic strategy on the basis of the simulated patient response, and act accordingly. At the end of the simulation training session using the EP system, the system could then feed back to the trainee prescriber, with an evaluation of the decisions they made.

Integrated Care Pathways and Clinical Guidelines

As discussed, EP systems have the potential to apply specific clinical guidelines or care pathways automatically to the prescribing process, as part of the decision support (DS) tools (see previous chapters). Because of the increasing emphasis on evidence-based medicine in clinical practice, together with the growing need to allocate resources and to regulate costs of treatment, government agencies see EP systems as a means of mandating the use of clinical guidelines and appropriate regimens for different medicines.

However, research on DS tools has shown that clinicians will not adhere to clinical guidelines, even when those guidelines are good, unless the guidelines are integral to a prescribing workflow, in a useable manner.[15] That is to say, the system has to be structured in such a way that the prescriber has to view and act upon the guidelines before they can prescribe medicines. As discussed in earlier chapters, there is a balance between implementing a workflow that forces the prescriber to produce an accurate prescription, and one that has too many steps to be workable in a busy clinical environment. However, if care pathways and guidelines can be successfully integrated into the prescribing workflow in an EP system, then not only are they likely to be followed, but also they are likely to be memorised and to have an impact on professional practice.

Another issue is the use of Web-based hospital formularies, which are usually mounted on a hospital intranet site. There is the potential to link an EP system with the intranet-based hospital formulary. Furthermore, this could be done in an advanced manner so that, when the therapeutic options in a particular care pathway are selected, a list of formulary-approved medicines are preferentially available to be prescribed. This would mean that supplementary prescribers and less experienced independent prescribers are guided by the EP system in an evidence-based manner.

EP Systems: A Gateway to Medicines Information Reference Sources

As discussed in Chapter 5, published sources of drug information have in the past consisted of the medical and pharmaceutical primary literature from hardcopy journal publications, together with secondary reference publications, such as recognised compendia – for example, the Martindale Extra Pharmacopeia (Martindale), and Stockley's Drug Interactions – and periodicals – for example, the British National Formulary (BNF), or the Monthly Index of Medical Specialities (MIMS). Now, however, many of the pharmaceutical compendia – for example, the BNF or Martindale – are available in electronic format, on CD-ROM for single-user or network access.

While, as previously discussed, these reference sources are not generally useful for supporting the drug data requirements of the EP system itself, they are well-respected

sources of detailed, impartial medical information for health professionals, and have an important role in supporting clinical practice for all professionals who are involved with the prescribing and supply of drugs.

As previously mentioned, electronic information sources are distributed according to license agreements, on the basis of platform (PC/LAN) and number of users.

Conclusion

All healthcare professionals conduct their professional activities within recognised legal and ethical constraints. Furthermore, it is recognised that healthcare professionals should seek to follow what is accepted best practice for their profession, as determined by peer evaluation. These are the marks of a profession. However, for many clinical professionals, the professional role is changing, due to changes both in society and within healthcare provider organisations. EP systems have the potential to facilitate best practice for clinical users and to be the framework for new professional roles and service provision.

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Chapter 7
Electronic Medicines Management and Non-medical Prescribing

Background to Non-medical Prescribing

Traditionally, in healthcare, the prescribing of medicines has been the preserve of the doctor. In the UK, the right to prescribe medicines was assumed by the medical profession following the 1858 Medicine Act and, during the century that followed, the roles of the health professions in relation to medicines have become well demarcated: doctors prescribed medicines, pharmacists dispensed or supplied medicines and nurses administered medicines. This distinction has persisted across the health professions, especially in secondary care, until relatively recently.

However, over the last 20 years, prescribing by other healthcare professions has been developed in a number of countries – the United States, Canada, Sweden, Australia and New Zealand, as well as the United Kingdom[1]. A number of social and economic factors have contributed to the development of non-medical prescribing:

(a) Government concerns about shortages of doctors
(b) The need to expand channels of prescribing in order to meet public health targets in certain disease areas
(c) The need to make the best use of the "skill mix" among the professions of the NHS, given their respective numbers and manpower issues
(d) A decline in the paternalism with which the public regard the medical profession, together with the political empowerment of other healthcare professions

The remainder of this section will describe the development of non-medical prescribing, and the issues it entails, specifically in the UK context. Space does not permit a full discussion of the development of non-medical prescribing in other healthcare economies.

As discussed, doctors have traditionally been the prescribers of medicines, and, in the UK, the Medicines Act, 1968, limited the legal right to prescribe medicines to doctors, dentists and veterinary surgeons. However, in 1986, the UK Government's Cumberledge Report – "Neighbourhood Nursing – A Focus for Care" identified the potential of non-medical prescribing. This report advocated prescribing by community nurses within their sphere of competence, and led to the establishment of

the Advisory Group on Nurse Prescribing in the UK, chaired by Dr June Crown. This group conducted two reviews of prescribing (known as "the Crown Reports"), which have been key to non-medical prescribing in the UK. The first Crown Report recommended that nurses with a district nurse or health visitor qualification should be able to prescribe from a limited formulary, and also that nurses should be able to supply medicines within "group protocols" (i.e. where a group of patients who fulfill certain criteria can be given a certain type of medicine on written instructions from a doctor or dentist). The second Crown Report defined the two key types of prescribers – *dependent* prescribers, or supplementary prescribers, and *independent* prescribers (see Table 7.1).

Dependent, or supplementary, prescribing – prescribing to a patient-specific clinical management plan (CMP) set up by an independent prescriber – was introduced for nurses and pharmacists in 2003. This was then extended to chiropodists/podiatrists, physiotherapists, radiographers and optometrists in 2005.

The first form of nurse independent prescribing was prescribing by community nurses from the Nurse Prescribers Formulary (NPF), which was piloted in 1994 and rolled out in 1998. The second form of nurse independent prescribing allowed nurses and midwives with additional prescribing training to prescribe from an extended formulary, a development which took place in 2002. From 2006, all extended formulary nurse prescribers have become nurse independent prescribers and can prescribe from a full formulary (within their area of competence and if authorised by their employer).

The first pharmacist independent prescribers began their training in 2006. Pharmacist independent prescribers can prescribe from a full formulary, with the exception of controlled drugs.

Table 7.1 Prescriber types and user roles

Professional group	User role	Prescriber type	Formulary prescribing permissions
Doctor	Consultant – Renal Medicine	Independent prescriber	Renal medicine specialist formulary
Doctor	Junior Doctor – Surgery	Independent prescriber	None
Pharmacist	Purchasing pharmacist	Non-prescriber	None
Pharmacist	Clinical pharmacist – Surgery	Supplementary prescriber	None
Pharmacist	Consultant pharmacist – Asthma care	Independent prescriber	Respiratory medicine specialist formulary
Nurse	Clinical nurse Specialist – oncology	Independent prescriber	Oncology and haematology specialist formulary
Nurse	Staff nurse – Surgical ward	Non-prescriber	None

This table shows a brief example schema for designation of hospital EP system users. A schema with this level of granularity may be used to support specialist formulary prescribing as well as non-medical prescribing

Experience of Non-medical Prescribing

There is now considerable documented experience with the work of non-medical prescribers. In 2004, a review of 18 papers was published describing the impact of the first phase of nurse prescribing, using the Nurse Prescriber's Formulary (NPF)[2]. The consensus of this review was that patients were generally satisfied with nurse prescribers, and that the nurse prescribers were happy with their role, albeit with some concerns about their pharmacological knowledge. However, the review highlighted prescribing variations between the types of nurse prescriber at that time (district nurses, practice nurses and health visitors) and the limitations of the NPF.

There are also published reports of specific clinics that are led by non-medical independent prescribers, primarily nurses and pharmacists. These clinics tend to be in well-defined specialties and are led by non-medical prescribers who have developed clinical expertise in that field and who generally work with a limited range of medicines.

Some examples of clinics led by non-medical independent prescribers that have been reported in the literature are sexual health clinics, diabetes clinics and asthma clinics run by primary care nurses and diabetes clinics and rheumatology clinics run by specialist hospital pharmacists[3,4].

In these clinics, non-medical prescribers will take professional responsibility for all prescribing decisions, together with a review of a patient's condition, and case-load management. In these clinics, there is a clear framework of referral for patients who encounter specific complications and who might need a medical referral, or the attention of a more experienced clinician.

Benefits and Risks of Non-medical Prescribing

There are a number of clear benefits of non-medical prescribing. Firstly, clinics led by non-medical prescribers are an important means by which services in the NHS can be expanded, at a time when resources are increasingly budgeted. Secondly, these clinics can facilitate an appropriate redistribution of the workload, in order to best utilise the various skills of health care provider staff (the "skill mix" issue). Thirdly, a review of nurse extended formulary prescribing in 2005[5] indicated that, in general, patients were satisfied with nurse prescribing. Many patients valued the way that non-medical prescribing improved access to treatment, although half of the patients said that they would still prefer to see a doctor for certain conditions. As part of the review, an expert panel examined a sample of observed consultations. The panel found that the nurse prescribers observed were prescribing medicines in a clinically appropriate way and were adequately communicating information to patients about the medicines, and exploring the patients' beliefs about treatment. This might reflect a perception on the part of patients that non-medical prescribers might have more time to spend with each patient than doctors.

Notwithstanding the various benefits of non-medical prescribing, in terms of appropriate use of skill mix, expansion of healthcare services, and improved access to treatment, a number of areas of risk have been highlighted with non-medical prescribing. These concerns centre on safety and clinical governance issues as given below.

Patient Safety

The patient safety aspects of prescribing by non-medical prescribers have been extensively discussed over the last 20 years as nurse and pharmacist prescribing has been rolled out. However, the fact remains that there are few comparative data on the rates of prescribing errors with prescribers of different professional groups. Moreover, it is recognised that there is a percentage of avoidable errors with medical prescribing.

As discussed previously, it is recognised that electronic prescribing and electronic health records reduce medication errors, including prescribing errors[6,7]. It is envisaged then that this benefit could be realised for all types of prescriber, using an integrated prescribing workstation in an EP system. This would certainly be the case if there were specific tools in the EP system to support and manage workflow for particular types of non-medical prescriber.

However, while supportive of non-medical prescribing in general terms, the Committee on Safety of Medicines has expressed some concerns about non-medical prescribing, around the area of records access and management[8]. The first issue was whether all prescribing professionals would have full access to the patient's records prior to prescribing, something that is a key prerequisite to making a clinically appropriate prescribing decision. The concern was that, while surgery, health centre or hospital-based staff would have access to patient records, peripatetic healthcare professionals and those who are community-based would not. Following on from this, if an EP system was in use, then certain non-hospital-based prescribers would subsequently not be able to log their prescriptions onto the system, if they did not have remote access. The second issue is concerning how access to prescribing records would be coordinated where there are multiple prescribers who may be working on a patient record. These logistical concerns may be addressed by the system architecture and logic of an EP system.

Training of Non-medical Prescribers

Concerns have been raised about the training of nurse and pharmacist prescribers in areas that have traditionally been the preserve of medicine, for example history taking, assessment and diagnostic skills. Given that some of the concerns about training of non-medical prescribers are because independent and supplementary

prescribing courses are too short in duration, the training of non-medical prescribers has implications for undergraduate education, as well as postgraduate education, in those disciplines. However, it should be remembered that, equally, there are potential training issues for medically qualified prescribers. Traditionally, pharmacology and therapeutics has been taught to medical students as a factual discipline, but the recent trend in medical education has been towards problem-based learning and away from the factual approach. There is therefore the potential for medical education in pharmacology and therapeutics to reflect more closely the realities of clinical practice, and for there to be some integration of therapeutics training for all major health professionals – i.e. a core syllabus at basic/undergraduate level. This opens up the possibility of the use of an EP system to facilitate prescribing and therapeutics training.

The potential for EP systems to support training and continuing professional development (CPD) has been discussed at length in Chapter 6. Nevertheless, there are certain ways that EP systems can assist with the training needs of non-medical prescribers – for example, use of care plans, incorporation of clinical guidelines, access to medicines information reference sources, and simulation training.

Clinical Governance

From an organisational perspective, healthcare providers need to have a robust system of clinical governance in place for the regulation of all prescribing activities, including the management and facilitation of non-medical prescriber led services. These would include the following:

(a) Information on the scope of competence and responsibility for different non-medical prescribers
(b) Records of the training, CPD and professional accreditation and professional insurance details of named non-medical prescribers
(c) Clinic procedures, with audit and risk assessments and, in particular, a procedure for management of critical incidents
(d) The advantage of an EP system is that many of these governance requirements can be embedded in EP functionality in a seamless way, so that the software will support non-medical prescribers, without giving the negative impression that it is restrictive to their activities.

Role of EP Systems in the Management and Support of Non-medical Prescriber-led Services

As discussed in previous chapters, electronic prescribing systems have the potential to automate routine aspects of prescribing workflow, and to revolutionise working practices. Consequently, many EP systems have the potential to address some of the

above risk management issues associated with non-medical prescribing, and thus have a role in supporting and enhancing the practice of non-medical professionals who are involved in prescribing. Nevertheless, as with other benefits of EP systems, the capacity of a system to support different prescriber workflows adequately is critically dependent on system design. The design areas that would need to be considered are described below.

EP Systems and Role-Based Access (RBAC)

An electronic prescribing system will usually have a comprehensive function set for managing user permissions and log-ons. This is essential, not only for the security of the system and the data on it (which is sensitive personal information), but also to control access to functionality and to generate an audit trail of user activity, which can be used to create management reports and to track critical incidents.

The granularity of the user permissions management function set is critical in the design of functionality to support different prescriber types. In a typical EP system, each user will have a role assigned to them, which is often based on their professional group – e.g. doctor, pharmacist, nurse. These general groupings may then be subdivided into more specific groups as shown in Table 7.1.

However, in order to support prescribing by professional groups other than doctors, the user permissions management dataset will also need to map prescriber type against each professional group. Thus, for each user name, there would be fields for (a) profession (e.g. pharmacist), (b) role (e.g. clinical pharmacist) and (c) prescriber type (e.g. independent prescriber).

Thus, for a user with the user profile of pharmacist/clinical pharmacist/ independent prescriber, the system would allow access to EP functionality at three levels (a) for pharmacists – e.g. verify/clinical check, pharmaceutical care planning; (b) for clinical pharmacists – e.g. management of specialty formularies, drug use review/clinical audit functions and (c) for pharmacist independent prescribers – e.g. prescribing rights, probably from a specialist formulary, after input of professional accreditation and training details for that user. Consideration should be given to possible role conflicts that might occur in the working practices of non-medical prescribers – for example, if a medicine is prescribed by a pharmacist independent prescriber, it should not be possible for the same pharmacist to perform a verify/clinical check on the order.

It is an important principle that a user's level of permissions to access records and use the system should be appropriate to their role. This is true for any business with client or customer responsibility, but is especially so for a healthcare setting, with the duty of care that health professionals have for their patients. Software vendors therefore need to ensure that datasets for user permissions are compliant with known regional or national standards. For example, role-based access (RBAC) is an important deliverable for the English Connecting for Health programme and when

National Care Records Service (NCRS) standards were first published, many vendors analysed the data structure and operation of legacy systems to determine what development was required to make them "spine compliant". One of the most important lessons to emerge from this process was that, as well as any internal development that was required to make software useable within a national system, the mapping of data items between the application database and the spine data requirements was crucial for ensuring appropriate communications between systems. This is especially the case with role-based access, where concepts within the user permissions data locally may not be supported by regional or national standards for data and communications channels. Thus, it may not be possible to replicate all aspects of local user permissions in a national system.

Records Management and Multi-user Systems

An important issue arising from discussion of the risks associated with non-medical prescribing concerns the management of records within an EP system, where there may be multiple simultaneous users of the system.

This issue is essentially concerned with the system logic for record access within an EP system, and is not unique to the situation where a patient's prescribing record may be accessed by two or more prescribers simultaneously. System designers will need to consider the rules for record access and record locking for a variety of multi-user system scenarios. Rules would need to be applied to different levels of the system to ensure the smooth operation of the system. For example, it would be appropriate to lock a patient's prescribing record if a prescriber attempted to alter a dose of one medicine while a second prescriber was in the process of adding a new medicine to the prescribing profile. It would also be appropriate to lock a patient record if a pharmacist was attempting to verify/clinical check a discharge prescription, while a prescriber was in the process of adding another medicine to the discharge prescription. However, it would not be appropriate to lock a patient record if a nurse was administering a prescribed and checked medicine on a patient's profile, while a prescriber was in the process of adding a new medicine to the profile; this would impede the normal use of the system.

If a record was locked against a second or subsequent user, a warning message would display, as shown in Fig. 7.1.

For two or more prescribers using the system simultaneously, it would be appropriate for the patient's record to be locked at the prescribing level for second and subsequent prescribers. This ensures that (a) the prescriber knows that they are viewing the full current prescribing history for a patient at the point where they are about to prescribe a new item and (b) the second prescriber knows that another prescriber is in the process of prescribing for the patient. A useful feature would be for the record locking warning message to display the identity of the first prescriber to the second prescriber, to facilitate communications between prescribers of different types.
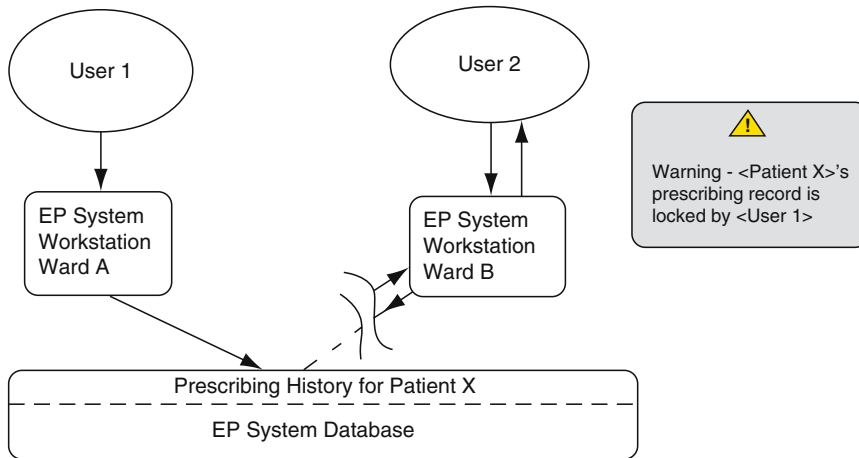
Fig. 7.1 Record locking

Once an item has been prescribed, consideration needs to be given to the time taken for all workstation screens to refresh with the amended prescribing record with the new item or amendment showing. This will depend on client–server communications in a networked system.

The other issue highlighted was that of access to prescribing records, and input of prescriptions by non-medical prescribers who may be peripatetic healthcare professionals. Electronic systems offer solutions to this problem, and there has been considerable experience of using portable devices for inputting medical information in peripatetic settings. Typically, a system might use a slave application mounted on a portable device, such as a personal digital assistant (PDA) or a palm PC or tablet PC. The slave application would have some, or all, of the functionality of the main system, together with a subset of patient records, depending on the memory capability of the device. The peripatetic health professional would enter the relevant patient information on the device and then, at some future time, the information on the device would be downloaded to the main application, either via a networked connection at the hospital or healthcare provider site, or via a telephone dial-up connection. This downloading process would also include the synchronisation of the patient data on the portable device with the patient data on the main application.

This type of solution has been used for clinical noting by peripatetic healthcare professionals involved with mental health and palliative care, and could be used to facilitate EP functions. There are, however, a number of issues with the use of this approach with EP:

(a) EP requires a drug database to work from, and there may be problems with mounting a comprehensive drug database on a portable device. However, nonmedical prescribers, even independent ones, are likely to be using a limited formulary within the context of a particular healthcare setting, which will reduce the size of the database required. Furthermore, certain care scenarios

can be catered for by a small and well-defined set of prescriptions, perhaps available on the device as pre-defined orders (PDOs).

(b) Because the portable device is not operating in real time, the synchronisation of the slave application with the main system is of particular significance in EP applications. If, at the point of synchronisation, a prescriber is already using the main system, then the data transfer from the portable device should be locked in exactly the same way as would happen if a second user was using the main system. Because of the real time problem, there may also be issues with provision of clinical checks – e.g. drug interactions, duplicate therapy, etc. The slave application cannot provide full decision support because it cannot view the full patient prescribing record. In any case, there may be issues with mounting data to provide prescribing decision support tools on the portable device. The decision support checking process would therefore need to take place retrospectively at the point of synchronisation with the master system, when the "full" prescribing history is known to the master system (and probably using decision support routines mounted on the master system). There would therefore need to be a process of clinical warning messaging to the portable device, and perhaps a function whereby certain orders are automatically inactivated on the main application if there are serious drug interactions. Another approach – the most likely approach in practice – would be not to implement decision support functions and to reduce clinical risks by limiting the prescribing functions on the hand-held device.

Workflow for Different Prescriber Types

As has already been discussed, one of the benefits of an EP system to prescribers of all professional backgrounds is that it facilitates the generation of clear, complete and accurate prescriptions[9,10]. This benefit is of value both to experienced prescribers who may be complacent about clarity and completeness of prescriptions, and also to newer prescribers from other healthcare professions, who may be inexperienced in the process of prescription writing. However, in addition to the standard prescribing workflow, consideration should be given to the specific needs and requirements for non-medical prescribers in the design of an EP system's prescribing workflow.

A number of extra factors in the prescribing process should be considered when designing an EP system to support non-medical prescribers.

Prescribing Permissions

For a user to be able to prescribe at all, they need the following attributes: (1) designation of a prescriber type under user permissions and (2) current details of professional accreditation, training and professional insurance to be entered onto the system under user information.

Structured Prescribing and Care Plans

As mentioned, an important distinction within non-medical prescribers is between dependent prescribers and independent prescribers. The former can only prescribe medicines for a patient within the context of an agreed CMP set up for that patient by an independent prescriber. In contrast, an independent prescriber can prescribe medicines for a patient independently of any care plan or pathway.

In practice, this would mean that there would be functionality in an EP system for an independent prescriber to set up a customised CMP for a patient or to implement a standard locally agreed care pathway for a specific patient. The CMP or care pathway would have embedded in it a series of orders, or an order set, which could subsequently be prescribed as a prescription by a dependent prescriber.

Therefore, on activating the prescribing function, an independent prescriber would have the option of prescribing for the patient directly from the system formulary, or setting up a CMP for the patient to be followed by a dependent prescriber. By contrast, when a dependent prescriber activates the prescribing function, any activated CMPs for the patient are displayed. If there are no valid CMPs setup for the patient, the dependent prescriber cannot proceed with the prescribing process for that patient. Each CMP will contain medicine orders, which can be activated by the dependent prescriber to generate prescriptions. It is likely that each CMP will have logic embedded in it possibly with limits to prescribing, dependent on time, test results or other medicines prescribed. There may be certain situations where the dependent prescriber is forced to refer the CMP back to the independent prescriber, and can no longer proceed with implementing the care plan. Possible prescribing workflows for non-medical prescribers are illustrated in Fig. 7.2.

To facilitate prescribing by supplementary prescribers, EP systems will need to have a library of local and national CMPs or care pathways. Correspondingly, hospitals and healthcare providers will need to have a robust procedure for the design, setup, validation and maintenance of the CMP/care pathway library, in just the same way as individual drug formulations and pre-defined orders (PDOs)/order sets (see Chapter 5).

Specialist Formularies

While, in the UK, nurse and pharmacist independent prescribers can, in theory, prescribe from a full formulary, the official recommendation is that they prescribe within their area of competence[11]. This recommendation, together with the need for healthcare providers to manage clinical risk and to control expenditure, will mean that independent prescribers working in the context of secondary care healthcare institutions will almost certainly be working with a specialist formulary. Depending on the work done by independent prescribers within an organisation, the specialist formulary will either be for all independent prescribers within the organisation, or there will be a specialist formulary for each specialty in the organisation. Thus, on
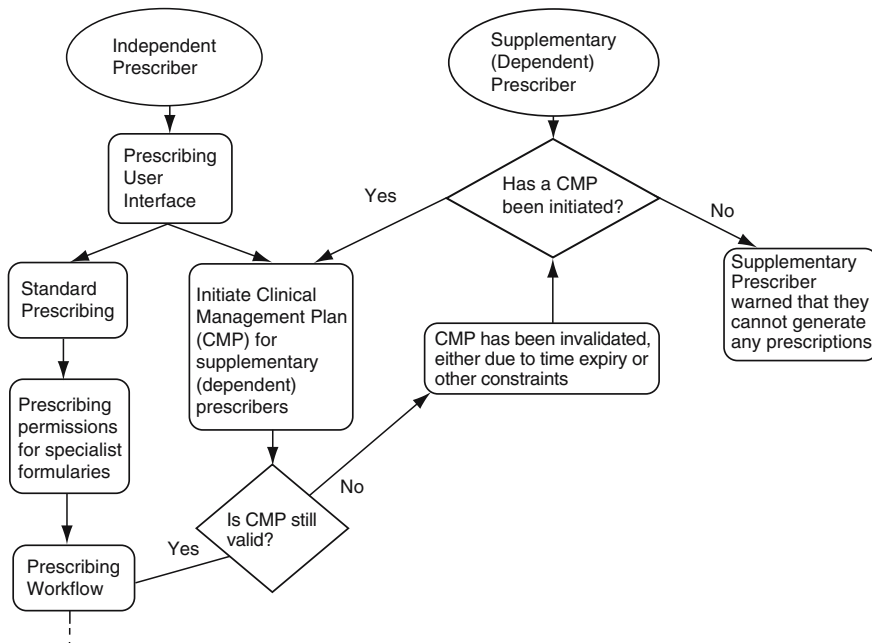
Fig. 7.2 Prescribing workflow for non-medical prescribers

activating the prescribing function on the EP system, a non-medical independent prescriber will be able to select medicines from a specialist formulary, compiled for their use. It should be noted that, at this point, there may be little distinction between medical (independent) prescribers and non-medical independent prescribers; some implementers of EP systems have set up core and specialist formularies, which prevent junior medical staff from prescribing specialist treatments that are outside the specialty of their current rotation.

Information Support for Different Non-medical Prescriber Types

As mentioned previously, there is now much information on medicines that is available in electronic form. This may take the form of electronic versions of standard pharmaceutical compendia, such as the BNF and MIMS, or alternatively web-based information from specialist centres such as the Cochrane Centre, and the Medicines Resource Centre (MeReC). In addition to the published information, there are also local clinical guidelines and other local documentation, which may be on a hospital intranet or local network.

Resources such as these can easily be made available for prescribing decision support within an EP system, subject to licensing arrangements for the published sources. This is typically done in a passive format, where a button is put within the EP software allowing the user to access the referential information, if required, by pressing the button.

Reference information on medicines is of equal value to all types of prescriber, especially for those medicines where there are very specific criteria for use. However, given the usual mode of using reference information for passive decision support within EP systems, consideration should be given to implementation of more active decision support for non-medical prescribers. For supplementary prescribers, the CMP or care pathway can be a useful vehicle for information to support the prescribing process. For independent non-medical prescribers, however, there may be a case for presenting prescribing support information actively within the prescribing process. For example, if a nurse independent prescriber were to prescribe the single-dose fluconazole 150 mg capsule for a woman with vaginal candidiasis (thrush), an EP system would actively display current national or local clinical guidelines for thrush treatment as part of the prescribing workflow.

Support for Patient Group Directions (PGDs)

In the UK, a patient group direction (PGD) is a written protocol, enabling the supply of a medicine, or group of medicines, to patients who fit certain criteria, where the patients do not have to be individually identifiable in advance of the supply being made[12]. PGDs can legally be administered by the following NHS professionals: nurses, midwives, health visitors, optometrists, pharmacists, podiatrists, radiographers, orthoptists, physiotherapists, ambulance paramedics, dieticians, occupational therapists, prosthetists, orthotists and speech therapists.[1] Other countries have similar provisions for group protocol supply arrangements.

PGDs are of importance where a high volume of patients will present for a specific treatment, but it is unknown who will attend. Examples of this are the supply of the antibiotic azithromycin for people with chlamydia infection at a sexually transmitted diseases (STD) clinic, or the supply of vaccines at a travel clinic.

While the use of a PGD is not a form of prescribing, it is a means by which a variety of health professionals might be involved with the supply of a medicine. It would be appropriate, therefore, for an EP system to be involved with the management of services involving PGDs in secondary care.

With PGDs or group protocols, the business process for medicine supply would centre on the PGD, rather than on the patient, and the part of the system dealing with PGDs would constitute a separate module to the system. Ideally, the system would provide a criteria checklist for the clinical user, attached to each PGD. This would enable the user to check that the presenting patient is eligible to be treated under the PGD, and would form an audit trail for healthcare managers.

Once eligibility has been established, the protocol treatment would be allocated to the patient, and a record of the treatment would be posted onto the prescribing record for the patient, if present within the system. System designers should consider the applicability of functionality to prevent sensitive personal information – for example, concerning the treatment of HIV infection and sexually transmitted diseases – from being visible on the general prescribing profile, which would be visible to a wide range of users in the healthcare organisation and beyond, but still be listed in the physical record, and be available for decision support checking.

Support for Training and CPD for Non-medical Prescribers

As mentioned previously, one of the key risk areas highlighted in reviews of non-medical prescribing has been the training of non-medical prescribers. Given that all clinical professions have requirements for CPD, the issue of training is continuous with that of CPD, as a non-medical prescriber is usually learning prescribing skills in order to develop their professional practice. It should be pointed out that training and development of prescribing skills is an area that is not limited to non-medical prescribers; it would also be applicable to less experienced medical prescribers, such as foundation grade doctors interns. Indeed, structured training on prescribing skills during the course of work experience would be a positive development for junior doctors in some areas.

The contribution that EP systems are able to make to the CPD of healthcare professionals has been discussed in detail in Chapter 6. However, EP systems are able to facilitate the development of prescribing skills and knowledge in all professional groups involved with medicine prescribing. As mentioned earlier, EP systems could be configured so that non-medical prescribers benefit from more active decision support during the prescribing process. CMPs and care pathways can be an invaluable source of prescribing information for both the independent prescribers who set them up, and the dependent prescribers who work from them.

In addition to this, the active clinical decision support that an EP system provides (drug interactions, sensitivities, cautions and contraindications) is a potentially rich source of guidance to less experienced prescribers, as long as it is implemented in such a way that warnings are clear, relevant and do not excessively impede the prescribing workflow.

There is the potential for EP systems to provide simulation training for less experienced prescribers. Such simulation might be active or passive. With passive simulated prescribing training, a particular workstation – preferably not in a clinical area – would be switched to draw patient data from a training database, to allow a user to practice their prescribing, using the EP software, but against dummy patients. The training database would need to be clearly identifiable as a non-live database. A further advance would be the development of an active prescribing simulation module, whereby the EP system would automatically present the trainee prescriber with a specific patient and a clinical scenario, and the prescriber would

then prescribe for the patient using the EP system. The system would then simulate a response – or lack of response – to treatment by the patient, in terms of clinical observations and test results fed back, etc. The prescriber would then review the therapeutic strategy on the basis of the simulated patient response.

The development of an active simulation module within an EP system would constitute a highly sophisticated and potentially complex enhancement, especially if a large number of clinical scenarios were incorporated. Consequently, this represents a highly advanced function of future EP implementations. Nevertheless, active simulation would enable prescribers not only to develop their prescribing skills, but also to increase their knowledge of the EP system and its functions.

Adverse Drug Event (ADE) Reporting

Following the thalidomide issue in the late 1960s, it became commonplace for the pharmaceutical industry and healthcare providers to monitor new medicines to assess their safety in use, and to detect common adverse drug events (ADEs). In the UK, the Committee on Safety of Medicines (CSM) was set up in order to oversee this safety monitoring, or pharmacovigilance, process. Since then, pharmacovigilance has become an increasingly sophisticated science. However, while pharmaceutical manufacturers still collate ADEs from pre- and post-marketing clinical studies on their products, and recent regulatory changes have required pharmaceutical manufacturers to scan published literature for evidence of new ADEs, a key route for identifying ADEs has been spontaneous reporting by health professionals.

The CSM's Yellow Card Scheme was designed to encourage the spontaneous reporting of ADEs by doctors[13] when patients returned to the prescriber to report a side effect issue with a prescribed medicine. On being informed of a potential ADE by the patient, the prescriber completes a yellow card, which is distributed with prescription pads and copies of the British National Formulary, and sends the report to the CSM to be added to their database, either as a hard-copy yellow card form or via the CSM yellow card Web site. The CSM reports regularly to pharmaceutical companies and also produces safety awareness bulletins.

It has long been acknowledged that the Yellow Card scheme detects only a proportion of the actual ADEs observed with a new medicine. Consequently, in 1999, the CSM expanded the Yellow Card reporting scheme to allow other healthcare professionals to report suspected ADEs in an attempt to increase the detection power of the scheme. Furthermore, in 2002, the CSM introduced a Web-based electronic yellow card reporting tool for health professionals. However, despite both of these innovations, there is still considerable under-reporting of spontaneous ADEs through the yellow card scheme.

Nevertheless, EP systems clearly have a potential role in the processing of electronically reported ADEs by health professionals, subject to the availability of appropriate regulatory channels for the electronic ADE reporting in a particular

healthcare economy. It has been suggested by UK commentators[14] and German commentators[15] that electronic ADE reporting via clinician workstations would lead to a significant increase in the numbers of spontaneous ADEs reported, simply because there would be an opportunity for the ADE data to be captured at the point of patient consultation. ADE data capture at the point of consultation would mean that more details of the ADE would be available at the outset, which would reduce the need for follow-up by pharmaceutical companies or regulatory bodies. Then, even if there were incomplete details of the ADE, and follow-up was required, the ADE record would exist and could be flagged for follow up.

The ways in which an EP system can be configured to collect and send electronic ADE reports will be a significant issue for future EP implementers, as well as for regulators, because of the growth in non-medical prescribing, together with the likelihood of increased use of EP systems by prescribers from other healthcare disciplines (which is why this issue is being considered under this chapter heading).

A possible process for electronic ADE reporting would be as follows:

(a) A healthcare professional (HCP) identifies an ADE in one of their patients.
(b) The HCP launches the ADE functionality of the EP system from whichever part of the EP system they are using (it would be important for the ADE functionality of an EP system to be accessed from many different parts of the EP system, in order to facilitate a high degree of ADE data capture).
(c) The ADE form would be launched. A patient identifier would be populated automatically (anonymised from the PAS).
(d) The HCP would be required to select which of the patient's current medications was implicated in the ADE. The system should allow selection of two or three suspect drugs. Selection in this way would allow the ADE form to be coded with the drug details.
(e) Using the coded drug details, there would then be an option for the HCP to view the known side effects of the suspect drugs for information.
(f) The HCP would then complete other ADE details – ADE type (MEDDRA code), ADE outcome (MEDDRA code), concomitant medication, and additional details.
(g) The reporter details (and clinician details, if different) would be supplied from the user database.
(h) If necessary, the ADE would then be flagged up to the attending doctor to be validated before transmission. In some countries, this might be a legal requirement; in others, it may be a convention for the healthcare provider organisation involved. However, it should be borne in mind that, if clinician validation is a prerequisite to submission of the ADE report, the number of reports submitted might be artificially limited, and ADEs may be lost to follow up.
(i) Once the ADE report has been sent, the details would need to be retained within the EP system database, with a unique identifier. Then, if the regulatory body or pharmaceutical company wanted to follow up the ADE report, to obtain further information, then the follow-up could take place. This might be by a message

to the EP system, triggering reactivation of the ADE record, or by an e-mail to the reporter, advising them to update the ADE record and resubmit it.

The functionality described here represents advanced EP functionality, and there are many potential barriers to its implementation. These include lack of agreement between the various stakeholders in both the regulatory and the healthcare sectors concerning data standards and reporting conventions, the organisational capacity of regulators to process the increased amount of ADE information that it might receive, and the likelihood that EP systems suppliers will incorporate such functionality into their systems in an appropriate and useable manner. Above all, there still remains the inertia of health professionals in reporting ADEs in the first place, despite the use of electronic systems to facilitate the process.

European regulatory bodies are working on a common dataset to allow the transmission of ADE data from pharmaceutical companies to licensing authorities. Furthermore, there is now an initiative where the European electronic ADE dictionary, MEDDRA, is being made available free to healthcare provider bodies,[16] which would provide the data support for electronic ADE reporting.

Non-medical Prescribing: Management and Clinical Governance

One of the advantages of all electronic systems is that they capture data on the business processes that they are designed to automate. Consequently, it is possible to extract data from these applications in order to manage and evaluate the business processes taking place. This may be to provide an audit trail – to ensure that the process is taking place in the way that it should, and that system users are working within their occupational roles. Alternatively, this data extraction may be to provide management reports, to show that levels of service are being met, to monitor the system throughput and to highlight areas of concern.

Management reporting and audit trails are an area of particular concern in prescribing and medicines management, where both standards of professional practice and the need to deliver health outcomes against costs are important drivers. General issues associated with management reporting from EP systems are discussed elsewhere in this book. However, it is important to note that the reporting and audit trail functions of an EP system have a particular role in management, training and service development of services and clinics led by non-medical prescribers.

One of the issues highlighted in publications on non-medical prescribing is that, at present, there is very little comparative data on the prescribing patterns of different professional groups[1] and, now that nurse and pharmacist independent prescribers are established, there is a pressing need for these data, in order to evaluate services provided and the skill mix required to provide them. The establishment of EP systems that support the activities of non-medical prescribers provides the environment

from which, in theory, such comparative data can be extracted. Nevertheless, as with reporting from electronic systems in general, there are some important caveats with the use of EP systems to provide management reports on prescribing patterns for different types of prescriber. These include (a) ensuring that prescribing data extracts for different prescriber groups are comparable and (b) ensuring that the user permissions dataset is structured in an appropriately granular manner to allow different prescriber types and details to be extracted reliably.

Conclusion

As a result of changes in service level targets, health professional availability and societal attitudes, there is a need for optimal use of "skill mix" within healthcare provider organisations. That is to say, all staff should be working to their maximum capability to enable the most effective service provision within the organisation. There is therefore a rationale for healthcare professionals other than doctors to take responsibility for prescribing in certain areas, for example, in specialty areas, or those where other professionals will have a greater knowledge of the products than doctors (e.g. dressings and dietary products). For this reason, prescribing by other professional groups is on the increase in countries around the world. EP systems have a number of benefits for a "mixed economy" of prescribers. They ensure that system access levels and prescribing processes are appropriate to each type of prescriber. Furthermore, EP systems are able to maintain records of training and accreditation for non-medical prescribers, and to provide support to different prescribers in terms of information support and CPD resources.

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Chapter 8
Electronic Prescribing and Future Priorities

As mentioned in the introduction, this book is not intended as an exhaustive review of EP research; rather, it is designed to help EP implementers and stakeholders to reflect on the various methodological, clinical and professional issues associated with electronic prescribing. The previous chapters have aimed to do this from the standpoint of a number of recognised benefit areas of EP systems. This final chapter is therefore arguably the most speculative chapter, as it aims to consider the future challenges and areas of development in EP implementation.

Many of the areas of innovation described here are very advanced, considering the proportion of healthcare providers in the UK and the US with EP systems, and the level of functionality provided by those EP systems. However, tender documents and output-based specifications (OBS) often consist of "blue skies" wishlists of possible future EP functions, often compiled by idealistic clinicians and managers, with no implementation experience, and it is worth exploring the possibility of some of these proposed functions.

Nevertheless, as a general rule, many implementers recognise the importance of implementing basic EP functions well within a hospital or healthcare provider, before enhancing the system to provide more advanced functions.

While this chapter cites some of the literature on emerging technologies which may have EP applications, it should be noted that these comments are made in the light of the author's experience across a range of medicines management IT applications.

The Challenge of Device Integration

As has been discussed in previous chapters, the interfacing of EP systems with other applications – in particular patient administration systems (PAS) and pharmacy systems – is desirable in order to promote the intraoperability of systems, and thus a seamless workflow for the user. As discussed, a seamless workflow promotes organisational efficiency and reduces risks associated with the rekeying of prescription data or the prescription data not being available to all users in real time. Therefore, an EP system should draw its patient demographic data from the PAS, take a feed

from the pathology system for test results and then transmit any medicine orders placed directly to the pharmacy system, which may also have an ongoing interface with a pharmacy robot.

The interfaces described above are established requirements with many EP implementations, and have been delivered in various different ways in different installations and with different products. However, an area as yet to be fully explored is that of interfaces or integration with other devices. The terms *interface* and *integration* are both used here, but they are not synonymous. In this context, *interface* is used to describe a data link between two stand-alone software applications, to enable the intraoperability of the two applications. *Integration* describes how a device, which may have limited operating software of its own, is linked into another system, which not only channels data to and from the device, but also provides the software routines to control and drive the device. The device thus becomes an integral part of the bigger system.

The point of interface or integration may be upstream from the prescribing workflow – monitoring devices, especially in the intensive care unit scenario – or downstream from the prescribing workflow – devices to facilitate therapy or drug delivery (Fig. 8.1).

Device integration upstream of the prescribing process generally has as its goal the facilitation of clinical decision support. It is recognised that decision support tools are an essential aspect of any EP system,[1] and that decision support applications have been in use in the US to support prescribing well before the widespread introduction of computerised ordering of medicines (CPOE).[2] However, as discussed in Chapter 5, decision support tools require accurate input information, in order to give an appropriate clinical warning to the user. Many decision support functionalities that have been developed thus far in EP systems – for example, drug
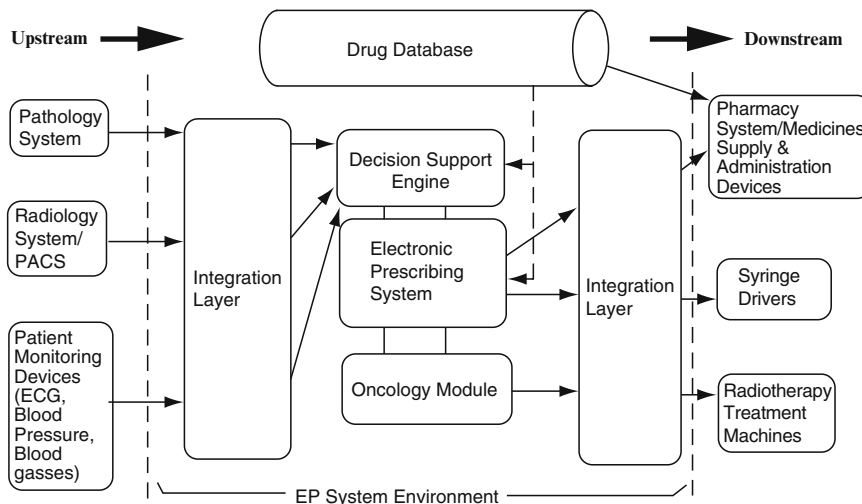
Fig. 8.1 Device integration upstream and downstream

interactions, duplicate therapy and drug doubling checking – are internally referential, as they use data that are already within the drug database of an EP system; data that are relatively static. Other decision support functions – such as sensitivity checking, contraindications and drug–disease warnings – rely on data from systems that are external to the EP system, usually data fields that are attached to the patient record on the PAS. These functions are more problematic because, although these data too are relatively static, there are potential issues with the currency of the patient-related data on a PAS record, with the effective transmission of that data between the PAS and the EP system and with conflict between data values stored in two different locations.

For example, an EP system may have links with a pathology system, or with a radiology system, with order communications and picture archiving computer system (PACS) functions. Many hospitals currently provide ward access to pathology systems, so that clinicians can review test results prior to prescribing drugs or amending drug doses. Electronic access to pathology system test ordering and results review functionality, along with EP functions, as part of an integrated clinical workstation is already a reality for some healthcare providers. However, it is to be hoped that in future there would be a direct data pull from a pathology system in order to facilitate the prescribing of certain drugs. For example, whenever a diuretic is prescribed, the system will automatically retrieve the latest potassium result from the pathology system, and display it (together with the date that the sample was taken) on the prescribing screen. There could also be the option for the prescriber to order new U&E tests from the prescribing screen. In addition to specific monitoring tests for individual drugs (for example, electrolytes with diuretics, or hematology results (hemoglobin, serum iron, etc.) for anemia treatments, there is the possibility of a batch feed of antibiotic susceptibilities to support a more complex decision support module for antibiotic prescribing.

Also, it is to be hoped that, eventually, hardware advances (monitor resolution enhancements) will allow an EP user to access radiology system functions and PACS on the same workstation as the EP system. However, full integration of PACS facilities into an EP system may be technically difficult and, in any case, with the possible exception of an oncology system where images are required for tumour staging, may not be a high priority, compared to some other integration requirements.

However, while the integrations described above can improve the prescribing decision support process, the logical goal of clinical decision support in electronic prescribing is a system that provides decision support intuitively, working with dynamic data from patient monitoring devices, such as blood pressure and blood gas monitoring devices.

In general terms, the EP software would respond to variations in dynamic monitoring data – for example, threshold or out-of-range triggers – and send a warning to the clinical user, either on screen on the application, or routed via a pager or SMS text message, advising them of the therapeutic options for the patient. In some care situations, especially critical care scenarios where the EP system was linked downstream to a syringe driver, it would be reasonable – and indeed necessary – for the EP system to make automatic dose adjustments, based on monitoring results.

Device integration downstream of the prescribing process is generally concerned with the automated scheduling and delivery of treatment to the patient. A standard example of this is the integration of a syringe driver with an EP system. Syringe drivers are devices that deliver injectable medicines from a syringe at a set rate of infusion. The device is programmable with the required infusion rate, and can detect blockages in the line and other interruptions to the flow rate. Syringe drivers with highly sophisticated control mechanisms are often referred to in the literature as "smart" pumps. However, it has been determined[3] that smart pump technology alone is unlikely to reduce medication errors without:

(a) Interface with an EP system, or an electronic patient record (EPR) system
(b) Bar-code-based medicines administration functionality
(c) Pharmacy information systems

Integration of a syringe pump with an EP system would enable, for example, a patient on an intensive care unit to be given a continuous infusion of isosorbide dinitrate injection in a Graseby type syringe driver, driven by an EP system. Then, if the patient developed hypotension, a warning message would be sent to a prescriber. The prescriber would adjust the infusion rate on the electronic administration profile of the EP system (possibly remotely), and the infusion rate would be automatically changed on the syringe driver.

Another area where there is established experience of integration with medical devices is in the field of oncology systems. Cancer treatment protocols are increasingly mixed-modality in their format; that is to say that a particular protocol for the treatment of a certain type of cancer might consist in total of some cycles of chemotherapy and some cycles of radiotherapy. Thus, in recent years, there has been an increasing need for oncology clinic management systems to be interfaced with radiotherapy treatment equipment, so that the clinic management software can schedule and deliver radiotherapy treatment as well as chemotherapy treatments. There are therefore a number of oncology systems that offer interfaces and integration with radiotherapy treatment machines. In some of these cases, clinic management software is developed as an add-on to the device control software, and this may not be satisfactory for providing full oncology prescribing functionality. In other cases, device integration is provided as part of a comprehensive suite of oncology clinic software. However, in either case, the fact remains that radiotherapy device integration expertise has been gained specifically within oncology management software and it may not be easy for software vendors to develop radiotherapy device integration within the context of a comprehensive general EP solution.

Other downstream device integrations might include integration with pharmacy systems and integration with ward-based medicine storage devices. Such integrations are designed to ensure the accurate and safe delivery of the medicine that has been prescribed. A number of EP systems have already been implemented with a link to the pharmacy system, with the data mapping issues that such a link entails. This integration enables the automatic ordering of medicines from the pharmacy and the seamless pharmaceutical supply chain, with the organisational benefits that it provides (see Chapter 3). A step further would be the integration of an EP system,

with a pharmacy system *and* a pharmacy robot, as this would facilitate automated, bar code mediated[4] product picking at the pharmacy. There is little experience of such an integration at the current time. Also, because of potential mapping issues with the data for each of the three systems, there is an argument for running the three systems from a single database platform. So, for example, if a comprehensive third-party drug database, mounted on a central server location, could be used as the data platform for all three applications, various technical issues associated with data mapping between the systems would be resolved.

In addition to facilitating the electronic ordering and supply of medicines using pharmacy system and robot interfaces downstream of the prescribing process, an EP system may also be integrated with medicine dispensing devices, such as ward-based electronic medicine dispensing cabinets (so-called "magic cupboards") and electronic drug trolleys.[5] Increasingly, in UK hospitals and elsewhere, medicines management services are patient-focussed and medicines for hospital inpatients are stored in a bedside medicines locker for each patient. A welcome future innovation, therefore, would be the development of electronic patient medicine lockers, so that medicines administration can be controlled on a patient by patient basis. In this way, the EP system will have close control over the medicine administration process.

By the integration of devices into the EP system in this way, decision support and monitoring processes for medicine use can be made automatic, closed-loop processes in just the same way that the diagnosis, prescribing and supply processes can be. Device integration, however, presents a number of major challenges to the advanced development of EP systems:

(a) The ability of EP software vendors to keep up with developments in medical device technology and produce appropriate interface and control routines for the devices that are in current use.
(b) The use of appropriate system algorithms for device control and data feeds.
(c) The development of appropriate data standards to support intraoperability between different device types.

Various larger software vendors have conducted some work on device integration but many of the interfaces and software routines developed are only at the prototype stage. The universal clinical use of a range of device interfaces in hospitals and healthcare provider organisations is still very much in the future, with the exception of centres where there is in-house healthcare informatics expertise, and a proven record of healthcare IT innovation.

Hardware Platforms and Infrastructure

Improvements in available hardware technology have impacted on EP system configuration. The earliest EP/CPOE systems consisted of a specific medicines management module of a hospital information system (HIS), which was usually configured as a series of terminals connected to a mainframe computer via a physical

local area network (LAN). Systems were subsequently developed on a client–server architecture, but still with a physical network connection.

While many such configurations provided adequate system performance for both EP order communication and decision support querying, the hardware was less than ideal for a clinical setting, consisting of large, cumbersome workstations, with a physical connection to each machine. Such hardware was not easily moveable, and the physical wiring had the potential to be a danger to staff. Most notably, it was difficult to structure such hardware around the operational environment, which is an important prerequisite for a successful EP implementation. Impractical hardware is one reason why clinical professionals may be ambivalent about EP implementation, and why systems may be unpopular at the outset, until actual benefits are demonstrated.

The development of smaller computers – laptop PCs and devices such as tablet PCs – together with wireless networks, have enabled workstations to become more portable, and thus support more clinical activities. The use of wireless workstations has enabled the development of electronic medicines administration, and allowed clinicians to prescribe medicines electronically while on the ward round.

There are, however, disadvantages and other considerations with these developments. While obviating the need for cumbersome cable connections, wireless networks have given rise to concerns about:

(a) *Network coverage*. Early implementers found that, due to the design of some old hospital buildings, wireless networks might have "cold spots" with no network coverage, which would interfere with the operation of the EP system.
(b) *Network security*. Without appropriate security measures, EP system data transmitted by wireless network could be accessed by unauthorised users. Since much of this data is relating to specific patients, this would constitute a confidentiality issue.

Also, while smaller, more portable devices offer the potential for fast functionality at the point of care, there are disadvantages with their use. Firstly, the smallest devices, such as personal digital assistants (PDAs), do not have a screen that is large enough and provides the necessary resolution for on-screen electronic medicines administration. Secondly, such machines are subject to wear and tear and damage due to spillage and knocks in the clinical environment. There is therefore the argument that, instead of using laptop PCs and tablet PCs, which are relatively expensive, durable workstations or thin client configurations should be used.

Consequently, implementers have looked to different device modalities to provide the right balance of functionality and durability in the clinical environment. Some of the earlier freestanding devices were very cumbersome, often with a battery pack that was heavy, yet which had a limited life. However, recent use of tablet PCs, with software mounted in a thin client configuration, has provided an inexpensive user interface, with an appropriate screen for medicines administration.

It is to be hoped that, in future, there will be development of portable hardware, specifically designed for EP applications, which will fully facilitate the prescribing

and medicines administration process in a near patient manner. PDAs are in routine use for other medical applications – most notably, clinical decision support, provision of reference information and clinical noting. Indeed, some clinical professionals use PDAs to support prescribing of medicines and to monitor medical treatment. While a PDA screen is too small to be used for electronic medicines administration, there is considerable potential for using PDAs for certain EP functions[6] – for example, monitoring functions, clinical noting for drug-related observations or decision support alerting functions.[7]

Assistive Technology

Most of the technology described in the previous section is concerned with stream-lining the patient care processes in hospital and enhancing professional practice. However, an important aspect of modern healthcare is the centrality of the patient in their treatment. As mentioned in earlier chapters, there has been a paradigm shift in the philosophy of healthcare in recent decades, which has been characterised by a number of factors:

(a) The consumerisation of medicine, where governments and health agencies are actively encouraging patients to exercise choice in their medical care, including the choices of therapy and practitioners.
(b) The diminishing paternalism of the medical profession, together with the rise in the autonomy and importance of other health professionals in service delivery, most notably nurses.

There have been many publications describing the role of the "empowered patient" in twenty-first century healthcare. Indeed, many aspects of the new NHS technology which is being implemented in the UK embody the principle of patient choice, for example the "choose and book" appointment booking system.

There is currently some empirical evidence, particularly in the area of renal medicine, to suggest that patients who are "empowered" in the care process may have improved disease outcomes.[8,9] This area warrants considerable further work in order to (a) develop research methodologies to quantify empowerment and (b) evaluate empowered patient care models for different disease areas.

It is clear that a significant area where patients can and should have a greater degree of autonomy, and play an active part in their own care, is in the management of chronic diseases. As discussed previously, it is recognised on both sides of the Atlantic that chronic diseases – such as diabetes, asthma and hypertension – are a major cause of increased patient morbidity and reduced quality of life, and therefore are a significant economic burden to the healthcare system. Such diseases are often treated with drugs whose role and pharmacological properties are well-established, but which require regular monitoring, and the most significant factor in the cost of these diseases is the cost of hospitalisation and acute treatment for a patient whose disease has become uncontrolled.

American commentators have identified the huge potential of EP systems to contribute to evidence-based medicine in patients with chronic diseases.[10] However, at the current time, in the US, EP systems are used in a small proportion of acute hospitals. There is therefore very little experience, if any at all, in the use of secondary care EP systems to gather monitoring data for patients with chronic diseases, either from GP systems (primary care systems) or from remote devices. This is a potentially major area of expansion for secondary care EP systems. There is the possibility that a healthcare-provider-based EP system might become the "hub" for care of chronic diseases in a series of patient populations in the community – for example, diabetes, asthma or hypertension, as shown in Fig. 8.2.

Appropriate technology – such as the Internet, digital televisions and mobile phones – would be used to support and enable the patient, as they take responsibility for their day-to-day self-care at home and in the community. Healthcare IT researchers have identified the potential of the electronic health record as a means of empowering the patient and supporting care process involvement.[11,12]

Such technology is termed in IT research as "assistive technology". Examples of assistive technology would include the following:

- Use of a mobile phone to submit blood glucose readings to a diabetes care module of an EP system. Warnings concerning the amendment of the monitoring schedule or the insulin regimen would then be automatically calculated and sent back to the patient via SMS text message.
- Use of a digital television in the patient's home to allow the patient to log on to patient monitoring Web facilities to view graphical monitoring information on their disease.
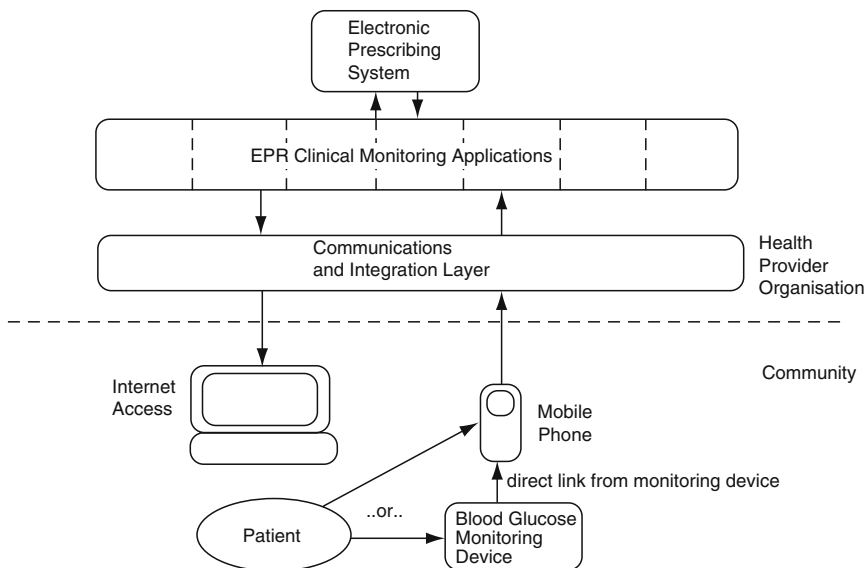
Fig. 8.2 An EP system as a "hub" for chronic disease management

It should be noted that, while the term, "assistive technology" is used in healthcare IT research to denote patient-centred technology, or "near patient" technologies, the term is used in the medical literature specifically to describe technology that helps to support people with specific disabilities – for example, wheelchair controls for those who are wheelchair bound.

While assistive technology to enable patients to manage chronic diseases might, at first sight, appear to be a form of device integration, assistive technology involves a wider range of device modalities and manufacturers than might be found in the acute clinical environment. Consequently, research in this area involves the coordination of a variety of stakeholders and is much more in its infancy, compared to medical device integration within the acute sector.

The remainder of this section will review a number of specific assistive technology prototypes. A number of studies have been conducted with the use of telemedicine software on mobile phones to help patients with the management of chronic diseases,[13] such as asthma and diabetes.

Anhoj et al.[14] evaluated a mobile phone SMS messaging system for collecting asthma diary data, in order to monitor asthma disease status, as an alternative to a Web-based data collection service. Previous experience had shown that the use of the Web site alone was suboptimal as a monitoring tool, due to variable availability; however, it was hoped that the use of mobile phones would be more successful for this application because of their ubiquitous presence and use in current society. The system trialled prompted users to make asthma diary entries on a regular basis, and if the collected data showed poor asthma control, the patient was automatically sent a text message telling them to make a doctor's appointment. This study concluded that an SMS text message service was a feasible way of collecting asthma diary data and had the advantage that, unlike clinical monitoring data uploaded from PDAs, SMS mediated data can be uploaded to the server in real time. However, users felt that access to the monitoring data via a Web site would still be useful, to enable patients to view collated data in personalised response graphs. While many mobile phone networks are now able to provide Internet access, many phones have a small screen which is not suitable for displaying detailed graphical information.

Farmer et al.[15] have studied the use of mobile phones for submitting blood glucose results by people with Type 1 diabetes. The patient texts both their reading and support data to the server, and the system responds by sending the patient a graphical feedback for their glucose monitoring results over a 2-week period. The graphical analysis was facilitated by nurse support. The study compared disease monitoring outcomes between two groups: an intervention group, using the telemedicine monitoring system, and a control group, using manual methods of blood glucose result recording. The study showed a significant reduction in median blood glucose levels with the telemedicine monitoring system, but no significant difference in the reduction of glycosylated hemoglobin (a marker of long-term blood glucose control) between the two groups. The authors concluded that the system would be enhanced by real-time decision support for medicine dosing, diet and exercise regimens.

Gammon et al.[16] studied the use of a system which transferred the blood glucose results for a child from the child's blood glucose testing device to a parent's mobile phone. The aim of the study was to conduct a preliminary assessment of the feasibility and use of the system, and the study was conducted with a group of 15 young people, between nine and fifteen years of age. The system was found to be easy to use, but its value was primarily as a means of reassurance for the parents; issues arose with the system concerning the independence and autonomy of the young person, and their attitude to parental control. Young people who were good at monitoring their blood glucose levels found that, with the system, the number of parental reminders was reduced, because the parents had evidence of the child's compliance with the monitoring requirement. As might be expected, for children who were less reliable at monitoring their blood glucose, the use of the system increased the number of parental interventions. The authors commented, however, that increased parental monitoring did not necessarily lead to improved glycaemic control, since it often led to conflict between the parent and the child, which had a negative effect on monitoring compliance.

Telemedicine monitoring systems such as this will need to be rigorously tested in future, firstly to ensure that they contribute to the efficacy and safety of patient care, and secondly to ascertain whether they have a beneficial effect on health outcomes. Gammon et al. indicated that such systems will need to be thoroughly tested, regardless of their likely effects on health outcomes, simply because their use will become widespread in the future.

Assistive technology and telemedicine may provide considerable benefits to well-motivated patients who are committed to monitoring their chronic diseases, and to the healthcare professionals that support them. In particular, real-time monitoring information feeds from stand-alone testing devices, or domiciliary telemedicine monitoring systems have the potential to contribute to decision support functions in EP systems both in the hospital and in the community. The interface of such systems with hospital EP systems, so that hospital clinicians can obtain a clear and reliable record of recent monitoring results (e.g. blood glucose readings with diabetes), may enable patients to be treated more efficiently in hospital for complications or relapses of their chronic diseases.

There are a number of barriers to adoption of assistive technology and telemedicine systems. They are as follows:

1. *Lack of a generic dataset*. A feature of many telemedicine prototypes is that their datasets are proprietary, and are specific to a particular device manufacturer. Work has recently been conducted on the development of a generic dataset, based on XML messaging, which can be used for a variety of devices and applications.[17]
2. *The willingness of stakeholders to cooperate in system development*. The development of such systems, together with their prototyping and testing, will require close collaboration between a wide range of stakeholders, including clinical professionals, health informatics specialists, hospital IM&T professionals, together with software and hardware/device vendors.

3. *The adoption of such modalities by patients and clinical professionals*. As discussed in Chapter 1, it is recognised that there is an adoption curve to a change or innovation. Depending on personality and worldviews, some individuals will embrace a change of procedure willingly, whereas others will be reluctant. Indeed, the greater the potential impact of a new technology on a patient's personal life – and a near-patient telemedicine monitoring system can have a potentially major impact of a patient's way of life – the more information and reassurance a patient will need to adopt a new technology or procedure. Patient attitudes to disease and illness will also be a factor. Some patients will not want to be "empowered" in the treatment of their illness; they would rather be passive and leave responsibility for treatment with a healthcare professional.

Identification and Communications Technologies

An EP system with decision support tools, full electronic medicine administration functions and an interface with the hospital pharmacy system is likely to lead to a considerable reduction in the risks associated with the prescribing and administration of medicines in hospitals, in particular the risks associated with the selection of a medicine, the dissemination and fulfillment of the order and the clarity of the administration instructions.

However, the use of identification technologies – optical bar codes and radiofrequency identification (RFID) technology – can further reduce the risk associated with medicine administration, by closing the loop of the medicine administration process. The ideal medicine administration scenario would therefore involve verifying both the identity of the patient and the identity of the drug to be administered. The patient's bar code on their wristband is scanned and the patient's identity is checked against the patient record on the EP system, where the demographic data are usually retrieved from the hospital PAS. When the identity of the patient has been confirmed, the identity of the medicine to be administered is then confirmed by scanning the bar code on the medicine pack before a dose of the medicine is administered to the patient.

The EP implementation at Charing Cross Hospital, London, UK,[5] used bar code identification of patients. At each medicine administration event, the EP system required the patient's bar code to be scanned, in order for the patient's drawer on the electronic drug trolley to be released, so that the nurse could access the patient's medication. This bar code patient identification function caused the percentage of occasions where the patient identity was not checked to be reduced from 82.6% to 18.9%. However, system compliance was limited by practices such as sticking the patient's bar code to their bedside cupboard, rather than to their wristband.

Bar codes are used for medicine identification by automated dispensing systems (pharmacy robots)[18] and within the pharmacy procurement process.[19] However, there is little documented experience of the use of medicine identification using bar codes in the context of EP system medicines administration at ward level. There are two main problems with the use of bar codes for medicine identification at the point of administration:

1. It is recognised that a proportion of medicinal products have erroneous or anomalous bar codes.[20] This is especially the case with branded generics and "specials". There would need to be an increase in the proportion of medicines that could be accurately identified by bar code for bar code medicine identification to be feasible in a variety of secondary care specialties.
2. Bar code medicine identification relies on original bar-coded packs being used for medicine administration at ward level. While this may be the norm in some countries, it is not routinely the case in the UK.

In due course, optical bar codes will be superceded by RFID technologies,[21,22] where an item is identified by a radiofrequency emitting tag. While this technology avoids the cumbersome and intrusive use of bar code scanners, which may be an advantage in the clinical environment, it is subject to the same issues that might arise with other wireless network technologies. These include (a) security of data transmission; (b) reliability of data transmission, given the geographical features of hospital buildings and (c) collision of data with data in other wireless networks.

While optical bar codes are not routinely in use for near-patient clinical applications, the use of RFID technologies for these applications is even further in the future. A major issue in the adoption of these identification technologies is the harmonisation of codes to allow their universal use at an international level. There is an initiative by the healthcare industries to standardise bar codes,[21] but the process is slow, and there is the danger that optical bar code technology will be obsolete by the time any international standard has been achieved, and that there will be no coherent standardisation strategy for RFID tagging. Nevertheless, system designers will need to consider how identification technologies can be incorporated into EP systems as they are developed over the next few years. Consideration will need to be given to where the identification codes are included in a database (and how they are implemented, if a third party dataset is used), as well as how the EP software would drive a bar code/RFID scanner.

At EP innovator sites such as Winchester in the UK, the need to have a physical connection to ward workstations initially limited the usefulness of the EP system. Peripatetic activities, such as electronic medicines administration at the patient's bedside, were simply not feasible in a busy acute setting, regardless of the hardware used. However, the growth of wireless network technology over the past decade has meant that EP software can be accessed from remote wireless units, be they laptop PCs, tablet PCs or trolley-type terminals. Thus, wireless networks have enabled near patient clinical activities such as real-time prescribing during a consultant ward round and electronic medicines administration by nursing staff. Wireless networks are also the way in which other EP system near-patient services will be facilitated in the future. These will include services such as medicines review, health education, clinical trial management and clinical audit, as discussed in Chapter 6. It is to be hoped that future refinements of wireless network technology – especially in the areas of data transmission and privacy – will be beneficial in developing expanded EP system features in a reliable and scaleable manner.

Issues and Limitations with Quantitative Research on EP Systems

In addition to the way in which hardware, software and communications technologies will affect the development of EP systems in future, consideration also needs to be given to the way EP systems are evaluated to assess their effects on organisational efficiency and risk management within a healthcare provider organisation.

While a number of large quantitative studies have been carried out in the US, there are very few quantitative data about EP system benefits for UK implementations. While qualitative reports have been published for a number of UK EP implementations,[23,24,25] only one centre – Charing Cross Hospital, London – has undertaken a systematic quantitative analysis of benefits.[5] In any case, there are many difficulties associated with the quantitative evaluation of EP system benefits. There are issues concerning the design and power of clinical informatics studies, such as those that would be designed to assess EP systems,[26] which have been discussed in Chapter 4. In addition, a number of issues have emerged during the actual conduct of EP system evaluation studies. These have included:

(a) The subjectivity of reviewers in the evaluation of adverse events and medication errors in these studies
(b) The lack of parallel studies between units with EP and those without EP in the same hospital
(c) Error detection bias in error reporting, due to the vigilance of researchers and users when evaluating a new system
(d) The extent to which the benefits reported are specific to the working practices of the sites studied. For these reasons, it has been suggested that there should be a formal methodology for validation of EP software, analogous to the process of licensing a new medicine[27]

As a consequence, there is an urgent need for ongoing quantitative analysis of new EP implementations and enhancements of existing systems. Moreover, there is a need for the quantitative evaluation of EP systems to keep pace with the development of the EP systems themselves, so that, as EP systems become more advanced, new benefits are statistically quantified and emerging risk issues are identified in an accurate and timely manner. This represents a huge future workload for EP implementers and health informatics specialists.

There is a particular need for quantitative benefits studies to be conducted on EP implementations in the UK, where the benefits identified are contextualised into the UK clinical setting. The extent to which benefits are offset by confounding factors associated with research methodology or systems design also needs to be evaluated in more detail.

Political Issues with EP

It is clear that there are various challenges for EP innovation in the future. These include:

(a) The development of advanced EP functionality and comprehensive decision support and, in particular, the various medical device interfaces that will be needed to support these advanced functions in a "closed-loop" process.
(b) The adoption of new hardware technologies and communications modalities to support expanded EP applications.
(c) Producing objective quantitative data on the operation of EP systems.

In addition to these issues, there is the work required to produce a comprehensive informatics infrastructure (i.e. coding and messaging of EP concepts) to support EP system interoperability across a range of healthcare provider settings (see Chapter 5).

The development of these advanced EP function sets will enable health professionals to develop the new paradigms of working practices described in Chapter 6.

However, EP systems are not developed in a vacuum. EP systems are designed and used by individuals who are clinical professionals and healthcare informatics specialists within particular healthcare provider settings, in association with particular software vendors, and working in a particular national setting. All of these will provide sociopolitical constraints, and new service developments in healthcare mediated by EP systems will only be developed if the political will exists to adopt them.

There are therefore a number of political issues that will have to be addressed during the next decade for EP implementation to gather pace. These are as follows:

• Engagement of clinical professionals

IT implementations in all sectors have not had a good record of designing software based firmly on recognised business processes or user needs, or of engaging their users with the proposed system prior to its implementation. Indeed, these two steps are interrelated: if the system is not designed so that it is "fit for purpose" for the actual processes that it supports, it will be correspondingly harder to win users over to using the system. Universal engagement with EP innovation by healthcare professions is an issue on both sides of the Atlantic. The English Connecting for Health programme conducted clinician engagement workshops in 2006,[28] but such consultations probably attract comments and input from clinical professionals who already have an interest in electronic prescribing. There is considerably more work to be done to engender interest in a broader constituency of healthcare professionals, in particular professionals who are involved with specialised clinical areas and whose input would be required to design advanced EP functionality in those specialties – for example, oncology, HIV infection treatment or mental health. In the US, it has been claimed that EP systems have only been fully adopted at urban centres of excellence, such as the Brigham & Women's Hospital, Boston, Mass., and that EP systems will not be implemented more universally across the US until there are national drug knowledge resources to support the implementation of such systems by healthcare professionals in more remote areas.[29]

- Engagement of a broad coalition of software vendors

At present, it is generally the case that EP system development is the preserve of specialist software developers. These may be IT personnel within healthcare provider organisations, or smaller, niche commercial organisations. In the UK, two organisations with considerable domain expertise in electronic medicines management (JAC Computer Services and Ascribe) are companies with a track record of developing and installing pharmacy management software. Currently, while many of the major players in health care IT development have established markets in systems such as PAS, order communications, laboratory and pathology systems, which are mature markets and therefore low-risk commercial propositions, few of these large companies have made headway in developing comprehensive EP solutions, either as stand-alone applications or as part of a larger suite of software. This is for a number of reasons, concerned with commercial risk compared to established functional areas, and the availability of pharmaceutical domain expertise to these companies.[30]

However, for EP systems to become more widely available, the active involvement of large IT vendors will be required. When larger software vendors become seriously committed to the development of EP solutions, designed to reflect actual healthcare processes, then (a) widespread adoption of EP systems will be facilitated, regardless of the existence of regional or national healthcare IT programmes and (b) the resources will be available to drive the development of some of the advanced EP functions described elsewhere in this book. The English national programme, Connecting for Health has proposed the development of a common user interface, so that all the screens for any given function set will look similar in any English hospital, regardless of the software vendor providing the software. However, such an initiative will only bear fruit when the larger IT vendors are willing to work in partnership with domain experts and niche software developers in developing the software.

- Fostering the emergence of national and international standards

While various international standards exist, or are in the process of being developed, for the storage and coding of medical and pharmaceutical concepts, there is no industry standard for EP system design, against which individual systems can be evaluated. This is undoubtedly due to the fact that EP systems are currently the preserve of a few specialist software houses, and are not currently in widespread use. Regional or national healthcare IT programme specifications, such as the CfH baseline specification, provide some guidance concerning required functionality, but quality standards, formulated from experience with actual implemented systems, are not yet available. Some work has already been done in this area, from the perspective of required decision support functions, in the US.[31] However, this task has not been embraced in other parts of the world, in particular the UK, where there has been some published experience with EP systems. The task of formulating standards is one that will come to the fore when EP systems are more widely available in first-world healthcare economies.

• Monitoring the efficacy of regional or national healthcare IT programmes

In the face of increasing diversity of available systems, together with a perceived need to rationalise the design process, so that the software for an entire healthcare economy is designed by just one or two software vendors, some countries have adopted a national programme approach to healthcare software innovation. England has such a programme with the Connecting for Health IT programme. However, CfH has been publicly criticised for its failure to deliver systems to time and to budget. There are a number of issues here. Firstly, some claim that the effectiveness of national and regional programmes are fundamentally flawed by competing commercial interests of IT vendors involved and the sheer scale of the project management process. Secondly, it is possible that the requirement to use CfH software has actually stifled EP innovation in some English hospitals.[32] Thirdly, it has been argued that large government-sponsored IT projects suffer from a lack of coordination which undoubtedly hinders their delivery schedule; this argument has been made in the UK for both hospital electronic prescribing[33] and the electronic transfer of prescriptions (eTP) in the community.[34]

It is essential, therefore, that in future the performance of government-sponsored national IT programmes in any healthcare economy is carefully monitored.

Conclusion

Currently, EP systems are in operation within just a small proportion of secondary care healthcare providers around the globe. An initial goal for all involved in EP system design, development and implementation must therefore be the more widespread adoption of EP systems. This may be facilitated by advances in hardware and communications technology, and also the development of robust data coding standards; a study of previous implementations suggests that technological changes in the past have led to the development of today's systems. However, current system functionality has only a proportion of the possible functions that could be mediated by a comprehensive EP system. The development of medical device interfaces and assistive technology applications will enable EP systems to play a role in telemedicine and near-patient healthcare management for the empowered patient. Thus, in addition to their potential for reducing risks associated with medicines management in hospitals, and improving the efficiency of healthcare provider business processes, EP systems also have the potential to play a key part in the management of chronic diseases, with profound effects on long-term healthcare expenditure and patient wellbeing.

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Appendix

Worldwide Experience of Hospital Electronic Prescribing

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North Carolina, USA	Spencer D.C., Leininger A. et al. Am. J. Health Syst. Pharm. 2005; 62: 416–419
Tennessee, USA	Fitzhenry F., Peterson J.F. et al. J. Am. Med. Informat. Assoc. 2007; 14: 756–764
Indiana, USA	Tierney W.M., Miller M.E. et al. J. Am. Med. Assoc. 1993; 269: 379–383
Salt Lake City, USA	Evans R.S., Pestotnik S.L. et al. New Eng. J. Med. 1998; 338: 232–238 (and other references)
Ohio, USA	Mekhjian H.S., Kumar R.R. et al. J. Am. Med. Informat. Assoc. 2002; 9: 529–539
Bristol, England	Gray S., Smith J. Healthcare Pharm. 2004; August: 20–22
Burton on Trent, England	Curtis C., Ford N.G. Pharm. J. 1997; 259: 734–735
Wirral, England	Farrar K. Pharm. J. 1999; 263: 496–501 (and other references)
Ayr, Scotland	Fowlie F., Bennie M. et al. Pharm. J. 2000; 265 (Suppl): R16
Sunderland, England	Foot R., Taylor L. Pharm. J. 2005; 274: 210–212 (and other references)
Birmingham, England	Nightingale P.G., Adu D. et al. Br. Med. J. 2000; 320: 750–753
London, England (University College Hospital)	Shulman R., Singer M. et al. Crit. Care 2005; 9: R516–R521
London, England (Charing Cross Hospital)	Franklin B.D., O'Grady K. et al. Qual. Saf. Health Care 2007; 16: 279–284
London, England (Institute of Child Health, UCH)	Jani Y.H., Ghaleb M.A. et al. J. Pediatr. 2008; 152: 214–218
Stockholm, Sweden	Sjoborg B., Backstrom T. et al. Int. J. Med. Inform. 2007; 76: 497–506
Heidelberg, Germany	Seidling H.M., Al Barmawi A. et al. Eur. J. Clin. Pharmacol. 2007; 63: 1185–1192
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