

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



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Electronic Medication Management Systems

A Guide to Safe Implementation

**Electronic Medication
Management Systems**
A Guide to Safe Implementation
2nd Edition

AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

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Preface

Medication errors remain the second most common type of medical incident reported in hospitals and, of all medication errors, omission or overdose of medicines occurs most frequently. Reducing all errors will significantly improve patient safety and the quality use of medicines.

An electronic medication management (EMM) system enables prescribing, supply and administration of medicines to be completed electronically. EMM covers the entire hospital medication cycle including prescribing by doctors, review and dispensing of medication orders by pharmacists, and administration of medicines by nurses. EMM reduces medication errors through improved prescription legibility, dose calculation and clinical decision support. It enables best practice information to be more readily available to prescribers and improves linkages between clinical information systems. It can also improve efficiency in the medication management process, such as reducing the time required to locate paper medication charts or to supply non-imprest medicines.

EMM systems can reduce medication errors, but they also have the potential to adversely affect safety and quality of care if the system is poorly designed and implemented, and under-resourced. This risk is highlighted in a number of studies that show increased medication errors following poorly planned implementations of EMM systems. With many Australian hospitals planning to implement EMM systems, it is essential that this risk is minimised by considering the international literature and learning from the experiences of early Australian EMM system implementations.

Implementing an EMM system within a hospital is a major transformational project that substantially affects clinical service delivery, hospital departments and the work of clinicians. It requires extensive pre-implementation planning, including initial scoping, developing a business case, evaluating and selecting an EMM system product, and conducting a detailed implementation planning study. It is essential that the project is adequately resourced, that change is managed effectively, and that the project has the endorsement and full support of the hospital executive and senior clinical staff.

Electronic Medication Management Systems – A Guide to Safe Implementation (2nd edition) has been produced by the Australian Commission on Safety and Quality in Health Care and the National E-Health Transition Authority to assist hospitals to safely implement EMM systems. The guide has been informed by a review of international literature, the experiences of previous Australian EMM system implementation sites and extensive stakeholder consultation to provide guidance on the activities required for a safe and effective EMM system implementation. This edition also incorporates

feedback from individual hospitals and jurisdictions that have either implemented EMM or progressed their EMM planning since the first edition of the guide. This edition includes additional sections on:

- use of the Pharmaceutical Benefits Scheme (PBS) in private hospitals
- use of the PBS in public hospitals that can access the PBS on discharge and in outpatient settings
- medication reconciliation
- alignment of discharge medicines with medicine information in discharge summaries.

The use of this guide by hospitals implementing EMM was endorsed by state, territory and Australian Government health ministers in November 2011. An implementation plan is also provided as the key planning tool for hospital EMM system implementation.

Acronyms and abbreviations

ACSQHC	Australian Commission on Safety and Quality in Health Care
ADR	adverse drug reaction
AMT	Australian Medicines Terminology
BCM	business continuity management
BPMH	best possible medication history
CDA	clinical document architecture
CEO	chief executive officer
CIO	chief information officer
CIS	clinical information system
DTC	drug and therapeutics committee
EMM	electronic medication management
ETP	electronic transfer of prescription
GP	general practitioner
HDU	high-dependency unit
HL7	Health Level 7 (a health standard messaging format)
ICT	information and communications technology
ICU	intensive care unit
IPS	implementation planning study
ISMP	Institute for Safe Medication Practices (United States)
ISO	International Organization for Standardization
NEHTA	National E-Health Transition Authority
NHS	National Health Service (United Kingdom)
NIMC	National Inpatient Medication Chart
NPC	National Product Catalogue
NPSA	National Patient Safety Agency (United Kingdom)
PAS	patient administration system
PBS	Pharmaceutical Benefits Scheme
PIR	post-implementation review
PRN	as required (medication)
UAT	user acceptance testing
XML	extensible mark-up language

Overview

This section outlines the purpose, scope, content and structure of this guide.

1.1 Purpose

This guide supports the safe and effective implementation of electronic medication management (EMM) systems in Australian hospitals. It reflects the overarching principle that the potential for harm as a result of poorly implemented EMM systems should be recognised and minimised through diligence in product selection, work practice change and end-to-end implementation. Specific goals are that this guide should:

- be relevant for use in all Australian public and private hospitals, and applicable in a software-independent manner
- provide advice that covers the range of EMM system functions and implementation strategies
- provide advice that is informed by published literature and Australian experiences in implementing and operating EMM systems.

1.2 Scope

The first edition of this guide was informed by a review of the publicly available literature (up to September 2010), the experience of early implementations of EMM systems in Australia and extensive consultation with stakeholders with considerable experience in medications safety.

Several key documents were also used to inform the guide:

- Australian Pharmaceutical Advisory Council (APAC). *Guiding Principles to Achieve Continuity in Medication Management*, APAC, Canberra, 2005.
- Australian Commission on Safety and Quality in Health Care (ACSQHC). *National Inpatient Medication Chart User Guide*, ACSQHC, Sydney, 2010.¹
- ACSQHC. *National Terminology, Abbreviations and Symbols to be Used in the Prescribing and Administering of Medicines in Australian Hospitals*, ACSQHC, Sydney, 2006.
- Institute for Safe Medication Practices (ISMP). *Guidelines for Standard Order Sets*, ISMP, Horsham, PA, 2010.
- National Health Service (NHS) National Patient Safety Agency (NPSA). *Design for Patient Safety: Guidelines for Safe On-Screen Display of Medication Information*, NHS NPSA, London, 2010.
- NHS. *ePrescribing Functional Specification for NHS Trusts*, NHS, London, 2007.
- Australia's National Medicines Policy.²

The literature review is available on the ACSQHC web site at:
www.safetyandquality.gov.au

1 www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/com-pubs_24380-NIMC-UserGuideIncPaed

2 www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-2 (accessed 28 March 2010)

This guide addresses the following aspects of EMM system implementation:

- the context and requirements for EMM, including the strategic context, business context, the place of EMM in the Australian healthcare system, and functional and technical requirements for EMM systems
- organisational considerations, such as the roles of principal stakeholders and key users, governance, change management and ongoing organisational requirements
- the implementation project, including developing the business case, evaluating and configuring an EMM system, go-live activities and post-implementation review.

The guide also includes a number of key functional and technical specifications required for an EMM system. These have been identified based on advice received through consultation with early Australian EMM implementers, expert stakeholders, and a review of Australian and international literature.

1.3 Exclusions

Some elements of hospitals' medication management processes have not been included in this edition of the guide because they have not yet been implemented as part of a comprehensive EMM system in Australia. These elements will be considered for inclusion in future editions, in line with Australian experience. Their exclusion from this edition does not imply that they are not important or are of lesser significance for the operation of a comprehensive EMM system.

Excluded elements are the prescription and management of specialty medicines and functions that have not yet been implemented in Australia as part of an integrated EMM solution, such as:

- infusions and monitoring of fluid balance
- chemotherapy
- renal dialysis
- paediatrics.

EMM systems for these specialist functions have been implemented either as stand-alone solutions or as part of other specialty-based information systems, such as intensive care systems. A supplementary paper, *Electronic Medication Management Systems – Specialist Functions*, considers these issues and is available on the ACSQHC web site.

Other elements that are excluded from this edition are interface requirements between the EMM system and hospital pharmacy stock control systems or automated dispensing systems (pharmacy or ward based); and interfaces with community prescribing and dispensing (including general practice, community pharmacy and aged care).

1.4 Additions

Electronic Medication Management Systems – A Guide to Safe Implementation (2nd edition) incorporates feedback from individual hospitals and jurisdictions that have either implemented EMM or progressed their EMM planning since the first edition of the guide. This edition includes additional sections on:

- use of the Pharmaceutical Benefits Scheme (PBS) in private hospitals
- use of the PBS in public hospitals that can access the PBS on discharge and in outpatient settings
- medication reconciliation
- alignment of discharge medicines with medicine information in discharge summaries.

An updated implementation plan is also provided as the key planning tool for hospital EMM system implementation.

How to use this guide

The Australian Commission on Safety and Quality in Health Care (ACSQHC) strongly recommends that the electronic medication management (EMM) project sponsor, project manager, project team and senior stakeholders read this guide in its entirety.

This guide consists of three sections:

- A EMM system context and requirements** – including priority implementation issues, and functional and technical requirements
- B EMM organisational considerations** – including key issues for stakeholders, governance, change management and the sustainability of the EMM system
- C The EMM implementation project** – including project management, the implementation planning study, system build, and implementation and go-live activities.

Not all aspects of EMM implementation will be relevant to all stakeholders; however, ACSQHC strongly recommends that the EMM project sponsor, senior stakeholders, the project manager and the project team read this guide in its entirety.

Senior stakeholders include the:

- chief executive officer
- chief information officer
- director of medical services or medical champions
- director of pharmacy
- director of nursing and midwifery
- drug and therapeutics committee.

Key users include:

- prescribers
- pharmacists
- nurses and midwives.

Key issues for senior stakeholders and users are discussed in Chapter 10. Relevant sections for stakeholders who require specific information are listed below. These include:

- clinicians
- private hospitals
- Australian Government-funded programs
- members of EMM governance
- information and communications technology (ICT) personnel participating in EMM implementations.

2.1 Clinicians

Clinicians must read the following sections of this guide:

- The case for change (Chapter 3)
- The role of the medical director or medical champions (Section 10.1.2)
- The role of the director of pharmacy (Section 10.1.3)
- The role of the director of nursing and midwifery (Section 10.1.4)
- The role of the drug and therapeutics committee (Section 10.1.6)
- Prescribers (Section 10.2.1)
- Functional component 4.0: Pharmacy review (Section 9.2)
- Functional component 5.0: Medication dispensing (Section 9.2)
- Functional component 6.0: Medication administration (Section 9.2)
- Reference group and specialty subgroups (Section 11.5)
- Identifying clinical champions and change agents (Section 12.5)
- Business process mapping and redesign (Section 16.3)
- Training and materials (Section 16.9.2)
- User acceptance testing (Section 17.7).

2.2 Private hospitals

Private hospitals should pay particular attention to:

- PBS for private hospitals (Section 7.3).

2.3 Australian Government–funded programs

Material related to Australian Government–funded programs can be found in:

- PBS for public hospitals (Sections 7.1 and 7.2)
- PBS for private hospitals (Section 7.3).

2.4 Members of EMM governance

Members of EMM governance should consider the following sections of this guide:

- Essential elements for EMM implementation (Chapter 4)
- Principal stakeholders and key users (Chapter 10)
- Developing the EMM business case (Section 15.1)
- Governance (Chapter 11)
- Risks and issues management (Section 11.6.4)
- Project reporting (Section 11.6.5)
- Implementation sequence planning (Section 16.6)
- Change management (Chapter 12)
- Evaluation planning (Section 16.7)
- Benefits management planning (Section 16.8)
- Education and training (Section 16.9)

- Project communications (Section 16.10)
- Quality management (Section 16.11)
- Escalation strategy (Section 18.5)
- Rollback (Section 18.7).

2.5 Information and communications technology personnel

ICT personnel, including the chief information officer, should read the following sections of this guide:

- Chief information officer (Section 10.1.5)
- Strategic context (Section 6.1)
- Technical components – software (Section 9.3)
- Technical components – hardware (Section 9.4)
- Technical components – business continuity management (Section 9.5)
- Reference group and specialty subgroups (Section 11.5)
- Acquiring technical infrastructure (Section 17.1)
- Planning business continuity management (Section 17.1)
- Building the technical environments (Section 17.3)
- Non-functional testing (Section 17.4)
- Developing interfaces to key support systems (Section 17.6)
- User acceptance testing (Section 17.7).



Section A

EMM system context and requirements

This section covers:

Chapter 3 The case for change

Chapter 4 Essential elements for EMM implementation

Chapter 5 The medication management continuum

Chapter 6 The EMM strategic and business contexts

Chapter 7 EMM and the Pharmaceutical Benefits Scheme

Chapter 8 EMM and the National Medication Work Program

Chapter 9 Functional and technical specifications for EMM systems.



The case for change

In Australia, around 2–3 per cent of hospital admissions are medication related and 10 per cent of patients attending general practice experience adverse drug events. Medication error rates are particularly high in elderly patients and during transfer of care between hospital and community settings — it has been estimated that 52–88 per cent of transfer documents contain an error. Apart from the need to minimise harm to patients, implementing systems to enable electronic transfer of prescriptions and safe management of a patient's medicines at the point of care will reduce duplication, waste and system-wide inefficiency.³

This guide provides advice on the activities required for the safe and effective implementation of an electronic medication management (EMM) system. It includes guidance on the scoping, selection, configuration, implementation and ongoing operation of a safe EMM system. With many Australian hospitals planning EMM system implementations, this guidance prevents hospital project teams from having to start from scratch, and ensures that the key factors that influence safe and successful EMM system implementation are considered at the outset.

The use of EMM for ordering medicines has been cited as the most promising application of information technology to help reduce serious medication errors.⁴ Automating the medication ordering process produces standardised, legible, complete orders⁵ and, when combined with clinical decision support systems, can reduce medication error.⁶ Incorporating clinical decision support within EMM improves the quality and safety of medicines use by increasing guideline uptake and adherence.

The first Australian study of the effect of EMM on error rates for hospital inpatients identified a significant decrease in prescribing errors related to incorrect documentation of medication orders. Effective clinical decision support was required to reduce errors related to ordering decisions.⁷

However, there is the risk of unintended consequences and introducing new errors if the EMM implementation is not well planned, has no clinical decision support or the system is not linked to other key hospital systems. As stated by Ammenworth et al., 'poorly designed applications and failure to appreciate the organisational implications associated with their introduction can introduce unexpected new risks in patient safety'.⁸

Australian and international professional bodies strongly endorse EMM implementation (Box 3.1).

3 National Health and Hospitals Reform Commission. *A Healthier Future for All Australians*. Final report of the NHHRC, 2009. www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report (accessed 23 January 2011).

4 Horsky J, Kaufman DR, Oppenheim MI, et al. A framework for analyzing the cognitive complexity of computer assisted clinical ordering. *Journal of Biomedical Informatics* 2003;36(1–2):4–22.

5 Khaushal R, Shpjana KG, Bates D. Effects of computerized physician order entry and clinical decision support systems on medication safety. *Archives of Internal Medicine* 2003;163:1409–1416.

6 Schiffman R, Liaw Y, Brandt C, Corb G. Computer-based guideline implementation systems: a systematic review of functionality and effectiveness. *Journal of the American Medical Informatics Association*. 1999;6(2):104–114; Khaushal R, Shpjana KG, Bates D. Effects of computerized physician order entry and clinical decision support systems on medication safety. *Archives of Internal Medicine* 2003;163:1409–1416; Ammenworth E, Schnell-Inderst P, Mcachan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. *Journal of the American Medical Informatics Association* 2008;15(5):585–600.

7 Westbrook J, Lo C, Reckmann M, Runciman W, Braithwaite J, Day R. The effectiveness of an electronic medication management system to reduce prescribing errors in hospital. In: Hansen D, Schaper L, Rowlands D, eds. 18th Annual Health Informatics Conference: Informing the Business of Healthcare. Melbourne Convention and Exhibition Centre, Melbourne: Health Informatics Society of Australia; 2010:96–100.

8 Ammenworth E, Schnell-Inderst P, Mcachan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. *Journal of the American Medical Informatics Association* 2008;15(5):585–600.

Box 3.1 Endorsements of EMM from professional organisations

- The Australian Medical Association 'supports the development of an ePrescribing system as a fundamental building block for a national health (eHealth) system in Australia'.
- The Royal Australian College of General Practitioners 'supports e-prescribing, which delivers considerable benefits to GPs and other medical practitioners'.
- The Pharmacy Guild of Australia endorsements include that 'electronic prescribing is a national priority', and that 'electronic prescribing is not technology for technology's sake — it has genuinely beneficial health consequences'.
- The Pharmaceutical Society of Australia considers ePrescribing as 'an exciting step forward that potentially can improve the continuum of care, reduce medication errors, and assist with management of "owing scripts" in aged care homes'.
- The National Health and Hospitals Reform Commission issued its report *A Healthier Future for All Australians* in June 2009. The report states that 'electronic prescribing and medication management capability should be prioritised and coordinated nationally, perhaps by the development of existing applications (such as PBS online), to reduce medication incidents and facilitate consumer amenity'.
- The Australian Government Department of Health and Ageing states that 'electronic prescribing and dispensing of medicines is a key eHealth initiative aimed at improving the delivery and quality of health care and achieving better health outcomes'.
- The National E-Health Transition Authority states 'e-Medication Management ... will result in an improved use of medicines and reduction of the number of adverse medication events! It will 'avoid hospitalisation or death due to adverse effects'.
- The Australian Health Ministers' Advisory Council's National E-Health Strategy includes electronic sharing of prescriptions as a priority, along with decision support for medication management.
- The United States Congress commissioned the report *Preventing Medication Errors* by the Institute of Medicine that states: 'Many efficacious error prevention strategies are available, especially for hospital care. In the hospital setting, there is good evidence for the effectiveness of computerised order entry [including e-prescribing] with clinical decision support systems'. It also states: 'Paper-based prescribing is associated with high error rates. Having all pharmacies receive prescriptions electronically would result in fewer errors than occur with current paper or oral approaches. Electronic prescribing is safer because it eliminates handwriting and ensures that the key fields (for example, drug name, dose, route, and frequency) include meaningful data'.
- The Institute for Safe Medication Practice published a medication safety alert entitled 'Savings offset costs associated with CPOE [computerized physician order entry]: can you afford to omit it in future strategic plans?', which concluded that 'CPOE [including e-prescribing] is a cost effective solution', and that 'every day lost in implementing [this] new technology means more lives lost'.

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Essential elements for EMM implementation

Australian hospitals where electronic medication management (EMM) systems have been implemented have indicated that EMM was the most complex system and process redesign project they had undertaken. EMM system implementation affects almost all the hospital's clinical staff and many aspects of the hospital's business.

This chapter identifies priority implementation issues that must be addressed when implementing EMM. The issues represent the main items that a successful EMM implementation will depend on.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) included this chapter at the request of hospitals that are either planning or implementing EMM. This chapter can help focus executive attention on the 'big-ticket' items that need to be addressed; however, ACSQHC recommends that the EMM project sponsor, project manager and project team read this entire guide.

Essential elements for safe and successful EMM implementation within hospitals are:

- medication safety
- top-level engagement, leadership and commitment from the chief executive
- sufficient funding to fully implement EMM within realistic timeframes
- robust governance structures that include strong clinical champions and EMM proponents from each clinical profession
- substantial engagement by staff specialists or visiting medical officers that are prepared to use EMM and encourage EMM use by colleagues and staff
- an experienced project manager and an appropriately resourced project team that reflects the EMM scope and complexity
- a carefully defined clinical scope for EMM (e.g. general inpatient areas, high-dependency or intensive care units, paediatrics, emergency department), including how medicines will be managed at the boundaries of the EMM scope
- clarification of the relationships between the EMM system and other clinical and administrative systems, where EMM is not part of a broader clinical suite. Of particular importance are the relationships between the EMM system and
 - diagnostic and pathology orders and results
 - allergies and adverse drug reactions records
 - medication histories on admission
 - discharge prescriptions and discharge summaries

- definition of the minimum level of clinical decision support that will be implemented with the EMM system and how this will be increased over time
- wireless bedside or point-of-care access to EMM
- robust technical infrastructure supporting EMM around the clock
- integration of EMM with pharmacy dispensing systems to avoid transcription errors and data duplication, and to improve the efficiency of pharmacy services
- business continuity plans that are implemented in the event that the EMM is unavailable, including the transition to and from paper medication charts
- the use of Australian health information and technology standards as they become available.

The medication management continuum

This chapter describes the medication management continuum and provides the context for the primary focus of this guide – medication management in hospitals. In Australia so far, electronic medication management (EMM) systems have only been implemented in the hospital inpatient setting. It is important to understand the context for inpatient medication management and the opportunities to extend the scope of EMM within hospitals to include ambulatory settings.

The medication management continuum in Australia incorporates:

- community-based medication management, including prescribing and dispensing in the out-of-hospital sector by general practitioners, specialists and community pharmacies
- inpatient medication management (the main focus of this guide)
- ambulatory medication management, including medication management in emergency, day procedure, outpatient and community settings
- the processes that support or impede the sharing of medicines information across these sectors.

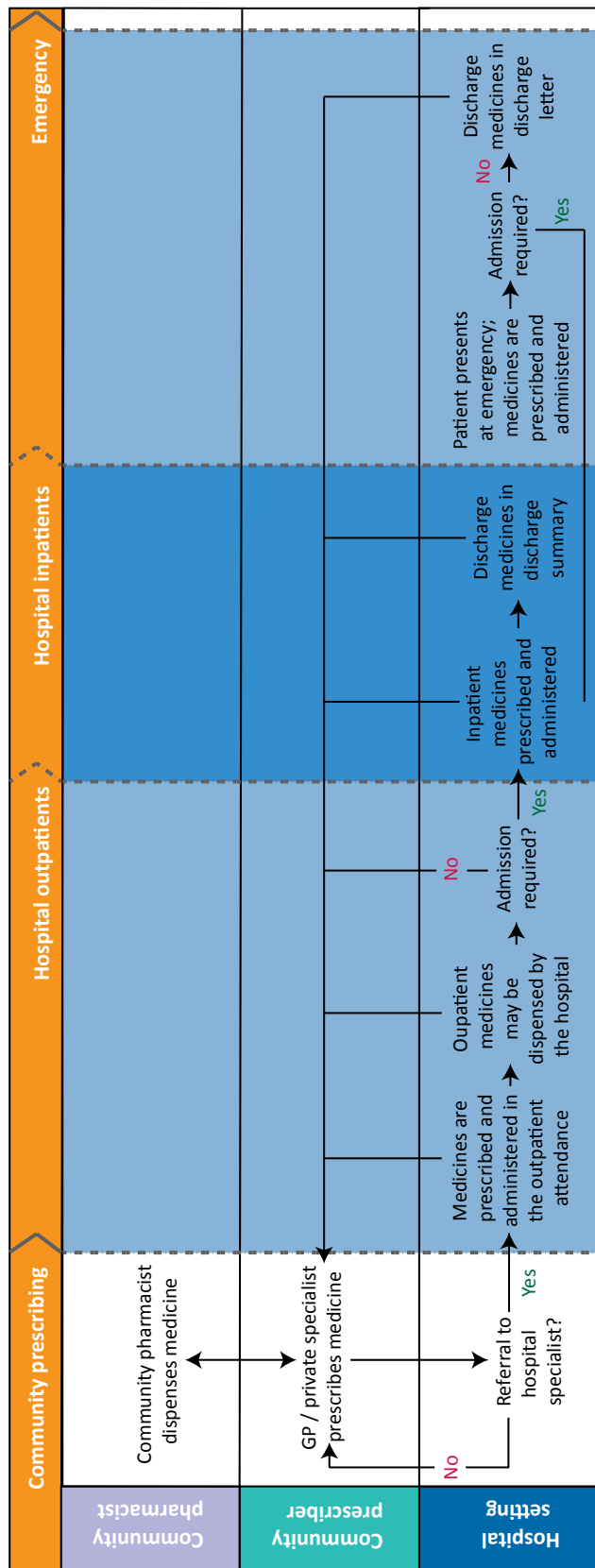
The medication management continuum is illustrated in Figure 5.1.

5.1 The inpatient medication management process

For the purpose of this guide, inpatient medication management consists of:

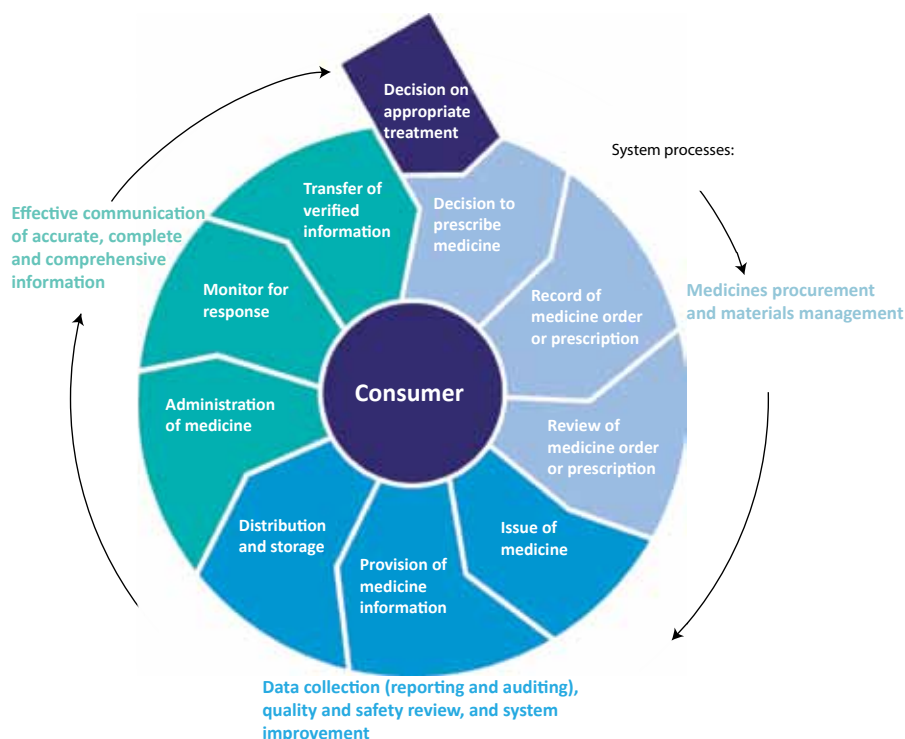
- reconciling medicines on admission
- prescribing medicines
- reconciling medicines ordered
- documenting the administration of medicines
- prescribing discharge medicines
- reconciling medicines on discharge.

This definition is consistent with the Australian Pharmaceutical Advisory Council (APAC) guiding principles to achieve continuity in medication management, illustrated in Figure 5.2.



Note: This guide considers the scope of hospital inpatient electronic medication management (EMM; shaded dark blue; see Figure 5.3 for more details). Opportunities to extend the EMM continuum within the hospital setting are shaded light blue.

Figure 5.1 The medication management continuum



Adapted from APAC 2005⁹

Figure 5.2 Guiding principles to achieve continuity in medication management

Figure 5.3 provides a high-level overview of the major components of a hospital's inpatient medication management process that must be supported by an EMM system. The diagram illustrates the medication continuum, and the typical relationship between the roles of prescribers, pharmacists, nurses and midwives in inpatient medication management. The responsibility for some of these roles may differ between organisations (e.g. pharmacists or nurses may record the medication history on admission in some hospitals).

The medication management components illustrated in Figure 5.3 consist of the following activities. In some instances, roles may overlap within activities.

On admission (or pre-admission):

- Prescribers, pharmacists, nurses or midwives record a current patient medication history, including all the medicines taken by the patient in the period before admission (prescription, over-the-counter and complementary medicines), information about any previous adverse drug reactions (ADRs) and allergies, any recently ceased or changed medicines, and an assessment of the patient's medication-taking behaviour.¹⁰ The medicines are verified using more than one source. This is known as the best possible medication history (BPMH).

⁹ Australian Pharmaceutical Advisory Council (APAC). *Guiding Principles to Achieve Continuity in Medication Management*, APAC, Canberra, 2005, p. 11.

¹⁰ Australian Pharmaceutical Advisory Council (APAC). *Guiding Principles to Achieve Continuity in Medication Management*, APAC, Canberra, 2005.

- Prescribers create a medication chart that includes the medicines to continue during the admission. They identify any new or changed medication orders, and document the medication plan for the patient.
- Prescribers record medicines ceased or withheld at admission.
- Medical officers, pharmacists, nurses or midwives check the medicines ordered against the BPMH. Any discrepancies are reconciled with the prescriber and reasons for changes are documented.

During the inpatient stay:

- Prescribers create new medication orders (either individually or in a set), edit or cease medication orders, record clinical notes regarding medication orders, review the patient's medication history and current medication chart, and view medicines reference information.
- Pharmacists review medication orders, suspend medication orders if inappropriate or unclear (and record reasons for suspending), record clinical notes regarding medication orders, review and reconcile the patient's medication history with the medicines on the current medication chart (on admission and transfer between wards), record the dispensing and supply of medicines, and view medicines reference information.
- Nurses and midwives record details of administration of medicines, review and edit medication administration record, record clinical notes regarding administration of medicines or other clinical information (e.g. physiological monitoring data), review the patient's medication history and current medication chart, create nurse-initiated medication orders, and view medicines reference information.

On discharge:

- Prescribers review the current medication chart, and decide to continue or cease medication orders.
- Prescribers create the discharge medicines prescription from the patient's medication chart and BPMH, consisting of medication orders prescribed during the inpatient stay that are to continue on discharge, new medicines prescribed, and any medicines withheld on admission that are to be resumed on discharge.
- Prescribers provide patient medicines information for the discharge summary reflecting medicines on admission, medicines prescribed during the admission and medicines on discharge, and listing reasons for any changes between admission and discharge.
- Pharmacists review the discharge medicines prescription against the BPMH and the current medication chart before dispensing. The pharmacist may amend the discharge medicines prescription following discussion with the prescriber. The discharge summary is then amended by the prescriber.
- Pharmacists prepare a complete list of medicines prescribed on discharge for the patient, including changes made to the medicines during the episode of care.

On readmission:

- Prescribers recall a patient's previous medication records including medicines recorded at previous admissions and discharges for review.
- Prescribers use the most recent discharge medicines list (when appropriate) to populate the medication chart as required for the new episode of care.

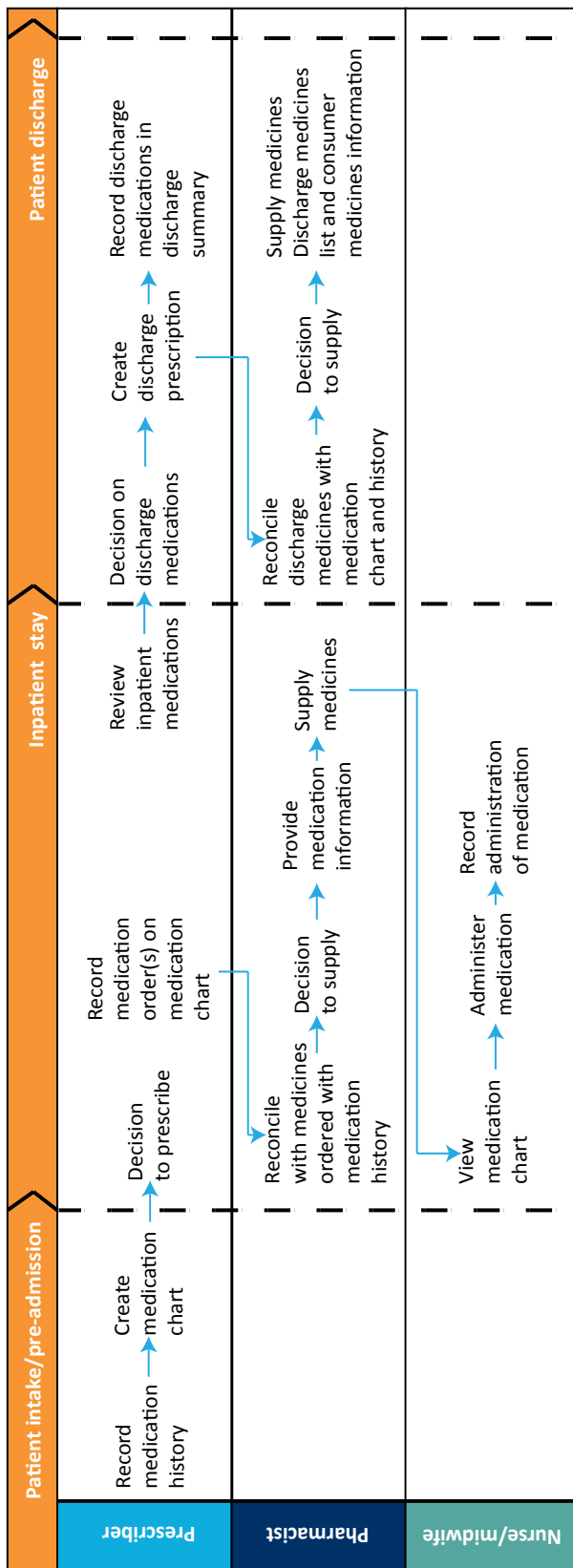


Figure 5.3 Inpatient medication management in hospitals

The EMM strategic and business contexts

Two critical elements need to be considered before developing an electronic medication management (EMM) business case or starting an EMM implementation planning study:

- the strategic context within which the EMM will operate, including how the medication components or systems relate to other clinical components or systems in the hospital (either existing or planned).
- the business context for the EMM system and how the boundaries of the EMM system will be managed to ensure medication safety across the medication continuum within the hospital.

6.1 The strategic context

In Australia, there are two main approaches to implementing an EMM system:

- as a separate EMM software product that is integrated with or interfaced to other key hospital systems (such as pathology and patient administration)
- as part of a comprehensive clinical system that may also include other functions such as orders and results reporting, clinical pathways and clinical documentation.

The approach taken will be influenced by the hospital's information technology strategy and application architecture. This is a critical decision for the hospital and is a priority for the hospital executive, guided by the chief information officer.

Where more than one EMM system is in use within the hospital, careful consideration should be given to the medication management continuum as patients move between areas of the hospital where different EMM systems are in use. For example, a hospital may have one EMM system for general inpatient areas and a separate system for intensive care or high-dependency units, or a specialist chemotherapy system that includes medication management. However, at the time of writing, no hospital has addressed the electronic medication continuum using two or more different EMM systems.

Where a separate EMM software product is chosen rather than a comprehensive clinical system, the following elements must be considered and planned for as part of the EMM implementation:

- How will clinicians access the EMM system — directly or via a third-party clinical system? How will this approach support clinical workflow?
- How will the patient's pre-admission medicines be made available for medication reconciliation on admission, transfer and discharge?
- Will diagnostic results be available for review within the EMM at the point of prescribing, or will clinicians access the results through another system before ordering medicines?
- Will diagnostic results be available to EMM decision support capabilities when placing medication orders?

- Will diagnostic test requests be available for order as part of the medication order set? This would mean that appropriate diagnostic tests can be ordered at the same time as the medication (e.g. ordering a potassium serum level at the same time as prescribing potassium-depleting medicines).
- Where will allergy information be held within different clinical systems, and how will this be made available to and maintained by the EMM system?
- How will the EMM system be accessed on ward rounds where medicines may be changed or discharge medicines ordered?
- How will discharge medicines be incorporated into discharge summaries?
- How will changes to medicines before discharge be reflected in the discharge summary?
- How will records of discharge medicines be available for post-discharge ambulatory visits?
- How will the medication information flow if the emergency department has a separate system to the rest of the hospital?

If some of these elements are not in scope for the EMM implementation, it is essential to document the rationale for their exclusion, along with how the medication safety risks will be mitigated (Table 6.1).

Table 6.1 Example strategic context considerations

Strategic context component	In EMM scope?	Explanation
Existing ICU / HDU systems	No	Manage at the boundaries – see business context
Existing chemotherapy systems	No	Manage at the boundaries plus interface at prescribing points – see business context
ED	Yes	EMM will be used for all ED presentations, not just admitted patients
Outpatient departments	Yes	EMM will be used in all outpatients
Diagnostic results	Yes	Results will be available at all points of the prescribing process within the EMM Images will be available from within the EMM through hyperlinks (embedded within reports) to the hospital PACS system
Allergies	Yes	EMM will interface to the hospital's clinical system to retrieve existing allergies and send medication allergies identified by EMM users
Discharge summaries	Yes	Discharge medicines will be available to the discharge summary – see business context
Pharmacy dispensing system	Yes	An interface will be built to electronically transfer non-imprest prescribed medicines to the pharmacy dispensing system

ED = emergency department; EMM = electronic medication management; HDU = high-dependency unit; ICU = intensive care unit; PACS = picture archiving and communications system

6.2 The business context

The business context of the EMM implementation needs to be clearly defined. Consider each care location or setting within the hospital to ensure that all areas where medicines are prescribed, dispensed or administered are included, such as:

- general wards
- intensive care or high-dependency units
- specialist areas such as chemotherapy and renal dialysis
- emergency department
- outpatients
- rehabilitation
- mental health
- operating theatres
- day procedure units
- diagnostic imaging
- hospital-provided community services
- any other areas of the hospital.

The emphasis of the EMM implementation must be on safe medication management. Before implementing an EMM system, the EMM governance and project teams must consider each aspect of medication management within the hospital, as well as how to maintain the medication continuum and ensure patient safety as patients move between different areas of the hospital. This must include an end-to-end medications process map that clearly indicates what will happen at the boundaries of each service delivery area. This will ensure that medication safety issues are thoroughly addressed in EMM planning, and that the EMM system supports streamlined and integrated workflow across the hospital.

If an area of medication use is not within the scope of the EMM system, the rationale for this decision should be fully explained and documented, as well as how the 'gap' in the medication continuum will be addressed to ensure medication safety. For example, if intravenous fluids are not within the proposed scope of EMM, how will they be managed? An example business context consideration is shown in Table 6.2.

Table 6.2 **Example business context considerations**

Business context component	In EMM scope?	Proposed management approach
Existing intensive care / high-dependency system	No	<p>ICU / HDU staff will update the EMM patient chart on commencement and suspension of the ICU / HDU stay, to alert EMM users of the existence and status of the ICH / HDU chart</p> <p>On transfer from ICU / HDU to a receiving ward, medications applicable on transfer will be printed as part of the ICU / HDU handover process and re-entered onto the EMM chart by a prescriber on the receiving ward until such time as the interface between the two systems has been thoroughly tested and implemented</p>
Existing chemotherapy system	No	<p>Chemotherapy unit staff will update the EMM patient chart on commencement and cessation of the period of chemotherapy treatment to alert EMM users of the existence and status of the chemotherapy chart</p> <p>The chemotherapy system will enquire on the EMM system and retrieve other medicines information at the following stages:</p> <ul style="list-style-type: none"> • whenever the chemotherapy medicine is changed • before each batch of chemotherapy medicine being manufactured
ED	Yes	<p>In the event that a non-admitted patient is subsequently admitted, the ED treating doctor will update the EMM system with the prescribed medicines from the paper chart and sign the paper chart to confirm this has been done</p>
Electronic discharge summaries	No	<p>Discharge medicines will be sent to the discharge summary system for incorporation into the discharge summary as soon as the EMM system generates the discharge script</p> <p>If the discharge medicines require subsequent changing, the prescriber will make the changes within the EMM system and the updated discharge script will be re-sent to the discharge summary system</p> <p>The pharmacists will request that all changes to discharge medicines discussed with the prescriber are updated by the prescriber within the EMM system before they are dispensed by pharmacy</p>

ED = emergency department; EMM = electronic medication management; HDU = high-dependency unit;
ICU = intensive care unit

The EMM implementation plan includes a template to help identify and manage medicines at the boundaries of a hospital's proposed EMM scope. The plan also includes a clinical risk log to manage the risks associated with the introduction of clinical software (reproduced with permission from WA Health).

EMM and the Pharmaceutical Benefits Scheme

This chapter considers the issues associated with accessing the Pharmaceutical Benefits Scheme (PBS) within electronic medication management (EMM) systems in both public and private hospitals.

The PBS is accessible for:

- patients attending or admitted to private hospitals (inpatients and outpatients)
- patients admitted to public hospitals on discharge, or patients attending public hospital outpatient clinics (including day chemotherapy and chemotherapy outpatient clinics), in states and territories that are implementing the pharmaceutical reforms.¹¹

Careful consideration must be given to the management of PBS prescribing within EMM systems. PBS prescriptions complicate EMM in both public and private hospitals because PBS scripts must be printed on approved forms and signed by the prescriber. The Australian Government Department of Health and Ageing requires Medicare Australia to ensure that all PBS prescriptions are signed by the prescriber.

In private hospitals, this requirement challenges the design of efficient work practices associated with implementing EMM. In public hospitals, the challenges are further complicated by funding arrangements that affect how prescriptions are handled for private patients being treated in areas of public hospitals where PBS-approved hospital prescribing paper is used to generate PBS prescriptions. In some cases, these prescriptions are not included within the EMM system, potentially compromising medication safety.

Electronic prescribing where paper prescriptions are also required for PBS purposes must be carefully managed to reduce the clinical risk of operating a dual system and minimise the opportunity for introducing errors into the prescribing process. The information required for an inpatient prescription is different from the information required for a medicine for discharge or for an outpatient. This has implications for EMM, particularly in jurisdictions that are implementing the pharmaceutical reforms. Medication prescriptions for inpatient use include (as a minimum) the drug name, dose, form and frequency. Discharge or outpatient prescriptions for PBS items also require this information, as well as other information that complies with a PBS-listed product, including a specific strength and pack size (or quantity) and, in some cases, PBS streamlined authority codes or other authority codes. Sometimes multiple strengths of the same medicine are required to provide the correct dose. For example, an inpatient order for warfarin (Coumadin) tablets 7 mg oral daily would need to be converted to two orders on discharge – warfarin (Coumadin) tablets 2 mg daily (pack 50) and warfarin (Coumadin) tablets 5 mg daily (pack 50).

Further information on electronic prescribing and the PBS can be found at: www.health.gov.au/internet/main/publishing.nsf/Content/eprescribing.

¹¹ Through the Public Hospital Pharmaceutical Reforms in 2008, the Australian Government offered to extend the Pharmaceutical Benefits Scheme into public hospitals for certain patients.

7.1 PBS prescriptions in public hospital outpatient settings

In jurisdictions that are implementing the pharmaceutical reforms, public hospitals can access the PBS for outpatients (including chemotherapy outpatients) and for day chemotherapy patients.

In this context, the EMM implementation process must provide:

- infrastructure that supports outpatient workflows and allows prescribers to access PBS prescribing as they move between outpatient consultation rooms. This is a key requirement for electronic PBS prescribing, and can be achieved using mobile technology, portable sessions, or rapid authentication and access to fixed computers
- education and training in using the PBS, particularly where the EMM implementation coincides with the introduction of the PBS, where prescribers may not be familiar with PBS requirements
- printers that support PBS script printing in each consultation room. Shared printers can introduce confusion at the printer and the risk of the wrong scripts being given to patients
- EMM support to incorporate monthly PBS updates.

7.2 PBS prescriptions for public hospital discharges

In jurisdictions that are implementing the pharmaceutical reforms, public hospitals can access the PBS for medicines on discharge. In this context, the EMM implementation process must include:

- the ability to bring forward inpatient medicines so the prescriber can stop, start or continue medicines on discharge
- the intelligent use of the Australian Medicines Terminology to convert inpatient prescriptions to PBS-compliant prescriptions on discharge, including conversion of dose requirements to multiple PBS products (where required)
- sufficient printers to print PBS prescriptions
- a consistent approach to identifying and naming PBS prescriptions stationery within printer drawers or trays so that prescribers can easily select the correct printer drawer
- integration of the process of generating a PBS prescription into the prescribers' workflow.

The following scenario is a real-life scenario from an Australian hospital that accesses electronic PBS scripts on discharge. This illustrates the importance of considering the workflow when implementing EMM.

Box 7.1 Scenario: PBS prescriptions for public hospital discharges

- An intern participates in the ward round, where it is decided that a patient is to be discharged.
- The intern has to decide whether to leave the ongoing ward round to complete the discharge script so that discharge medicines can be prepared, or wait until the completion of the ward round before doing so (ward rounds can take several hours).
- The intern has no access to electronic prescribing at the bedside, so they find a fixed computer and prescribe the PBS discharge medicines.
- PBS prescription paper is kept in a secure location and must be manually inserted in the shared ward printer. The intern leaves the computer and inserts the paper into the printer.
- The intern returns to the computer to press 'print', then goes back to the printer to collect and sign the PBS script.
- Another staff member takes the PBS script to the hospital pharmacy and the intern returns to the ward round.
- The pharmacist reviews the script and needs to clarify the script with the intern. The intern is paged and leaves the ward round again to discuss the script with the pharmacist. They agree that the script needs to change.
- The intern then updates, prints and signs the revised PBS script, which is required by pharmacy before the script can be dispensed.

The risks associated with this workflow need to be identified and managed. In this scenario, the risks are:

- inadequate clinical information sharing or misinformation when the intern leaves the ward round to produce the script or discuss it with the pharmacist
- transcription errors if the intern annotates some form of paper record other than the medication chart (which is electronic) and produces the prescription afterwards
- opportunities for other errors when the intern is absent from the ward round for part or all of the discussions and clinical decisions about subsequent patients; this also compromises the intern's learning and development experience
- medication errors if the intern forgets to complete a discharge prescription and the patient is discharged without the required medicines
- misalignment of records if the pharmacist changes the discharge medicines after discussion with the intern, but the intern does not update the EMM chart with the altered medicines.

7.3 PBS access in private hospitals

Inpatients at private hospitals can access the PBS for the medicines required during their inpatient stay.

The Australian Government Department of Health and Ageing requires Medicare Australia to ensure that all PBS prescriptions are signed by the prescriber. This requirement poses substantial challenges when implementing EMM in private hospitals, and the requirement for handwritten scripts negates many of the benefits of EMM systems.

A small number of private hospitals have dispensation from printing and signing PBS scripts; however, this dispensation only applies to non-authority PBS scripts, and a signature is still required for authority and S100 items.

Until electronic prescriptions are available, the management of unsigned prescriptions is a serious impediment to the use of EMM in private hospitals, and requires careful consideration of:

- EMM workflow
- EMM process mapping
- EMM solution design
- managing prescribers' expectations
- implementing change management.

EMM and the National Medication Work Program

The focus of this guide is on electronic medication management (EMM) in hospitals; however, national initiatives that include medication elements in other areas of health care will affect the future requirements of hospital EMM systems. These are the:

- electronic transfer of prescriptions (ETP)
- personally controlled electronic health record (PCEHR)
- Australian Medicines Terminology (AMT).

8.1 Electronic transfer of prescriptions

ETP can occur in all care settings that make use of formal and legal electronic prescriptions, particularly those involving the transfer of a prescription across an organisational boundary (e.g. from general practice to community pharmacy). ETP services are emerging in Australia, but they still depend on paper prescriptions for the prescriber's signature. A national approach is needed to ensure that consumers can obtain their medicines in a timely manner from the pharmacy of their choice. This will be achieved by developing common prescription information, encryption and interface specifications.

In 2008, the Australian Health Ministers' Advisory Council endorsed the National E-Health Strategy. Within this strategy, the highest priority initiative for EMM is to establish an electronic prescriptions service.¹² This will provide an early opportunity for connecting healthcare providers at the national scale.

The 2010–11 Federal Budget identified ETP as a key indicator of progress in e-health and called for the completion of nationally agreed ETP specifications by 30 June 2011.¹³ In September 2010, the National E-Health Transition Authority (NEHTA) released the Electronic Transfer of Prescriptions version 1.1 (ETP v1.1) for consultation. ETP v1.1 is primarily concerned with the electronic transfer of prescriptions from the prescriber to the pharmacist and on to Medicare Australia for payment.

The Fifth Community Pharmacy Agreement¹⁴ subsidises pharmacists who dispense from e-prescriptions that have been generated and transmitted by software that complies with nationally agreed specifications and standards. Connecting prescribing and dispensing systems (via intermediary repositories) using ETP v1.1 specifications will drive the adoption of national standards for clinical information, terminology and secure communications in both general practice and community pharmacies. This standards-based connectivity should deliver immediate benefits to healthcare providers and consumers, as well as laying foundations to achieve the longer term goals of the National E-Health Strategy.

¹² www.health.gov.au/internet/main/publishing.nsf/content/national+Ehealth+strategy

¹³ Australian Government Department of Health and Ageing. Australian Government 2011–12 Health and Ageing Portfolio Budget Statements.

¹⁴ [www.health.gov.au/internet/main/publishing.nsf/Content/C3DB799DB360AF0CCA25772000249FA8/\\$File/5CPA%20Agreement%2005%20August%202010.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/C3DB799DB360AF0CCA25772000249FA8/$File/5CPA%20Agreement%2005%20August%202010.pdf)

More information on ETP is available at:
www.nehta.gov.au/e-communications-in-practice/emedication-management.

8.2 The Personally Controlled Electronic Health Records program

The 2010–11 Federal Budget allocated \$466.7 million over two years for the PCEHR program, as one of the funded recommendations of the Health and Hospital Reform Commission. The current PCEHR program consists of a combined top-down and bottom-up approach, where local e-health sites inform national PCEHR developments. The current PCEHR program consists of:

- three wave-1 and nine wave-2 PCEHR sites
- a National Infrastructure Partner
- a National Benefits and Evaluation Partner
- a National Change and Adoption Partner.

A PCEHR Concept of Operations has been issued for consultation.¹⁵ It will incorporate a shared health summary and event summaries based on the clinical information content standards specified by NEHTA, including medicines and allergies.

Clinical systems, such as general practitioner (GP) practice management systems, specialist practice management systems and hospital clinical systems, will interoperate with the PCEHR and, with consumer consent, medication and allergy information will be available for use within local systems. This will enable EMM systems to make use of medication information within the PCEHR during hospital attendances and supply hospital medication information to the PCEHR for access by community-based providers.

8.3 The Australian Medicines Terminology

The AMT uniquely and unambiguously codes and describes commonly used medicines, including all Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme items, and other products approved for use by the Australian Therapeutic Goods Administration. Items in the AMT are described according to their active ingredients, form and strength. Where medicines are not listed in the AMT, NEHTA provides a submission process that enables other medicines to be added, such as Special Access Scheme items. It is expected that the AMT will be used in clinical activities, such as prescribing, recording, review, dispensing, administration and transfer of medicine information, across care settings.

Stakeholder engagement will be fundamental in the future development of the AMT, including expanding the coverage of medicine items used in Australia, and identifying and recommending cases that will further develop the AMT, its attributes and components. AMT will also endeavour to further develop capability as required by the needs to the e-health environment, specifically in areas where patient medication safety can be realised such as standardising representation of dose and facilitating decision support systems.

15 www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/pcehr

NEHTA is reviewing the scope of the AMT and how it can be incorporated with other initiatives such as Tall Man lettering, short names for medicines and synonyms. Linking the AMT to global trade item numbers in the national product catalogue is also under consideration.

The Australian Commission on Safety and Quality in Health Care (ACSQHC) recommends that readers contact NEHTA for information on the latest AMT developments.

8.4 Implications for EMM systems

When these national initiatives are fully implemented, they will have important implications for medication safety and EMM in hospitals:

- Patients' current medicines, taken before presentation to hospital, will be available to ambulatory care and inpatient clinicians during hospital visits. This will also improve medication reconciliation on admission to hospital.
- Hospital-generated prescriptions in ambulatory care and discharge settings will be transmitted electronically to community pharmacies, avoiding transcription errors.
- Hospital-prescribed medicines will be available to GPs for electronically updating the GP-held current medication lists (where appropriate), 'closing the loop' on medicines.

Hospital project teams planning to implement EMM should consider these initiatives in their planning, including consulting the hospital's chief information officer about any local plans to adopt these initiatives.

Functional and technical specifications for EMM systems

This chapter outlines the functional and technical specifications required for ensuring that electronic medication management (EMM) systems support safe medication management practice. These have been developed based on the experience of early Australian implementers of EMM systems, publicly available literature from Australian and international sources, and the advice from stakeholders who are experts in medication safety and medication management.

The functional and technical components identified in this guide as being of greatest significance in terms of medication safety represent a broad but not exhaustive list.

A number of comprehensive functional specifications have been developed for electronic prescribing and medication management systems, and are publicly available. These include *ePrescribing Functional Specification for NHS Trusts* (National Health Service)¹⁶ and *ePrescribing Certification Handbook* (Certification Commission for Health Information Technology).¹⁷

In addition, a number of published research articles and evaluations have also developed functional specifications for ePrescribing^{18, 19, 20, 21} that may inform the development of EMM system specifications for hospitals. Hospital project teams are encouraged to review these specifications alongside the material presented in this chapter when developing their own detailed specifications for EMM systems.

9.1 Prioritising EMM functional and technical components

Commercial EMM system software applications and EMM system implementations within hospitals vary in the degree to which EMM system functionality is available, being developed or actively used. However, some EMM system functional and technical components are critical for ensuring that the level of clinical risk and safety is maintained to an acceptable level following implementation of an EMM system.

In this section, a risk-based approach has been used as the basis for determining the extent to which certain EMM system components are more or less critical than others. The identified EMM system components have been categorised according to whether they are core, desirable or aspirational features.

16 National Health Service (NHS). *ePrescribing Functional Specification for NHS Trusts*, NHS, London, 2007.

17 Certification Commission for Health Information Technology (CCHIT), *ePrescribing Certification Handbook*, CCHIT, Chicago, 2011. Available by application at: www.cchit.org/certify/2011/cchit-certified%20%AE-2011-eprescribing

18 Ryan M. Australian electronic medication management policy and systems. *Journal of Pharmacy Practice and Research* 2007;37:49–55.

19 Wang CJ, Marken RS, Meili RC, Straus JB, Landman AB, Bell DS. Functional characteristics of commercial ambulatory electronic prescribing systems: a field study. *Journal of the American Medical Informatics Association* 2005;12:346–356.

20 Bell DS, Marken RS, Meili RC, Wang CJ, Rosen M, Brook RH, Electronic Prescribing Expert Advisory Panel. Recommendations for comparing electronic prescribing systems: results of an expert consensus process. *Health Affairs* 2004;(1):w4.305–w4.317.

21 Bell DS, Cretin S, Marken RS, Landman AB. A conceptual framework for evaluating outpatient electronic prescribing systems based on their functional capabilities. *Journal of American Medical Informatics Association* 2004;(11):1:60–70.

9.1.1 Core features

Core features are components of an EMM system that are essential to ensuring a safe and successful EMM system implementation. These features:

- focus on medication safety
- must be implemented as a priority
- do not negatively impact or increase the health service's risk profile (e.g. do not increase the frequency of adverse medicines events).

These features ensure that existing risks are maintained to an acceptable level and that no new risks are introduced that may lead to adverse outcomes for clinical care.

9.1.2 Desirable features

Desirable features complement core features and lead to a more successful implementation. When evaluating and selecting EMM systems, the EMM team should consider the capability of EMM systems to incorporate desirable features as far as is practicable. These features:

- may constitute 'selling points' to help gain user 'buy-in'
- reflect functional capability that adds value to organisational and clinical outcomes, and may lead to a sustained decrease in the overall clinical risk profile compared to pre-implementation status
- should be implemented concurrently with core features, but may be implemented after core features, where necessary.

9.1.3 Aspirational features

Aspirational features are those that would obtain the best clinical, operational and efficiency outcomes from an EMM system. When hospital project teams are evaluating and selecting EMM systems, they should consider the capability of EMM systems to provide for aspirational features over the longer term. These features:

- would be ideal to include as part of the overall EMM system capabilities, even if considered at a later date
- aim to minimise clinical risk, and promote safe and quality use of medicines to an extent that may not be met by current systems or processes
- may include functionality that does not currently exist, but may be considered for future development.

The prioritisation of functional and technical components shown in the summary tables in Sections 9.2–9.5 represent the consolidated view of a group of expert stakeholders²² who were asked to categorise each component based on the criteria outlined above. However, there was limited feedback and the prioritisations provided are a guide only.

It should also be noted that the prioritisation of components may vary depending on the context of the organisation implementing the EMM system, particularly whether they are public, private, single or multiple site implementations. It is recommended that hospital project teams undertake their own prioritisation (core, desirable, aspirational) as part of developing their own detailed EMM specifications.

²² Except where yellow ticks are observed, which depict new components added following the expert validation process; these represent the views of the authors of this guide.

9.2 Functional components

The components identified in this section are the individual functions of an EMM system that should be considered to ensure that the process of medication management remains safe. This section includes:

- general considerations applicable to all users of the EMM system and across the continuum of the medication management process
- sections that are relevant to each of the core functions of medication management (ordering, review, supply and administration)
- a section dealing with clinical decision support considerations.

Functional components		Core	Desirable	Aspirational
1.0	General			
1.0.1	Configuration of access to EMM system	✓		
1.0.2	Continuity of medication management	✓		
1.0.3	Rapid access to medication order data	✓		
1.0.4	Compliance with information privacy principles	✓		
1.0.5	Compliance with legislation and regulation	✓		
1.0.6	Use of national terminology, abbreviations and symbols	✓		
1.0.7	Onscreen display of medication information	✓		
1.0.8	Access to pathology results	✓		
1.0.9	Access to patient clinical information	✓		
1.0.10	Access to patient demographic information	✓		
1.0.11	Access to current and previous medication records	✓		
1.0.12	Recording of medication history on admission	✓		
1.0.13	Support for medication reconciliation		✓	
1.0.14	Patient information present on every screen	✓		
1.0.15	Patient identification through electronic technologies		✓	
2.0	Medication orders			
2.1	<i>Selection of medicines and directions</i>			
2.1.1	Entry of medicine name, form, frequency, route, strength and dosage	✓		

continued

Functional components		Core	Desirable	Aspirational
2.1.2	Modification of an existing medication order	☑		
2.1.3	Specification of review or stop dates for orders	☑		
2.1.4	Recording of reason or indication for medication orders	☑		
2.2	<i>Standard order sets and order lists</i>			
2.2.1	Development of standard order sets and order lists		☑	
2.2.2	Maintenance and refinement of standard order sets and order lists		☑	
2.3	<i>Public hospital formulary</i>			
2.3.1	Ability to highlight local public hospital formulary list	☑		
2.3.2	Management of non-formulary items	☑		
2.3.3	Maintenance of local public hospital formulary	☑		
2.4	Allergy and adverse drug reaction (ADR) information			
2.4.1	Recording of allergy and ADR information	☑		
2.4.2	Source of allergy and ADR information	☑		
3.0	Clinical decision support			
3.1	<i>Active alerts</i>			
3.1.1	Configuration of active alerts	☑		
3.1.2	Managing different types of active alerts	☑		
3.1.3	Recording of reason for overriding serious alerts	☑		
3.1.4	Maintenance of alerts	☑		
3.2	<i>Passive clinical decision support</i>			
3.2.1	Medicines reference information	☑		
3.2.2	Guidance on valid forms, routes, frequencies, strengths and doses		☑	
3.2.3	Standard order sets		☑	
3.3	<i>Local policies and protocols</i>			
3.3.1	Requirements for ordering or administration of some medicines		☑	

continued

Functional components		Core	Desirable	Aspirational
4.0	Pharmacy review			
4.0.1	Access to medication orders for review	✓		
4.0.2	Prioritisation of medication orders for review		✓	
4.0.3	Access to current medication record during order review		✓	
4.0.4	Suspension of medication orders if required		✓	
4.0.5	Recording of clinical and other notes when reviewing medication orders	✓		
5.0	Medication dispensing			
5.0.1	Recording of medicines dispensed	✓		
5.0.2	Compliance with labelling standards and guidelines	✓		
5.0.3	Recording of substitution of medicine		☐	
6.0	Medication administration			
6.0.1	Recording of administration, dose, time and status	✓		
6.0.2	Scheduling of medicines for administration	✓		
6.0.3	Identification of person(s) administering medicines, and patient and medicine details prior to administration	✓		
6.0.4	Dual witnessing and checking of medication administration	✓		
6.0.5	Management of telephone and verbal medication orders	✓		
6.0.6	Management of nurse-initiated medication and standing orders	✓		
7.0	Discharge medicines			
7.0.1	Population of discharge medicines and discharge summaries from current medication record		✓	
7.0.2	Reintroduction of medicines ceased or withheld on admission		✓	
7.0.3	Reconciliation of medicines on discharge		✓	
7.0.4	Reconciliation of discharge summary and dispensed discharge medicines		✓	
7.0.5	Generation of 'take-home' discharge medicines list		☐	

Functional component 1.0: General

Functional component 1.0.1: Configuration of access to EMM system

Access to EMM system functionality needs to be restricted based on staff roles and accountabilities in medication management. These access rules must be developed and agreed by the EMM reference group and may be governed by state or territory legislation, or local hospital policy. A medical officer must have the ability to order medicines; nurses must be able to view the system, record when doses are administered and order medicines (e.g. telephone and nurse-initiated medication orders); pharmacists must be able to review, approve and supply medication orders; other clinical and nonclinical staff (e.g. physiotherapists, occupational therapists, medical records) must be able to view but not update the EMM system. The EMM system must also support access by temporary or relief staff.

The EMM system needs to allow nonmedical staff to prescribe; for example, nurse practitioners and other clinical staff who are authorised to prescribe medicines within their scope of practice, and state or territory legislation.

The EMM system must only allow modification of an individual patient's medication record by one user at any time. This prevents double ordering of medicines or administration of a medicine while the medication chart is being updated. The name of the user already logged on to the EMM system should be clearly displayed if other users attempt to access the system. The name of the user logged in on a device should be displayed on screen at all times.

The EMM system should allow use of all functions from all locations within the hospital where medicines are ordered, supplied and administered, as well as locations external to the hospital. Allowing clinicians to commence and alter medication orders remotely reduces (and may eliminate) the requirement for telephone orders and their associated risks (such as lack of follow up, or not being formally validated or countersigned).

The EMM system should be configured to allow easy access to other systems that relate to the safe management of medicines (e.g. pathology results, clinical information systems). A range of technologies may be used to improve ease of access to the EMM and other systems, including machine-readable smart cards or swipe cards, and fingerprint readers or other biometric devices.

Functional component 1.0.2: Continuity of medication management

It is recommended that the EMM system supports all clinical settings in which medicines may be prescribed or administered, including pre-admission clinics, inpatient admissions, outpatients and emergency departments. The ability to manage medicines across all settings of care reduces medication error and eliminates the need to maintain paper medication charts. An EMM system that is available across all settings within the hospital will better support medication reconciliation (refer to *Functional component 1.0.13*), continuity of care, and reduce the risk of miscommunication and medication errors as the patient moves through the hospital and between healthcare settings.

Box 9.1 Linking to the patient administration system (PAS)

Some Australian sites report that their EMM systems require patients to be 'admitted' in the PAS for medication orders and charts to be generated by the EMM system. This prevents the EMM system being used for patients not admitted to the hospital (i.e. in emergency, outpatients or pre-admission clinics).

Although linking the EMM system and the PAS is essential to ensure access to basic patient demographic information and identification, the status of a patient within the PAS must not dictate the ability to generate electronic medication orders. Similarly, the transfer of a patient within a facility or 'administrative' discharges must not require a new medication chart to be generated in the EMM system.

Mechanisms are also required to reinstate medication orders in the event that the patient is erroneously discharged.

Functional component 1.0.3: Rapid access to medication order data

Robust processes need to be in place to ensure changes to a medication order are instantly evident to all other users of the EMM system, including remote users (see *Functional component 1.0.1*). This eliminates the risk of medication errors caused by time lags between changes being accessible to other users of the EMM system.

The EMM system must ensure that all medication order-related transactions are date, time and user stamped, and an audit trail is maintained. This information must be available for auditing purposes, and to conform with state or territory legislation.

Functional component 1.04: Compliance with information privacy principles

The EMM system must comply with Australian Government, and state and territory information privacy principles, which are designed to guide how personal information is handled.

Functional component 1.0.5: Compliance with legislation and regulation

The EMM system must comply with Australian Government legislation and regulation in relation to ordering and supply of Pharmaceutical Benefits Scheme or Repatriation Pharmaceutical Benefits Scheme items, and state or territory legislation and regulations regarding prescribing, dispensing, supplying and administering medicines.

Functional component 1.0.6: Use of national terminology, abbreviations and symbols

A major cause of medication errors is the use of potentially dangerous abbreviations and dose expressions.²³ To reduce this risk, EMM systems must adopt the recommended terms and acceptable abbreviations outlined in *National Terminology, Abbreviations and Symbols to be used in the Prescribing and Administering of Medicines in Australian*

23 Joint Commission on Accreditation of Healthcare Organisations (JCAHO). Sentinel Event Alert: Medication errors related to potentially dangerous abbreviations. JCAHO, Chicago, 2001. www.jointcommission.org/assets/1/18/SEA_23.pdf

*Hospitals*²⁴, published by the Australian Commission on Safety and Quality in Health Care (ACSQHC), in the short term.

A broader and more comprehensive terminology will be required as EMM system implementation increases. The Systematized Nomenclature of Medicine–Clinical Terms (SNOMED CT) is the preferred national terminology for Australia.

As SNOMED CT does not provide total coverage of all concepts and descriptions used in the Australian health sector, the National E-Health Transition Authority (NEHTA) supplements SNOMED CT by developing specific extension terminologies to cover local clinical information requirements.

SNOMED CT remains freely available for e-health software developers to use in their Australian products under NEHTA's new licensing arrangements.²⁵

Functional component 1.0.7: Onscreen display of medicine information

Standards in the onscreen display of medicine information should reduce the risk of medication errors due to misreading information. A recent publication by the National Health Service (NHS) National Patient Safety Agency (NPSA) presents guidelines for the safe onscreen display of medication information.²⁶ These guidelines should be used to assist the evaluation and selection of EMM systems by adopting good design principles. The *Guidelines for Hazard Review of ePrescribing Systems*²⁷, the *List of High-Alert Medications*²⁸ and Design Guidance — Medications Management — Drug Administration²⁹ (Microsoft) should be considered in conjunction with the NPSA guidelines when evaluating EMM systems.

'Tall Man' lettering should be used to help differentiate between like-sounding and like-looking medicine names. Examples of Tall Man lettering are:

- nEURONTin
- nOROXin
- nexAVAR
- nexIUM
- niMODIPine
- niFEDIPine.

The *National Tall Man Standard List* can be accessed at:
www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06_NTMS.

24 ACSQHC. *National Terminology, Abbreviations and Symbols to be used in the Prescribing and Administering of Medicines in Australian Hospitals*, ACSQHC, Sydney, 2006.

25 For details of NEHTA's SNOMED CT licensing arrangement see: https://nehta.org.au/aht/index.php?option=com_content&task=view&id=5&Itemid=35 (accessed 31 May 2010)

26 NHS NPSA. *Design for Patient Safety. Guidelines for Safe On-Screen Display of Medication Information*, NHS NPSA, London, 2010.

27 NHS. *Guidelines for Hazard Review of ePrescribing Systems* NHS, London, 2008.

28 Institute for Safe Medication Practices (ISMP). *List of High-Alert Medications*, ISMP, Horsham, PA, 2008. www.ismp.org/Tools/highalertmedications.pdf (accessed 16 April 2010)

29 Design Guidance – Medications Management – Drug Administration version 2.0.0, Microsoft, 2007. www.mscai.net

Functional component 1.0.8: Access to pathology results

Access to up-to-date pathology results is important when making decisions on medication orders, interpreting the reason or indication for medication orders, and when administering medicines. Pathology results should be accessible either by integrating the pathology results system with the EMM system, or through external links to the pathology results system.

Ideally, the pathology results systems would integrate with the EMM system, via a Health Level 7 (HL7) message (refer to *Technical component 8.0.3*). An integrated pathology results system should display pathology results in the EMM system relevant to the medication order being completed, reviewed or administered. Clinical business rules would facilitate general and patient-specific clinical decision support (refer to *Functional component 3.0*) such as alerting the need for reduced doses in impaired renal or hepatic function, or where therapeutic drugs levels are high (refer to *Functional component 3.1*).

Note that private hospitals may need to receive pathology results from several pathology service providers.

Functional component 1.0.9: Access to patient clinical information

The EMM system should have the ability to directly record patient clinical information; for example, blood pressure, pulse, weight (actual, estimated or ideal), height or body mass index, or for patient clinical information to be accessed through the clinical information system (CIS) via bidirectional HL7 messaging to allow the CIS to display changes or updates made to physiological information in the EMM system.

The ability to record patient clinical information supports medication orders (see *Functional component 2.0*) and clinical decision support (see *Functional component 3.0*). Access to the physiological data directly through an interface with the CIS would also reduce transcription errors associated with re-entering patient clinical information.

The EMM system should provide prompts to use the patient clinical information if it is required to calculate the dose of a medicine.

Functional component 1.0.10: Access to patient demographic information

The EMM system should directly record patient demographic information (e.g. sex, age) or allow access to patient demographic information through the PAS via bidirectional HL7 messaging (to allow for changes or updates made to demographic information in the EMM system to be reflected in the PAS).

The ability to record patient demographic information supports patient identification (see *Functional component 1.0.15*), medication orders (see *Functional component 2.0*) and clinical decision support (see *Functional component 3.0*). Access to the demographic data directly through an interface with the PAS would also reduce transcription errors associated with re-entering patient demographic information.

The system should provide prompts to use the demographic information if it is required to calculate the dose of a medicine. If the medicine or dose range is for a particular demographic (e.g. a specific gender or age group), the system should provide an alert in cases where patients do not fit the required parameters (e.g. when ordering adult strength medication for use in children).

Functional component 1.0.11: Access to current and previous medication records

The EMM system must have the capacity to display and print, at any time, an up-to-date summary of current medicines, medicines previously ordered, administered, ceased or withheld during current and previous episodes of care. Where possible, the reasons for any amendments to the medication record should be available. This function supports medication reconciliation (see *Functional component 1.0.13*) and ensures that clinicians are fully informed of a patient's current and prior medication orders before making any clinical decisions.

The ability to sort the medication record by current or noncurrent medicines, chronologically (based on initial order date), alphabetically, drug class, specialty or prescriber is also desirable.

The EMM system may also be integrated with a consolidated electronic medical record, with bidirectional HL7 messaging, ensuring that changes to information in either system is automatically updated in the other.

Functional component 1.0.12: Recording of medication history on admission

A medication history is a record of all the medicines (prescription, over-the-counter and complementary medicines) actually taken by the patient in the period before admission or presentation for the episode of care. It includes:

- for each medicine, the
 - drug name, dosage, frequency and route
 - indication
 - duration of therapy
 - plan to withhold, cease or change the medicine
- sources used to confirm the history
- any recently changed or ceased medicines
- information about previous adverse drug reactions (ADRs) and allergies.³⁰

It should be possible to record a complete medication history (including prescription and other medicines, such as over-the-counter and complementary medicines) within the EMM system. This should be informed, where possible, by a structured interview conducted with the patient or carer at admission, or by accessing current primary care records such as the general practitioner or community pharmacy records. Accessing these records electronically may depend on the links that exist between systems or the existence of an individual electronic health record (or similar). The history should be confirmed with a second source.

30 Australian Pharmaceutical Advisory Council (APAC). *Guiding Principles to Achieve Continuity in Medication Management*, APAC, Canberra, 2005.

The history should also include an assessment of the patient's medication-taking behaviour and risk for medication misadventure, as defined in the *Medication Management Plan* available at: [www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/OAAD5CC37045BF99CA257751001C2543/\\$File/medicationsafetyplan.pdf](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/OAAD5CC37045BF99CA257751001C2543/$File/medicationsafetyplan.pdf).

Functional component 1.0.13: Support for medication reconciliation

Medication reconciliation is a critical area for EMM consideration, and the EMM system must support medication reconciliation. However, current Australian EMM implementations lack integrated medication reconciliation functions.

Medication reconciliation is the process of creating the most accurate list possible of all medicines a patient is taking — including drug name, dosage, frequency and route — verifying the list with more than one source, and comparing that list against the admission, transfer, and/or discharge orders for each hospitalised patient. Any discrepancies are clarified with the prescriber and changes documented. At the end of each episode of care, the verified information is transferred to the next care provider, and provided to the patient or carer. The goal is to provide correct medicines to the patient at all transition points — coming into a hospital, moving within it, or being discharged home or to another hospital.³¹

Maintaining an audit trail of all modifications to a patient's medication record as they transition through their admission (e.g. on admission, during admission — including transfers — and at discharge) will assist with reconciliation at points of transfer of care. The system should record that the reconciliation process occurred and who performed the task. Users should be able to record reconciliation of individual medicines as well as all medicines listed.

Medication reconciliation is a four-step process:³²

1. medication history — see *Functional component 1.0.12*
2. confirmation — verification of medication history by other sources or means to ensure information is correct and comprehensive
3. reconciliation — occurring
 - on admission — confirming and documenting that the medication history matches the medicines ordered, while taking into account the admission plan
 - during inpatient stay — checking that the medication history and current medicines are accurately transcribed for every transition the patient makes from one setting or facility to another, or when a new medication chart is written up
 - on discharge — checking that the medicines ordered match both the medicines administered at the point of discharge and the discharge plan; reviewing the medication history to check that any medicines withheld on admission have been included where appropriate and that any changes have been noted; and ensuring that the reconciled medicines are accurately listed in the discharge summary with reasons for any changes between admission and discharge

31 Massachusetts Coalition for the Prevention of Medical Errors. Reconciling medicines — safe practice recommendations. www.macoalition.org/Initiatives/RecMeds/SafePractices.pdf (accessed 10 January 2012); Society of Hospital Pharmacists of Australia. Standards of practice for the provision of medication reconciliation. *Journal of Pharmacy Practice and Research* 2007;37:231–233.

32 Society of Hospital Pharmacists of Australia. Standards of practice for provision of medication reconciliation. *Journal of Pharmacy Practice and Research* 2007;37(3):231–233.

4. transfer of verified information — ensuring that verified medicines information is communicated between all involved in the patient's care (including the patient).

The system needs to support the use of the history obtained on admission to generate the medication orders for the current episode of care. The medication history obtained on admission also needs to be available at time of discharge to reconcile with the current medication orders, discharge prescription and discharge summary.

There may be times, particularly during a staged rollout or in circumstances where paper-based processes are still in place, that medication reconciliation at admission, and clinical handover or transfer of care (including discharge) involves a combination of paper-based and electronic records. The EMM system should allow users to identify and flag, along with commentary, any changes to orders within the system. Users should also be able to highlight discrepancies between either paper-based medication orders and electronic, or the medication orders recorded before a patient transfer event and those displayed after the transfer event.

Medication reconciliation systems have been implemented in numerous hospitals where EMM systems are not yet in place, and are being considered by some hospital project teams as a precursor to full EMM implementation. Electronic systems for medication reconciliation have been implemented by Queensland Health (Electronic Liaison Medication System, or eLMS), and at Launceston General Hospital in Tasmania and the Mater Health Service in Brisbane.

Functional component 1.0.14: Patient information present on every screen

Patient information must be prominent on all patient-specific screens within the EMM system to support accurate patient identification. The minimum information that should be visible is the patient's name, date of birth and medical record number. The EMM system should alert users when there are patients with identical names and prompt users to verify patient identification through additional means (e.g. home address) at the time of prescribing and administration.

Functional component 1.0.15: Patient identification through electronic technologies

Electronic patient identification is a desirable component of the EMM system. Computerised patient verification helps reduce errors that may occur during all stages of the medication management process — prescribing, dispensing, reconciling, monitoring and administering medicines. The coding system should use at least three patient identifiers (e.g. name, date of birth and medical record number) to ensure the medication record being viewed or modified is for the correct patient.

A number of existing technologies could be interfaced with an EMM system to help verify patient identification. These include digital photos, barcodes printed on existing patient identification bands³³, radiofrequency identification tags, biometric technologies (iris scanning) and 'smart cards'. A review of some of these, and other technologies, was engaged by ACSQHC in 2008³⁴, and this review should be considered if the EMM system is to employ one of these technologies to ensure the benefits, limitations and suitability of each technology is considered for the local hospital environment.

33 Should conform with the Commission's standards for patient identification bands: [www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EAC2DBC0F54777B5CA2574DE00111B73/\\$File/Specs-PatID-Band.pdf](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/EAC2DBC0F54777B5CA2574DE00111B73/$File/Specs-PatID-Band.pdf) (accessed 3 March 10)

34 ACSQHC. *Technology Solutions to Patient Misidentification — Report of Review*, ACSQHC, Sydney, 2008.

Functional component 2.0: Medication orders

Functional component 2.1: Selection of medicines and directions

Functional component 2.1.1: Entry of medicine name, form, frequency, route, strength and dosage

The EMM system should allow prescribers to select medicine names, form, frequency, route, strength, dosage and duration of therapy from prepopulated lists (see *Functional component 3.2.2*).

Both brand and generic medicine names should be available within the EMM system. The search and selection capabilities for medicine names should minimise entry and importation of medicine names that do not comply with appropriate nomenclature.

Lists should only show the form, route, strength, dosage and frequency appropriate for each individual medicine. For example, medicines that can only be administered by oral or intravenous routes should not show intramuscular route as an option when selecting route of administration.

A default dose may be set up for each medicine, as determined by the hospital drug and therapeutics committee (DTC) in conjunction with relevant specialists. This will not be appropriate for some medicines (e.g. insulin, opioids). Where multiple medicine strengths are available, the default strength should be determined by the DTC.

The system should also allow the entry of non-formulary medicines, form, frequency, route, strength and dosage to accommodate deviations from the prepopulated fields where appropriate. If deviations from the prepopulated options are made, the system should also require recording of a reason for the deviation (e.g. 'nonstandard dosing frequency required').

For regularly scheduled medication orders, the EMM system should be able to record the duration of the order and the maximum number of doses to be given.

For PRN medication orders (medicines that are only taken as required), the EMM system should be able to record the duration of the order, the minimum dosing interval and maximum allowable dose (e.g. hourly, daily, monthly).

The EMM system must prevent ordering or administration of medicines once the maximum dose or maximum number of doses has been administered. The system must alert the user and require additional authorisation if further ordering or administration is required.

The terminology used to designate medicine form, frequency, route, strength and dosage should be aligned with the *National Terminology, Abbreviations and Symbols to be used in the Prescribing and Administering of Medicine in Australian Hospitals*³⁵ in the short term. The Australian Medicines Terminology (AMT) and SNOMED CT-AU will be the comprehensive terminologies used in EMM systems (see *Technical Component 9.0*).

Children and neonates

When prescribing medicines for children, the EMM system must default to a paediatric or neonatal hospital formulary to avoid prescribing medicine strengths and doses that are intended for adults.

35 ACSQHC. *National Terminology, Abbreviations and Symbols to be used in the Prescribing and Administering of Medicines in Australian Hospitals*, ACSQHC, Sydney, 2006.

Variable doses

The system must be able to manage variable doses of an individual medicine. The process for variable doses should be uncomplicated and not require multiple entries. In particular, loading doses or reducing courses should be entered within one order, and not require multiple entries.

Complex orders

The system should highlight medicines (e.g. with bold or coloured text) with complex dosing and administration schedules to draw the user's attention to these medicines and orders. Complex orders should also be supported by tools and templates (e.g. dose calculators) that assist decision making regarding form, dose and frequency. These tools should be integrated in the EMM system and accessible at the time of prescribing, review and administration.

Functional component 2.1.2: Modification of an existing medication order

When modifying an existing medication order, the EMM system should ensure the two orders are linked and the basis for the change is clearly indicated. The EMM system must retain a record of the person altering the order and the change made. The EMM system should provide a way to record the reason for the modification. The information regarding the modification should be available to other users. The EMM system must also provide clinical decision support and alerts for the new order.

Functional component 2.1.3: Specification of review or stop dates for orders

The EMM system must support specifying a review or stop date for medication orders at the time of prescribing. This date should be able to be specified in number of days, number of doses, or pending investigation or monitoring results. The review or stop date must raise an alert when the date is reached, which mandates prescriber review of the medication order and the reason for the review. Without the ability to mandate a review or stop date for the medication order, there is potential for the medication order to continue when not medically required. However, this requirement needs to be balanced against the situation where medication orders that have not been reviewed are automatically ceased, leading to discontinuing medicines that are still required.

Functional component 2.1.4: Recording of reason or indication for medication orders

The EMM system should support the ability to add the reason or indication for each medication order. The ability to add an indication for each medication order supports advanced clinical decision support, as described in *Functional component 3.0*. It also supports the review of the medication order by other clinicians who may be involved in the patient care, and supports drug use evaluation audits and monitoring of clinical indicators. Common indications should be provided in drop-down boxes in addition to the ability to record comments. Indication descriptions within the EMM system should be consistent with SNOMED CT-AU, as identified by NEHTA as the preferred terminology for Australia.

Functional component 2.2: Standard order sets and order lists

Functional component 2.2.1: Development of standard order sets and order lists

A standard order set is a group of individual medication orders that are frequently initiated together at the same time, often as part of clinical protocols or pathways. They facilitate consistent prescribing for a given indication and reduce time spent on ordering in cases where multiple medicines are commonly ordered together, and calls to prescribers for questions or clarification of orders.

Standard order sets should be developed. For public hospitals, these need to be approved by the local DTC (or equivalent) within the hospital or health service, and may be set up according to specialty, condition or procedure, with input from the appropriate prescriber groups. For private specialists, order sets need to be developed in conjunction with each specialist. The *Guidelines for Standard Order Sets* can help organisations develop electronic order sets.³⁶

In an EMM system, standard order sets should be available for selection at the time of ordering medicines and automatically display the order set contents to support their use. The preferred choice of medicines (as defined by local policies) should be shown as the first option. The standard order sets should present the default strength (where required), dose, form, route and frequency (refer to *Functional component 2.1.1*) for all medication orders within the set.

The prescriber must acknowledge all the medication orders within the standard order set. A standard order set may include compulsory medication orders (which must default for selection), choice options within a compulsory group (e.g. one antifungal to be selected from a choice of antifungals), as well as optional medication orders (e.g. ganciclovir in a bone marrow transplant protocol). The EMM system must guide the prescriber to activate or select check boxes for the choice options and optional medication orders to ensure all medication orders in the standard order set are acknowledged individually. This also allows the prescriber to make any required adjustments for individual patients on a case-by-case basis.

The EMM system should also support the configuration of order lists, which are lists enabling quick selection of individual medication orders frequently ordered by a specialty, ward, or clinician. Order lists should present the default strength (where required), dose, form, route and administration frequency for the relevant medicine, but allow the prescriber to make any required adjustments on a case-by-case basis.

Functional component 2.2.2: Maintenance and refinement of standard order sets and order lists

If standard order sets and order lists exist, they should be regularly reviewed (at least twice per year³⁷) and modified in light of changes in prescribing behaviour (identified through EMM system audit data), adjustments to local public hospital formulary and policy changes. They should undergo development when new research evidence suggests that standard order sets or order lists should be revised. This process should be managed by the local DTC, with input from the appropriate clinicians. This process must include removing the older version of the standard order set or order list, or including an auditable record of changes made to a standard order set or order list. Communication of significant changes should be made to relevant staff.

³⁶ Institute for Safe Medication Practices (ISMP). *Guidelines for Standard Order Sets*, ISMP, Horsham, PA, 2010.

³⁷ Ibid.

Functional component 2.3: Public hospital formulary

Functional component 2.3.1: Ability to highlight local public hospital formulary list

The database in the EMM system must be configured to allow the local public hospital formulary (determined by the local DTC) to be highlighted and available to the prescriber when a prescribing decision is being made. The EMM system must also be able to restrict ordering of certain medicines to certain prescribers (e.g. cytotoxic medicines limited to oncology specialties, restricted antibiotics to infectious diseases specialists) or until specific requirements are undertaken (e.g. INR test results recorded and checked before prescribing warfarin).

The EMM system must allow hospitals or health services with paediatric patients to set up a specific paediatric and neonatal medicines list or hospital formulary to avoid adult doses being prescribed in error. The system should default to this medicines list or hospital formulary whenever medicines are prescribed for neonates, infants and children. More information on paediatric EMM is in *Electronic Medication Management Systems – Specialist Functions* on the ACSQHC web site.³⁸

Functional component 2.3.2: Management of non-formulary items

For the instances when a public hospital prescriber requires a medicine not on the local public hospital formulary, the prescriber must be able to view a list of all medicines available in Australia at the point of ordering. This may include over-the-counter (OTC) medicines, complementary medicines and nutritional supplements. These medicines may only be ordered in accordance with local policies and protocols as defined by the local DTC. The permanent addition of any therapeutics to the local public hospital formulary should be approved by the local DTC.

The EMM system must also be able to support ordering and administration of unregistered medicines such as clinical trial medicines and those under the Special Access Scheme. These need to be clearly marked as such and, in the case of clinical trial medicines, include contact details for the trial investigator. Policies and protocols as determined by the local DTC should govern access to and use of these medicines. They should automatically be highlighted as a priority for pharmacy review.

Functional component 2.3.3: Maintenance of local public hospital formulary

Pharmacy resources must ensure that the EMM system's local public hospital formulary is kept up to date at all times, and that the content aligns with the local policies and decisions (including purchasing decisions) about which medicines are available to local prescribers. This includes the addition, deletion and modification of any or all medicines, as required. The local public hospital formulary database should reflect the Australian environment and be compliant with AMT, SNOMED CT-AU and other relevant standards.

³⁸ [www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1B99DC757963C97CCA257872001DFB76/\\$File/EMMS%20Specialist%20Functions%20June%202011.PDF](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1B99DC757963C97CCA257872001DFB76/$File/EMMS%20Specialist%20Functions%20June%202011.PDF)

Box 9.2 Management of dual formularies

Where the pharmacy dispensing system and the EMM system are not integrated, it is essential that a protocol for reconciling the two separate formularies exists. This should be managed by the pharmacy staff, who must ensure that consistent terminology is used between the medication ordering and dispensing systems.

Functional component 2.4: Allergy and adverse drug reaction (ADR) information

Functional component 2.4.1: Recording of allergy and adverse drug reaction information

It is desirable that patient allergy information and ADR status is captured before any prescribing takes place in the system (either at initial patient registration along with patient demographic information, or during the interview to obtain the medication history). Capturing this information before prescribing medicines may not always be possible (e.g. where patients are confused, unconscious, uncooperative or psychotic). In these instances, the EMM system must alert users that no allergy or ADR information has been recorded, and request that this information be collected as soon as practicable.

The basic information required is the name of the medicine (or class of medicines), the date of the allergy or ADR, a description of the reaction and the name of the person recording the information. In cases where a patient has no history of allergies or ADRs, an entry of 'no known allergies or ADRs' must be recorded. Completion of allergy and ADR information must be mandatory.

The EMM system must be able to bring medicine-related allergy and ADR information forward from previous admissions (if available). This information should be confirmed with the patient during either defined patient activities (e.g. at subsequent admissions or subsequent initial appointments with a clinician) or other opportune times, and updated electronically. The allergy and ADR information database should be accessible by all relevant staff so they can update the information as necessary.

Functional component 2.4.2: Source of allergy and adverse drug reaction information

Allergy and ADR information is not only related to medicines, but is used throughout a patient's episode of care. Therefore, there is a risk that multiple versions of this information may exist, based on when the information is collected or verified, and which system it was entered into. To ensure the integrity and accuracy of this critical information, the DTC (with input from appropriate clinicians) should decide which database will be considered the overriding source.

The information must be stored in one up-to-date database only and linked with all other relevant hospital systems, including the EMM system. For example, the information could be recorded at admission within the PAS or CIS, and stored within a centralised database (which may or may not be a PAS). It should then link to the EMM system (using bidirectional HL7 messaging). Irrespective of where the allergy and ADR information is stored, it must be stored in a format that can be used by the EMM system to trigger clinical decision support alerts.

Functional component 3.0: Clinical decision support

Clinical decision support includes any functionality that provides guidance or incorporates knowledge to help clinicians make the most appropriate clinical decisions for patient care. Clinical decision support includes active alerts and passive support, and should be provided to staff at the decision-making point within their workflow.

It is important to determine how and when clinical decision support is applied within the EMM system implementation. Too much clinical decision support at the start of the EMM implementation could alienate clinicians, but too little may make it more difficult to introduce additional decision support later.

The EMM project team should clearly state its intentions for clinical decision support as part of the EMM implementation planning process so that clinicians understand what decision support rules will be implemented and at what stage in the EMM implementation. Even if the initial level of support rules is low, there are substantial medication safety benefits in implementing EMM systems, including legibility, auditability, accuracy, compliance and the opportunity for clinical practice review.

Functional component 3.1: Active alerts

Active alerts (e.g. prompts, reminders, error alerts) provide immediate and overt notification of potential errors or safety risks to the clinician at the time of making a decision, based on the information that the clinician has entered into the EMM system. These can be triggered by clinical parameters, pathology results, order duplication, drug-drug interactions, known allergies and ADRs (including to medicine excipients), and medication contraindications.

'Alert fatigue' can result from multiple alerts occurring during order entry (see Box 9.3). This can cause clinically relevant alerts to be inadvertently overridden among those that are less relevant. It is important that the local DTC, in conjunction with relevant clinicians, determine the degree to which alerts should be implemented at different stages of EMM system implementation. The design, maintenance and inclusion of specific alerts should be managed by the DTC, and be informed by input from appropriate clinicians and local policies.

As the configuration of active alerts used within hospitals may vary based on the local setting, policies and protocols (e.g. adult compared to paediatric dosages), all clinical staff need to understand which alerts are active and what risk they are designed to mitigate and, more importantly, which alerts are not activated.

As more hospitals implement EMM systems nationally, there may be benefits in sharing lessons learned around alerts, their management and implementation to prevent sites implementing new systems and having to configure alerts from scratch. This may include development of a common set of 'base' alerts for inclusion in clinical decision support systems, which may then be tailored to the local environment and requirements.

Alerts should focus on known, frequent and important errors. Therefore, analysis of an organisation's previous medication error data may help prioritise active alerts.

Box 9.3 Alert fatigue

Active alerts should be kept to a minimum when initially commissioning an EMM system. This prevents the possibility of clinicians getting alert fatigue, a common occurrence documented in the literature where alerts are routinely ignored, including those that are clinically important. Alerts for high-risk medication interactions, order duplication, allergies and contraindications must be activated initially, with other alerts added over time and as necessary.

To further avoid alert fatigue, alerts should be relevant from a patient safety point of view, occur at the point in staff workflows where decisions are made, and ensure a high signal to noise ratio within the system.

The configuration of drug–drug interaction (DDI) warnings may be particularly difficult due to the large number of potential DDIs that may lead to excessive alerts. For this reason, demonstration sites generally disabled DDI alerts during the initial go-live stage.

It may also be useful to review the paper by Bates et al. (2003)³⁹ when developing clinical decision support rules and configuring alerts.

Functional component 3.1.1: Configuration of active alerts

To have the greatest impact on the clinician, active alerts need to balance the risk of the hazard or error (in terms of both likelihood and patient impact), with minimising the level of alert fatigue experienced by clinicians. Active alerts should be relevant, clear, precise, noticeable and brief. In addition, alerts deemed to be essential by the DTC (e.g. high-risk medicines such as warfarin), should be represented in a consistent manner and made more intrusive or noticeable than standard alerts. Multiple alerts for the same error or hazard should be avoided (e.g. an order duplication alert for both the individual medicine and medicine class).

Active alerts should provide recommendations for the clinician as to how to minimise the risk of the hazard or error occurring, rather than just providing an alert that the hazard or error may occur.

An EMM system should enable active alerts to be tailored to clinician type or role (e.g. intern, consultant, nurse), and – ideally – to an individual clinician. This would help filter 'noise' alerts and ensure that only the alerts that are relevant, essential or tailored to a particular specialty or clinician group are presented. This should minimise alert fatigue and maximise the likelihood of the alert being incorporated into the clinician's decision making. Having alerts tailored by group also enables them to be efficiently updated as and when required.

Functional component 3.1.2: Managing different types of active alerts

At the time of a clinician generating a medication order, the EMM system must check the clinical decision supports described below to ensure that an alert, if necessary, is triggered prior to accepting the medication order. The EMM system should allow configurable options so that hospitals or health services can mandate that these alerts trigger when medicines are reviewed, dispensed and administered. Alternatively, the

39 Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Spurr C, Khorasani R, Tanasijevic M, Middleton B. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *Journal of the American Medical Informatics Association* 2003;10:523–530.

EMM system should provide look-up functionality for clinicians to view the alert that triggered during medicine ordering, and any clinical notes recorded by the prescriber or reason for overriding the alert (refer to *Functional component 3.1.3*).

Drug to drug interactions, drug to disease interactions and contraindications to use

Numerous international reference sources rate drug–drug interactions according to severity classification, such as mild, moderate, or severe. The selection of a third-party clinical decision support database should be undertaken by the DTC and supporting clinicians, who should ensure its suitability to the local site. Importantly, it must be integrated into the EMM system and developed for, or adapted to, the Australian context. There must be a protocol in place and a person responsible for updating the clinical decision support database periodically (i.e. monthly) and the DTC must decide on the severity classifications of drug interactions that will trigger alerts in the EMM system.

Managing alerts for drug–drug interactions is often difficult due to the high number of potential drug interactions (of varying severity), which may cause excessive alerts for prescribers resulting in alert fatigue. This needs to be considered by the DTC when making decisions as to which drug–drug interaction warnings to turn on (see Box 9.3).

An ideal EMM system would:

- provide for drug interaction checking at the point of prescribing a new medication to a patient
- allow a doctor, pharmacist or nurse to run a complete drug interaction check against the patient's medicines in the system, as part of a clinical review, at any time separate to a prescribing or dispensing function
- check the complete current medication list of the patient (and perhaps recently ceased medicines) as well as allow for checks against past medicines
- allow the clinician to document the reason for overriding or accepting the information provided
- log a record of who conducted the drug interaction check together with the date and time
- include drop-down check boxes to facilitate communications of actions taken by the clinician and include comment fields that are visible to all system users
- allow flexibility in the level of severity settings required at the different points of performing the drug interaction check; for example, higher severities (contraindicated or hazardous) may be more appropriate to 'fire' at the time of prescribing whereas all severity levels could be activated for a drug interaction check performed as part of a clinical review
- include ability to cross-check individual patient characteristics (e.g. genetic polymorphism) and procedures (e.g. splenectomy, partial thyroidectomy, renal dialysis).

Similar requirements apply for drug–disease interactions.

Order duplication

The EMM system must alert the prescriber where an order for the same medicine already exists for the patient (including PRN medicines). The alert should prompt the prescriber to either confirm or cancel the new order following review of the current medication orders and any recently ceased orders.

Allergies and adverse drug reactions

Allergy and ADR information may be stored either in the EMM system or another hospital database (e.g. a separate clinical information system; see *Functional component 2.4.2*), and where a medicine allergy – or allergy to a medicine excipient – is recorded, the EMM system should display an alert. Allergies and ADRs may be categorised at different levels of severity and the DTC must decide, with clinical input, which level(s) of severity will trigger alerts in the EMM system. These alerts should provide the prescriber with a reason for the alert and, ideally, guidance on potential solutions (e.g. alternative choices for medicines that avoid the allergy or ADR).

Dose range checking

The EMM system must display alerts when a medication order contains dosages that are outside the defined range for the patient or medicine, noting the appropriate dose and prompting review of the order. Factors that may influence the allowable dose range for a patient may include age, weight, pre-existing condition and indication. The definition of dose ranges for each combination of medicine and patient factor should be determined through the DTC and stored in the EMM system clinical decision support database. This work requires substantial resources, and the EMM team should focus on high-risk medicines first.⁴⁰

Pregnancy status

The EMM software must have the ability to record the pregnancy status of the female patients and provide alerts or information on the basis of the category⁴¹ of medicine prescribed. Alternatively, if the software cannot record the pregnancy status, the system must provide a warning on every occasion that medicines in categories other than Category A are prescribed to check the pregnancy status of the patient.

Clinical parameters and pathology results

The EMM system should display a reminder to check specific clinical parameters or pathology results when certain medicines are ordered (e.g. to check INR results before confirming an order for warfarin).

This information may be recorded in separate pathology results or clinical information systems (see *Functional components 1.0.8 and 1.0.9*). Clinical parameters or pathology results should be accessible either by integrating the CIS or pathology results systems into the EMM system, or through external links to the CIS or pathology results systems.

In addition, the EMM system should display an alert when a medicine is ordered that is contraindicated in cases where the patient's clinical parameters or pathology results are outside the allowable range (e.g. ordering digoxin where the patient's pulse rate is lower than the prescribed threshold). In this case, the EMM system must interface with the CIS or pathology results systems to ensure the appropriate alerts are triggered.

Functional component 3.1.3: Recording of reason for overriding serious alerts

When a clinician decides to override an alert deemed to be 'essential', the EMM system should require the clinician to record a reason for overriding the alert. This justification should be viewable by the other system users (e.g. nurses and pharmacists) in real-time. The reasons for overriding alerts should be monitored to identify trends in prescriber behaviour.

40 Institute for Safe Medication Practices (ISMP). *List of High-Alert Medications*, ISMP, Horsham, PA, 2008. www.ismp.org/Tools/highalertmedications.pdf (accessed 16 April 2010)

41 Refers to medicines that should be prescribed with caution or not be prescribed at all where the woman is pregnant. www.tga.gov.au/docs/html/medpreg.htm (accessed 18 February 2010)

Functional component 3.1.4: Maintenance of alerts

All alerts must be reviewed periodically for currency and appropriateness. This should be managed through the local DTC, with expert clinician input. This review needs to assess not only the relevance and appropriateness of the alert content, but also the accuracy of the data source used for generating the alert. In addition, a review of the data generated by the EMM system regarding the handling of alerts (e.g. viewed, ignored or 'skipped', overridden, accepted) should provide insight into the effectiveness of individual alerts and guide the refinement of individual alerts. These data may also identify where specific clinicians or specialties require further training or education on clinical decision support and alerts. It is essential that the date of introduction of different clinical decision support alerts is recorded to allow evaluation of the effect of their introduction.

Functional component 3.2: Passive clinical decision support

Functional component 3.2.1: Medicines reference information

Access to relevant, up-to-date and accurate medicines reference information is essential at all stages of the medication management pathway. The EMM software should incorporate an electronic version of an approved medicines reference information resource (e.g. the *Australian Medicines Handbook*⁴², or similar) or, at the very least, include a link within the EMM to an external source where the equivalent information can be obtained.

If medicines reference information resources are not specifically developed for Australia, they must at least be tailored for Australian practice, and the version and date of last update of any medicines reference information resource should be available within the EMM software. Ideally, the EMM software should also include hyperlinks to the relevant medicines reference information whenever it displays a medicine or medication class name. This would improve ease of access to the information and prevent the need for clinicians to exit the EMM system or spend excessive time locating the relevant information.

Functional component 3.2.2: Guidance on valid forms, routes, frequencies, strengths and doses

To minimise medication errors caused by incorrect selection during ordering, the EMM system should default medication order entries to valid and appropriate forms, routes, frequencies, strengths or doses (refer to *Functional component 2.1.1*). This may be achieved by preselecting appropriate options from the relevant drop-down boxes and restricting data fields to particular numbers, words, ranges or combinations. The choices for selection in drop-down boxes should be determined through the DTC processes and regularly reviewed. This guidance must facilitate ease of use for prescribers, but allow the selection of non-default entries where required.

The use of decimal places displayed when selecting numerical inputs (e.g. strength) should also be defined to allow differentiation of similar-looking numbers. For example, the number one expressed as '1.0' may be mistaken for '10' (ten) and should therefore be displayed as '1'. Conversely, 'half' should be expressed as '0.5' as opposed to '.5', which may be mistaken as '5' (five).

42 www.amh.net.au

Functional component 3.2.3: Standard order sets

The use of standard order sets is a form of passive clinical decision support. It provides guidance on a suggested medication plan or protocol for a given patient or indication. See *Functional component 2.2* for further details.

Functional component 3.3: Local policies and protocols

Deploying clinical decision support is complex and requires significant local support in appropriate governance structures, stakeholder agreement, education and training, staging, and evaluation. Local policies and protocols regarding clinical decision support and medication orders should be managed by the local DTC.

Functional component 3.3.1: Requirements for ordering or administration of some medicines

State and territory legislation, and hospital or health service policies regarding the ordering or administration of certain medicines (e.g. restricted medicines such as Schedule 8 medicines) may dictate that additional processes are undertaken before they can be ordered or administered. An EMM system needs to have a mechanism to allow for these additional requirements. For example, where dual witnessing and approval of administration of restricted medicines (e.g. Schedule 8 medicines) is required, the system must allow for electronic recording of the witness details and some form of validation that these details are authentic (e.g. username and password login, witness's smart card or personal identification number).

Similarly, the EMM system should support policies and protocols approved by the hospital or health service DTC to reduce risk of harm from medicines. For example, where a prescriber orders a high-risk medicine, the system may request acknowledgement that related test results have been reviewed before confirming the order. Examples of high-risk medicines are:

- warfarin — at minimum, the EMM system should allow recording of INR results and a target INR for warfarin orders
- venous thromboembolism (VTE) prophylaxis — the EMM system should prompt for a VTE assessment on all adult patients, enable recording of whether prophylaxis is required or not, and allow ordering of mechanical as well as pharmaceutical prophylaxis. Alternatively, where a CIS is interfaced with the EMM system, mechanisms may be in place for a VTE assessment to be performed in the CIS, with an alert generated in the EMM system to prompt ordering of appropriate VTE prophylaxis as required.

Functional component 4.0: Pharmacy review

An EMM system should reduce the risk of potentially harmful medication orders by requiring pharmacy review and approval of medication orders, including automatic highlighting of orders that are created outside the accepted parameters, and targeted high-risk medicines or patient groups. There should also be a clear indication of the medication orders that have been reviewed by pharmacists and those that are pending review.

Functional component 4.0.1: Access to medication orders for review

The EMM system needs to ensure fast access to medication orders by pharmacists for review, and should include access to the EMM system from the pharmacy and other areas of the hospital. This removes the need for pharmacists to physically locate paper medication charts, provides them with opportunities for remote pharmacy review of medication orders (when required) and may provide more time for clinical tasks. Ideally, the EMM system should indicate the time period(s) that pharmacists are available to review medication orders, and details of where an out-of-hours or on-call service is provided.

Functional component 4.0.2: Prioritisation of medication orders for review

The volume of medication orders for review in the EMM system may exceed the pharmacists' capacity to review them, particularly since the majority of hospital pharmacies are not staffed on a 24-hour basis. The EMM system should support prioritising medication orders for review, such as orders from 'high-risk' wards, 'high-risk' patient groups or 'high-risk' medicines, as identified by the local DTC.

Functional component 4.0.3: Access to current medication record during order review

Pharmacists need to be able to use the EMM system to access the current medication record (refer to *Functional component 1.0.11*) for a patient when reviewing a specific medication order. This information must be up to date to enable the pharmacist to conduct an effective clinical review of the new medication order.

Functional component 4.0.4: Suspension of medication orders if required

During review of the medication order, pharmacists need to be able to use the EMM system to suspend orders where appropriate, and quickly clarify the order with the relevant clinical staff member. The EMM system needs to enable the pharmacist to record a reason for the suspension and include feedback or queries for the prescriber, including a suggested alternative medication order.

Functional component 4.0.5: Recording of clinical and other notes when reviewing medication orders

During review of the medication order, pharmacists need to be able to use the EMM system to record clinical and other information, and this should be visible to relevant staff in real-time. Examples include administration instructions to nursing staff for intravenous (IV) medicines, 'do not crush' instructions and drug level monitoring instructions.

Functional component 5.0: Medication dispensing

Ideally, the EMM system is fully integrated with the pharmacy dispensing system to remove the need for pharmacists to access two separate systems (e.g. one system presenting the full patient medication record and another system presenting dispensing information). This may require bidirectional HL7 messaging if the pharmacy dispensing system is separate from the EMM system (see *Technical component 10.0.6*). This interfacing component requires particular attention due to the risks to patient safety if errors occur at this interface.

Functional component 5.0.1: Recording of medicines dispensed

Where the EMM system is not integrated with the pharmacy dispensing system, it should be capable of recording when a medicine has been dispensed for a particular medication order. The dispensing status of the order should be visible to pharmacists when reviewing medication orders within the EMM system and to nurses when viewing the medication order for administration. Where the pharmacy dispensing system is integrated with the EMM system, it should update the dispensing status of a medication order in the EMM system (through HL7 messaging) when the medicine has been dispensed.

Functional component 5.0.2: Compliance with labelling standards and guidelines

Medicine labels produced using the EMM system or pharmacy-dispensing system must comply with state or territory legislation, guidelines or standards for the labelling of dispensed medicines. The ability to increase font size and type of print on labels should be available for patients with impaired vision.

Functional component 5.0.3: Recording of substitution of medicine

In some cases, the pharmacist may need to supply an alternative or equivalent medicine to that recorded on the medication order (e.g. where the specific medicine ordered is not available). In these situations, the pharmacist must be able to record the actual medicine dispensed and the reason for supplying the alternative in the EMM system. This information should also be available to other system users.

Functional component 6.0: Medication administration

An EMM system should support the administration of medicines across all settings within a facility (e.g. emergency departments, pre-admission clinics, outpatients, wards, discharge) to achieve a paper-free administration record.

Functional component 6.0.1: Recording of administration dose, time and status

The EMM system must enable recording of the administration of a medicine dose, the time the dose was administered and the status of the medication order if a scheduled dose was not administered (e.g. missed, delayed, withheld). Similarly, where administration of the medicine is not completed, the system must have the capacity to record the reason in the same manner. The recorded reasons for not administering a scheduled dose should be in line with the terminology on the current National Inpatient Medication Chart (NIMC).⁴³

43 ACSQHC. *Guidelines for use of the National In-patient Medication Chart*, ACSQHC, Sydney, 2006.

It must also be possible to alter the time for one or all doses of medicines to be administered (with a reason for the change recorded)⁴⁴ and the system should allow the retrospective entry of a medicine administration event, if permitted by local hospital policy. This function is required if, for example, a patient goes on ward leave and is given medicines to take while out of the facility. On their return, the nurse should be able to record the patient's report that they have taken the medicine. The administration time should be the time stated by the patient, not the time the data was entered.

Functional component 6.0.2: Scheduling of medicines for administration

The EMM system must accurately schedule the administration of medicines and should highlight medicines that have particular administration time requirements (e.g. different text colour or bold type). Warnings must be displayed when the medicine is not given within an appropriate window of time (e.g. a pop-up dialogue box displayed for the most clinically appropriate person, or a flashing icon on a medicines administration summary). The timeframe for administration may be governed by clinical requirements (e.g. medicine half-life) or decided by the local DTC with input from appropriate clinicians. If the medicine is not available, a reason for this should be recorded to inform improvements to business processes.

A summary of all medicines that are scheduled for administration, or have been administered, overdue, withheld, missed or cancelled (and the reasons for each, where appropriate) should be available in the EMM system for viewing by clinicians at any time. This summary should be able to be filtered according to ward, specialty, nurse, group of patients or time period. This function should assist the workflow of nurses and others involved in administration of medicines, reduce the number of doses missed, and ensure consistency in the timing of medicine administration.

Functional component 6.0.3: Identifying person(s) administering medicines, and patient and medicine details prior to administration

It is critical that the correct patient, medicine, dose, time and route of administration are established before the administration of any medicine. The identity of the person(s) administering the medicine (e.g. name, role and employee number) must also be clearly recorded in the EMM system. Patients, medicines and clinicians administering medicines may be identified electronically using, for example, machine-readable barcode checking (see *Functional component 1.0.15*).

Functional component 6.0.4: Dual witnessing and checking of medication administration

A number of medicines require tight controls on their administration, defined by legislation (e.g. Schedule 8 medicines or warfarin) or local policy (e.g. some antibiotics). There are two distinct processes:

- witnessing – requires two approved clinicians (usually nurses) to be present when the medicine is retrieved (e.g. from a medicine or storage room) and administered; most commonly required for restricted medicines (e.g. Schedule 8 medicines)
- checking – requires a second approved clinician to check the medication order and the medicine, but not be present during the actual administration of the medicine (this may be required for antibiotics).

44 Ibid.

For witnessing, the EMM system must be able to record both retrieval and administration of the medicine, with the same identification requirements for both clinicians (i.e. the second clinician must be a registered user of the EMM system and have access to perform the witnessing). For checking, there must be capacity to record (in a comments field or equivalent) the details of the person who checked that the medication order and medicine were correct.

Functional component 6.0.5: Management of telephone and verbal medication orders

It is desirable that the EMM system incorporates a mechanism for recording and approving medication orders that are not entered into the EMM system by prescribers, such as telephone and verbal orders. A complete audit trail of these types of medication orders is essential, including the person(s) recording the order (two people are required in some cases to listen to and confirm the order) and the person giving the order. The EMM system should clearly show that the order was initially received via telephone or verbally. Formal validation or countersigned approval of the medication order should be performed in the EMM system by the original prescriber.

Access to this function should be restricted according to local policies. Some hospitals may not allow this function at all, so it should be able to be switched off.

Functional component 6.0.6: Management of nurse-initiated medication and standing orders

Nurse-initiated medicines are those that are approved by a healthcare facility to be administered by a registered nurse (or an accredited enrolled nurse) or midwife without a medical practitioner's authorisation.

Standing orders must be in the form of a detailed written instruction, signed and dated by a medical practitioner, endorsed by the health facility's DTC and reviewed at appropriate intervals. Medication administered according to a standing order must be confirmed by a medical practitioner (or a nurse practitioner authorised to prescribe that medication), by their countersignature within 24 hours.⁴⁵

Medicines that may be nurse-initiated or are contained within standing orders are governed by state and territory, and Australian Government legislation. In addition, the local DTC may be required to approve the specific subset of medicines that can be nurse-initiated and the protocols for standing orders.

The EMM system must be able to support the generation of such medication orders by appropriate nursing staff and the subsequent administration and countersigning (for standing orders) of the medicines ordered. The EMM system should support the generation of medication orders by other approved nonmedical prescribers in the future, if appropriate.

⁴⁵ New South Wales Nurses' Association (NSWNA). *Guidelines on Nursing Responsibilities in Relation to Medications*, NSWNA, Sydney, 2004. www.nswnurses.asn.au/infopages/2890.html (accessed 15 February 2010)

Functional component 7.0: Discharge medicines

EMM systems can help maximise safe medication practice and provide organisational efficiencies when ordering discharge medicines and preparing discharge summaries. Consider providing:

- mobile technology infrastructure that allows the prescriber to produce the discharge prescriptions during ward rounds
- the opportunity for pharmacy to be alerted of the discharge prescription before the Pharmaceutical Benefits Scheme (PBS) prescription is printed and signed (this can support early discharge and maximise bed utilisation)
- ward-based printing facilities with PBS stationery
- the ability to incorporate discharge medicines electronically within the electronic discharge summary (this saves prescribers time on discharge).

Functional component 7.0.1: Population of discharge medicines and discharge summaries from current medication record

It is recommended that the EMM system links with the system generating electronic discharge summaries (e.g. the clinical information system or electronic health record) to populate the discharge summary with discharge medicines. This will be based on the current medication record, the medication history on admission, as well as details of the actual discharge medicines dispensed. This ensures that the discharge summary is accurate and reflects the patient's current medicine needs, including medicine(s) withheld during the admission to be restarted on discharge. The status of pharmacy review of the medication orders should also be visible upon population of the discharge summary.

Functional component 7.0.2: Reintroduction of medicines ceased or withheld on admission

When prescribing discharge medicines, it is recommended that the EMM system can reintroduce (where necessary and as decided by the prescriber) medicines that were ceased or withheld on admission.

Functional component 7.0.3: Reconciliation of medicines on discharge

The medicines ordered on discharge should be reconciled against the current medication record and the medication history on admission (best possible medication history, or BPMH). The medication reconciliation system may be linked to:

- the electronic discharge summary system
- PBS discharge dispensing
- systems for providing patient medicines information (e.g. discharge medicines list).

See also *Functional component 1.0.13: Support for medication reconciliation* and *Functional component 7.0.5: Generation of 'take-home' discharge medicines list*.

ACSQHC's report on electronic discharge summary systems⁴⁶ and a self-evaluation toolkit⁴⁷ are available on the ACSQHC web site.

46 [www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/4A03BE727F85043CCA2578C3001A5CAF/\\$File/EDS%20Evaluation%20Final%20Report%20August%202011.pdf](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/4A03BE727F85043CCA2578C3001A5CAF/$File/EDS%20Evaluation%20Final%20Report%20August%202011.pdf)

47 [www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1BD1A83B20D4CD65CA2578C3001AC3D4/\\$File/EDS-self-eval-toolkit-sept2011.pdf](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/1BD1A83B20D4CD65CA2578C3001AC3D4/$File/EDS-self-eval-toolkit-sept2011.pdf)

Functional component 7.0.4: Reconciliation of discharge summary and dispensed discharge medicines

It is essential that the medicines in the discharge summary are aligned to the discharge medicines. The safest approach is to ensure that discharge medicine orders have been completed and (where required) dispensed before they are incorporated into the electronic discharge summary, and before the discharge summary is signed off and transmitted to the referrer. This ensures that any late changes to the discharge medicines are incorporated in the discharge summary. However, some changes may need to be made to the discharge medicines after the discharge summary is created, but before physical discharge of the patient.

Where the EMM system is not fully integrated with the pharmacy dispensing system or the system that generates electronic discharge summaries, pharmacists should be able to annotate discharge medicines and make last-minute changes to discharge summaries generated by the EMM system. This function is critical because it ensures reconciliation between the discharge medicines listed on the discharge summary, and the actual discharge medicines dispensed and supplied. This helps other healthcare professionals (e.g. general practitioners) who rely on the accuracy of the discharge summary for the patient's ongoing care.

See also *Functional component 1.0.13: Support for medication reconciliation*.

Functional component 7.0.5: Generation of 'take-home' discharge medicines list

The EMM system should be able to generate a discharge medicines list for the patient's or carer's records. This should include medicines to be continued on discharge and any changes made to the medicines during the episode of care. Pharmacists should be able to annotate the discharge medicines list with additional information (where required), such as administration instructions (e.g. take with food), indications for use (e.g. for blood pressure), how to store the medicine and list familiar brand names to assist the patient with safe use of medicines. An example is shown in Figure 9.1.

Hospital pharmacy department								
Test patient UR: 1234567 DOB: 01 Jan 1945								
Discharge medication record: 24 Aug 2011					Ward: Banksia ward			
If you have any questions, please phone 3000 1234 pager 123 and ask for Joe Bloggs (pharmacist)								
Medicine names	Brand name	Used for	Directions	Daily time table				Changes
				Morning	Noon	Evening	Night	
Rampiril 5 mg tablets	Ramace Tritace	Treating high blood pressure	Take 1 tablet in the MORNING	1				New
Atvorstatin 40 mg tablets	Lipitor	Treating high cholesterol	Take 1 tablet at NIGHT				1	Unchanged
Paracetamol 500 mg tablets	Panadol Panamax	Treating pain or fever	Take 2 tablets FOUR times a day when required	Take 2 tablets FOUR times a day when required				Unchanged
The following medicines were CEASED by your hospital health practitioner. Do not take these medicines without further advice.								
Date ceased	Medicine	Brand name	Explanation					
22/08/2011	Amoxycillin 500 mg capsules	Amoxil	Course completed					
Allergies and adverse drug reactions:								
Date	Medicine / causal agent	Reaction						
	Patient has no known drug allergies.							
IMPORTANT: Please note that this medication record may not be a complete and accurate record of all your medications. This medication record is based on: a) information from you and/or your GP and/or other sources; b) information gathered during your hospital stay; and c) discharge instructions. You should contact your regular GP or primary treating doctor to check the accuracy and completeness of this medication record. Please take it to your medical appointments and ensure that your medical records are updated.								
PMGID: 9624		Printed at: 24/08/2011 10:13		Authorised by: Joe Bloggs (pharmacist)			Page 1 /1	

Reproduced with permission from Queensland Health

Figure 9.1 'Take-home' discharge medicines list

9.3 Technical components — software

This section outlines the technical components of software that should be considered when selecting and configuring an EMM system. The software ensures that the EMM system supports the safe management of medicines, and provides appropriate interoperability and integration with other systems, within and potentially outside the hospital. This includes:

- appropriate standards and terminology that provide a basis for consistency in the management and security of health data
- appropriate e-health clinical information standards to ensure interoperability in clinical communications
- interface requirements for integration between the EMM system and other systems.

Technical components — software		Core	Desirable	Aspirational
8.0	Standards and terminology			
8.0.1	Health data standards	✓		
8.0.2	Health data security standards	✓		
8.0.3	Health data messaging standards	✓		
8.0.4	Healthcare Identifiers	✓		
8.0.5	Barcoding standards		✓	
8.0.6	Web services standards	✓		
9.0	e-health interoperability			
9.0.1	Australian Medicines Terminology	✓		
9.0.2	National Product Catalog	✓		
9.0.3	Electronic Transfer of Prescriptions		✓	
9.0.4	Electronic discharge summary	✓		
9.0.5	Medication data specification	✓		
10.0	Support system integration			
10.0.1	EMM system interface requirements	✓		
10.0.2	Configuration and testing of EMM system interfaces	✓		
10.0.3	Interface with patient administration systems	✓		
10.0.4	Interface with pathology test results systems	✓		

continued

Technical components — software		Core	Desirable	Aspirational
10.0.5	Interface with allergy and adverse drug reaction (ADR) data	✓		
10.0.6	Interface with pharmacy dispensing systems	✓		
10.0.7	Interface with discharge summary systems	✓		

Technical component 8.0: Standards and terminology

This section outlines current technical and information management standards and guidelines that should form part of the EMM system. The intention is to raise awareness of the standards, not to repeat them.

The technical and information standards applicable to EMM systems are:

- data
- data security
- data messaging
- user identification
- barcoding
- web services.

Whenever possible, the selection and implementation of an EMM system should adhere to these national and international standards.

Technical component 8.0.1: Health data standards

Guidelines describe important principles for the development and application of quality, consistent health information standards. These include three handbooks published by Standards Australia (via SAI Global):

- HB 303–2007 *Guide to the use of Abbreviations, Acronyms and Local Terms in Health Care*⁴⁸ seeks to minimise the risks associated with the use of abbreviations, acronyms and local terms in health information and health information systems.
- HB 304–2007 *Guide to Australian Electronic Communication in Health Care*⁴⁹ outlines a process for managing any type of electronic communication, irrespective of the technology, device or infrastructure used, and identifies the following principles for consideration
 - risk assessment
 - data protection and privacy
 - data security
 - archiving, disposal and retrieval
 - workflow
 - patient guidelines.

48 <http://infostore.saiglobal.com/store/Details.aspx?DocN=AS0733784208AT> (accessed 17 December 2010)

49 <http://infostore.saiglobal.com/store/Details.aspx?DocN=AS073378481XAT> (accessed 17 December 2010)

- HB 306–2007 *User Interface Requirements for the Presentation of Health Data*⁵⁰ includes guidelines for designing effective user interfaces for health information systems to ensure that user interfaces
 - fit with workflow
 - have consistent pattern recognition
 - prioritise information in the design
 - are suited to intermittent users
 - are suited to multiple users of single machines
 - do not overload the user with error or warning messages
 - are acceptable to the end user.

NEHTA manages Australian licensing arrangements for:

- Australian Medicines Terminology (AMT v2.9)⁵¹, which delivers standard identification of branded and generically equivalent medicines and their components, and standard naming conventions and terminology to accurately describe medicines
- SNOMED Clinical Terms (SNOMED CT), which describes the preferred terminology in Australia and the internationally pre-eminent clinical terminology. SNOMED CT-AU⁵² is available for e-health software developers to use in their Australian products, under NEHTA's licensing arrangements.

Technical component 8.0.2: Health data security standards

The protection of health information is addressed by HB 174–2003 *Information Security Management – Implementation Guide for the Health Sector*⁵³, which considers the protection of health information and the preservation of:

- confidentiality – information should only be accessible and available to those authorised to have access
- integrity – information should be stored, used, transferred and retrieved in ways that ensure confidence that the information has not been tampered with or modified unless authorised
- availability – information is accessible to authorised individuals when and where required.

More general information and communications technology (ICT) security techniques and guidelines are supported by the following Australian standards, also published by Standards Australia:

- AS/NZS ISO/IEC 27002:2006 *Information Technology – Security Techniques – Code of Practice for Information Security Management*⁵⁴
- AS/NZS ISO/IEC 27001:2006 *Information Technology – Security Techniques – Information Security Management Systems – Requirements*.⁵⁵

50 <http://infostore.saiglobal.com/store/Details.aspx?DocN=AS0733784844AT> (accessed 17 December 2010)

51 www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/australian-medicines-terminology (accessed 1 December 2010)

52 For details of NEHTA's licensing arrangements for SNOMED CT-AU see www.nehta.gov.au/connecting-australia/terminology-and-information/clinical-terminology/snomed-ct-au (accessed 1 December 2010)

53 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=568742> (accessed 25 February 2011)

54 <http://infostore.saiglobal.com/store/Details.aspx?productID=1017612> (accessed 1 December 2010)

55 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=394887> (accessed 4 March 2011)

Technical component 8.0.3: Health data messaging standards

The format of the messages to be delivered between systems is specified in Australian Standard AS 4700.3–2005 *Implementation of Health Level Seven (HL7) Version 2.4 – Electronic Messages for Exchange of Information on Drug Prescription*.⁵⁶ This standard covers implementation of the HL7 protocol, the consistent use of data definitions, commentary, and references to the International Organization for Standardization (ISO) and the national health data dictionary (NHDD) browser.⁵⁷ This standard does not specifically deal with commercial transactions with suppliers.

The following standards⁵⁸ are addendums to the original AS 4700.3–2005 since its release in 2005:

- AS/NZS 4700.3:2005/Amdt 1:2006 *Implementation of Health Level Seven (HL7) Version 2.4 – Electronic Messages for Exchange of Information on Drug Prescription*
- AS 4700.3–2005/Amdt 2–2006 *Implementation of Health Level Seven (HL7) Version 2.4 – Electronic Messages for Exchange of Information on Drug Prescription*
- AS/NZS 4700.3:2002/Amdt 1:2006 *Implementation of Health Level Seven (HL7) Version 2.3.1 – Electronic Messages for Exchange of Information on Drug Prescription*.

In the future, there may be a move towards the use of the clinical document architecture (CDA) messaging mark-up standard, and opportunities for the use of CDA may be part of any evaluation of proposed systems.

CDA is an Extensible Markup Language (XML)-based platform that ensures the message contents are readable by people, yet contain a formal structure to allow the use of codes such as SNOMED CT (medical terminology) and Logical Observation Identifiers Names and Codes (LOINC; laboratory observations) within the message. CDA documents can be used independently (e.g. sent as email attachments or transferred between machines). CDA is based on international standard ISO/HL7 21731:2006 *HL7 Version 3 – Reference Information Model Release 1*.⁵⁹

Technical component 8.0.4: Healthcare Identifiers

The Healthcare Identifiers (HI) Service operated by the Department of Human Services Medicare provides identifiers for healthcare providers and healthcare recipients to improve the positive identification of healthcare providers and their clients.

The HI Service uses the following standards:

- AS 3523–1:2008 *Australian Standard Identification Cards – Identification of Issuers, Part 1: Numbering System*, 2008⁶⁰
- AS4846–2006 *Healthcare Provider Identification*, 2nd edition, 2006⁶¹
- AS5017–2006 *Healthcare Client Identification*, 2006⁶²
- ISO/PDTS 22220 *Healthcare Informatics – Identification of Subjects of Healthcare*, International Standards Organisation, 2005

56 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=317503> (accessed 1 December 2010)

57 <http://meteor.aihw.gov.au/content/index.phtml/itemId/268110>

58 Each of these standards can be located on the SAI Global web site by entering the identifier and title in the search engine at <http://infostore.saiglobal.com/store> (accessed 1 December 2010)

59 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=411677> (accessed 1 December 2010)

60 www.saiglobal.com/PDFTemp/Previews/OSH/AS/AS3000/3500/3523.1-2008.pdf (accessed 25 February 2011)

61 www.saiglobal.com/PDFTemp/Previews/OSH/as/as4000/4800/4846-2006.pdf

62 <http://infostore.saiglobal.com/store/Details.aspx?productID=320426>

- ISO7812–16/IEC 7812–1:2000(E) *Identification Cards – Identification of Issuers*, International Standards Organisation, 2000.

Technical component 8.0.5: Barcoding standards

Barcode scanning is governed using the following international standards and these should be considered during system evaluation:

- ANSI/AIM BC11–1996 *International Symbology Specification (Barcodes)*⁶³
- ISO/IEC 16022:2000 *Information Technology – International Symbology Specification – Data Matrix (Barcodes)*⁶⁴
- GS1 Global Trade Item Number (GTIN)
- ISO/IEC 15417 *Information Technology – Automatic Identification and Data Capture Techniques – Code 128 Bar Code Symbology Specification* (for electronic transfer of prescriptions to an external pharmacy).

Technical component 8.0.6: Web services standards

The Australian Government, NEHTA and some jurisdictions have identified web services as an important component in supporting and enriching electronic messages in the healthcare sector.

NEHTA has identified the following specifications for the design of web services:

- Australian Technical Specification (ATS) 5820–2010 *e-health Web Services Profiles*⁶⁵
- ATS 5821–2010 *e-health XML Secured Payload Profiles*⁶⁶
- ATS 5821–2010 *e-health Secure Message Delivery*⁶⁷
- NEHTA *Interoperability Framework Version 2.0*.⁶⁸

Other web service technical standards can be located at the NEHTA web site.⁶⁹

Technical component 9.0: e-health interoperability

NEHTA contributes to e-health interoperability by standardising key clinical information, such as the format of clinical communications and the data they contain. The concepts and descriptions (or terms) used in clinical communications that describe diagnoses, procedures, therapies, medicines and so on must be accurately and consistently interpreted by all health ICT systems and the clinicians that use them.

When evaluating EMM systems, consideration should be given to the following interoperability standards published by NEHTA.

63 Available from the Association for Automatic Identification and Mobility web site www.aimglobal.org/technologies/barcode/2d_symbolologies_matrix.asp#Data%20Matrix (accessed 17 December 2010)

64 Available from the International Organization for Standardization web site www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=44230 (accessed 17 December 2010)

65 <http://infostore.saiglobal.com/store/Details.aspx?productid=1391033> (accessed 1 December 2010)

66 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=1391034> (accessed 1 December 2010)

67 <http://infostore.saiglobal.com/store/Details.aspx?ProductID=1391035> (accessed 1 December 2010)

68 www.nehta.gov.au/component/docman/doc_details/391-interoperability-framework-v20 (accessed 1 December 2010)

69 www.nehta.gov.au

Technical component 9.0.1: Australian Medicines Terminology (AMT)

AMT delivers standard identification of branded and generically equivalent medicines and their components, and standard naming conventions and terminology to accurately describe medicines. The terminology is for use by medication management computer systems, in both primary and secondary health care. For more information on AMT refer to Section 8.3.

Technical component 9.0.2: National Product Catalogue (NPC)

NEHTA, in association with GS1 Australia, has rolled out the National Product Catalogue (NPC). Endorsed by all state, territory and Australian Government health departments, the NPC is a centralised, standardised data repository that uniquely identifies healthcare products, including all medicines, medical devices, equipment and consumables.

The NPC, hosted by GS1 Australia on GS1net⁷⁰, is a single repository of product, pricing and healthcare data for all health industry product categories for the purpose of data synchronisation. These categories include pharmaceuticals, medical devices (e.g. orthopaedics, implants, dental, imaging), catering and food services, cleaning products and so on. The internationally recognised GTIN is used to uniquely identify the products on the NPC and the Global Location Number (GLN) is used to uniquely identify locations.

Technical component 9.0.3: Electronic Transfer of Prescriptions (ETP)

*Electronic Transfer of Prescription Release 1.1*⁷¹, released by NEHTA in December 2010, defines the minimum requirements for the interoperable exchange of prescriptions between general practices and community pharmacies within Australia. This standard may be applicable to EMM systems to enable the transfer of discharge medicines to community pharmacies (either directly or via a prescription exchange service).

Technical component 9.0.4: Electronic discharge summary

The electronic discharge (e-discharge) summary standard by NEHTA enables the electronic exchange of comprehensive and accurate patient reports between hospitals and primary healthcare sectors.⁷² As described in *Functional component 7.0*, the ability for the EMM system to interface with and populate electronic discharge summaries will support accurate transfer of patient medicines information at transitions of care.

Technical component 9.0.5: Medication data specification

NEHTA 0013:2006 Medication Data Specification v1.0⁷³ standardises various clinical concepts to form clinical documents to deliver interoperability in the Australian healthcare setting.

⁷⁰ www.gs1au.org/services/gs1net

⁷¹ www.nehta.gov.au/media-centre/nehta-news/704-etp-11 (accessed 21 January 2011)

⁷² www.nehta.gov.au/e-communications-in-practice/edischarge-summaries (accessed 2 March 2010)

⁷³ www.nehta.gov.au/data-group-library/data-specifications

Technical component 10.0: Support system integration

Technical component 10.0.1: EMM system interface requirements

The ability to interface with existing clinical systems is an important success factor when delivering an EMM system. Interfacing with the following systems is a key consideration when selecting and integrating an EMM system:

- patient administration systems for demographic data (see also Box 9.1)
- laboratory systems for access to pathology data
- systems managing allergy and ADR data (may be the PAS or other system)
- pharmacy dispensing systems for public hospital formulary and stock information, avoiding conflicting information or terminology between the two systems, and transcription errors associated with entering medication orders from paper
- discharge summary systems for the inclusion of discharge medicines and patient medicines information in the discharge summary
- clinical information systems for clinical parameter monitoring data.

Technical component 10.0.2: Configuration and testing of EMM system interfaces

Interface specifications are complex, and require design and specifications by technical staff with substantial experience of interfacing clinical systems.

Each of the configured interfaces needs to be extensively tested to ensure that the EMM process operates seamlessly and supports all of the required functions. This configuration and testing should be overseen by the project team (and will require the assistance of a specialist in systems integration) to ensure that all interfaces meet the requirements of the local site. This testing should be incorporated into the EMM system build and configuration phase (refer to Chapter 17).

Technical component 10.0.3: Interface with patient administration systems

See *Functional component 1.0.10*.

Technical component 10.0.4: Interface with pathology test results systems

See *Functional component 1.0.8*.

Technical component 10.0.5: Interface with allergy and adverse drug reaction data

See *Functional component 2.4.2*.

Technical component 10.0.6: Interface with pharmacy dispensing systems

The pharmacy dispensing systems should accurately and securely obtain patient medication order information directly from the EMM system. This interface should prevent transcription errors associated with the transfer and entry of medication orders between the two systems.

Similarly, the EMM system should accurately and securely obtain information on the actual medicines dispensed directly from the pharmacy dispensing system. This interface (with bidirectional HL7 messaging) should ensure that the EMM system has an up-to-date record of the medicines dispensed for a particular patient. This record would assist with the generation of patient medicines information for inclusion in discharge summaries. As shown in Box 9.4, the interface with pharmacy dispensing systems is potentially the most complex interface the EMM may require.

Box 9.4 Interfacing with pharmacy dispensing systems

Previous implementations have noted that the interface between the EMM and pharmacy dispensing systems is the most complex of the interfaces that may support EMM. There is little Australian experience with full (bidirectional messaging) integration between the two systems.

One of the key issues is that prescriber orders often do not directly translate into what pharmacists must supply to meet the order.

For example, a prescriber may order 'gentamicin nebulising solution'. Such a product does not currently exist, and to meet the order a pharmacist may need to supply the gentamicin as an IV injection, and then provide sodium chloride ampoules along with instructions on how to make up the nebulising solution.

Therefore, to operate seamlessly, such interfaces may need to consider the development of complex translational tables that interpret medication orders from the EMM system into the items necessary for supply from the pharmacy dispensing system.

Technical component 10.0.7: Interface with discharge summary systems

The EMM system should populate the medicines section of an e-discharge summary by direct transfer of patient medicines information to the discharge summary system using messaging standards. The medicines section of the discharge summary should include details of medicines to continue on discharge, medicines ceased or changed during admission or episode of care (including reasons or comments explaining changes), and details of the actual discharge medicines dispensed.

9.4 Technical components — hardware

This section outlines the technical components of hardware to be considered. This includes broad ICT infrastructure requirements and specific advice regarding device selection.

Technical components – hardware		Core	Desirable	Aspirational
11.0	Infrastructure			
11.0.1	General ICT infrastructure	✓		
11.0.2	Back-up and business continuity hardware	✓		
11.0.3	Implementation of permanent test and training environments	✓		
12.0	Devices			
12.0.1	General device considerations	✓		
12.0.2	Specific device considerations	✓		

Technical component 11.0: Infrastructure

Technical component 11.0.1: General ICT infrastructure

ICT infrastructure is a critical component of the successful implementation of an EMM system, and requires detailed consideration and planning during the implementation planning stage.

In addition to the hardware, it is important that the expected demand on the ICT network infrastructure is fully understood and, where required, quality of service is implemented to ensure network performance for EMM system users. Problems with wireless networks (e.g. 'dead spots' within the hospital) and where underspecified networks are unable to cope with the volume of traffic (e.g. the impact of clinical decision support on system responsiveness) can cause major issues. These issues should be identified and resolved during the implementation planning stage.

Technology planning should involve clinicians and ICT staff in the assessment of technology options available for the EMM system, including examining workflow processes and physical space within each ward or area of the hospital to determine the most appropriate technology to support the EMM system.

Technical component 11.0.2: Back-up and business continuity hardware

Hardware for back-up and business continuity is a core component of an EMM system. The processes and protocols to be developed, along with the associated hardware requirements to support business continuity management, are described in *Technical component 13.0*.

Technical component 11.0.3: Implementation of permanent test and training environments

Permanent environments for system testing and training are essential. It is important that these environments exactly mirror the production (live operational) environment.

The test environment should enable testing of new or modified configurations before the live system is updated. Any changes that do not pass user acceptance testing and system testing in this environment should not be implemented in the live system until all defects are resolved (see Section 17.7).

The training environment must exactly mirror the live system and should be continuously available for access by EMM system users, as discussed in Sections 16.9 and 17.6.

Technical component 12.0: Devices

A number of hardware devices are available for EMM systems and their selection depends on the local environment. This section outlines some of the general considerations that may be relevant to selection of any device and some considerations that are specific to particular device types.

Technical component 12.0.1: General device considerations

The following general considerations may apply, irrespective of the type of device selected:

- Device screen size and resolution should meet or exceed the requirements of the EMM software package to minimise or prevent the need for scrolling to see important information.
- It is essential to have a sufficient number of devices to allow access from the bedside (including a number in reserve to replace 'out-of-service' devices).
- Devices should be clinical grade (i.e. robust and support infection control requirements).
- Devices should be highly mobile (including a sufficient battery life in mobile devices).
- Devices should have appropriate hardware for the mode of security authentication selected (e.g. swipe or smart card, fingerprint scanning).
- All devices in a facility should provide a consistent and standardised interface, irrespective of machine or type of device used (e.g. booting to a wireless, standard profile that has access to all relevant clinical applications).
- The way in which the device will be used may have implications for the standardised operating environment; for example, some EMM devices may also require access to other clinical applications or the Microsoft Office suite.
- All devices should be on an appropriate maintenance schedule to minimise the number of devices that are out of service at any one time, and to ensure the replacement of ageing or damaged devices.
- Policies and protocols should be developed for charging devices to ensure they are functional when required.
- The frequency and timing of ward rounds should be factored in to device planning, as these affect the number and potentially the type of devices required (see Box 9.5 for more information).

Box 9.5 Number of devices required

Experience from early Australian EMM system implementations suggests that each ward requires a different number of devices, and the requirement depends on the volume and timing of ward rounds. The total number of devices at a given site should be determined through consultation with clinicians in each ward, with consideration of ward round times and volumes. There must be sufficient devices to accommodate the peak times of EMM system use. As a general guide, sites with EMM systems found the following to be workable:

- one mobile device per 4–5 beds
- one dedicated mobile device for the clinical ward pharmacist
- an appropriate number of fixed devices dependent on ward layout and volume of users.

Technical component 12.0.2: Specific device considerations

Different types of devices may be required for different clinical situations in hospitals. Examples include:

- 'infotainment' devices in wards with fixed-bed configurations
- fixed devices in isolation areas to prevent cross-infection
- fixed devices rather than mobile devices in paediatric areas to prevent accidents involving children and equipment
- mobile devices in day procedure recovery areas
- mobile devices in mental health wards to reduce opportunities for self-harm
- shared devices (e.g. one per 2-bed bay) in intensive care areas.

EMM project teams should visit other EMM implementation sites to understand their experience in using different devices.

Fixed devices (e.g. desktop computers) may be used within pharmacy for dispensing, within a ward for reviewing the EMM system, as a dedicated 'offline medication charts' machine (see *Technical component 13.0.3*), or in a clinician's office for remote access to the EMM system. Ordering or administration of medicines should be recorded at the bedside, and therefore a fixed device (unless dedicated to the bed) should not be used for these purposes. Where the fixed device is used as an 'offline medication chart' machine, it should be connected directly (not via the network) to a dedicated printer and back-up power supply.

Computers on wheels are typically laptop computers mounted on trolleys and are frequently the device of choice for use in the wards. The trolleys should allow easy movement around the ward, have adequate space for writing notes in paper-based patient clinical records, and adequate storage for frequently used forms or stationery. Some demonstration sites also found that incorporating a locked medicine drawer in the trolley for frequently administered medicines prevented the need to continually access a central ward stock during medication rounds. Issues associated with computers on wheels include storage space requirements when they are not in use and, for older devices, poor battery life and associated recharging protocols.

Infotainment systems are computer systems that are typically installed permanently at the bedside (on individual beds) and provide access to the EMM system as well as additional media content such as pay TV and digital movies, or access to consumer medicines information for patients. They may also allow patients to order tailored meals. Some infotainment systems also provide access to other clinical information systems (e.g. electronic nurse handover) at the bedside. As the devices are fixed to individual beds, they avoid a number of the problems associated with computers on wheels and other mobile devices, including:

- the potential to select the incorrect patient, as the EMM system can retrieve the bed details automatically through the PAS and retrieve the relevant patient record according to the specific bed
- the need for charging, as they are constantly connected to power.

However, some issues were identified for infotainment devices. They are generally more expensive than other devices, and the requirement to have one per bed may considerably increase the cost of the overall EMM system implementation. It may be possible to offset some of these costs by charging patients for media access, as has been proposed by one site. Also, further development of the current EMM systems may be required to maximise their use with touch screens, such as those employed in infotainment systems and tablet computers.

Tablet computers are, in general terms, slate-shaped mobile computers fitted with a touch screen, and generally do not have a dedicated keyboard. Tablet computers are designed to be portable and therefore may seem ideal for delivering EMM. However, none of the demonstration sites had widely employed tablet computers, mainly due to their high cost, heavy weight, lack of robustness (prone to damage through dropping) and lack of tailoring of current EMM software for use with touch screens.

Improvements in tablet computers that reduce some of these barriers may support their wider adoption in the future, and they should be considered as part of the device planning. In addition, the findings of at least one primary research study suggest that additional training in use of the EMM system on tablet computers may improve their adoption.⁷⁴ The current tablet computers may be useful for the specific purpose of dual witnessing for selection and administration of restricted medicines that are in medication rooms that are not conducive to the use of other types of devices (see Box 9.6).

74 Anderson P, Lindgaard A, Prgomet M, Creswick N, Westbrook JI. Mobile and fixed computer use by doctors and nurses on hospital wards: Multi-method study of the relationship between clinician role, clinical task and device choice. *Journal of Medical Internet Research* 2009;11(3):1–15.

Box 9.6 Devices for medication rooms

Medicines that require dual witnessing are often kept in separate locked rooms or cupboards on the ward. EMM system demonstration sites noted that these rooms were often too small to accommodate a computer on wheels, or more than one computer on wheels during busy medication rounds. Where administration of such medicines was required and alternative devices were not available (e.g. a tablet computer), staff often either relied on their memory or a written note to recall the details of the patient and medicine for recording administration in the EMM system. As these medicines often require dual witnessing of selection and administration, recording administration at a terminal away from the bedside presents a safety issue.

To avoid this workaround, a device that can be used at both the bedside and in the medication room should be employed (e.g. a tablet computer). Alternatively, the medication room should be large enough to accommodate the device selected for use on the ward (e.g. a computer on wheels) or have a dedicated desktop computer that can use machine-readable smart cards or swipe cards with 'follow-me' technology.

9.5 Technical components — business continuity management

This section outlines the technical components of business continuity management, which is critical for successful implementation of an EMM system and its safety.

Technical component — business continuity		Core	Desirable	Aspirational
13.0	Business continuity			
13.0.1	Planning and protocols	✓		
13.0.2	Periodic failover testing	✓		
13.0.3	Offline medication charts	✓		

When planning an EMM system implementation, consideration should be given to business continuity management (BCM). BCM consists of the procedures and protocols that are implemented in the event of a failure (in whole or in part) of the EMM system. The worst-case scenario for BCM is the complete failure of the EMM system and the process by which the hospital reinstates paper medication charts, and how the EMM system is updated from these charts when it resumes operation. However, BCM can also apply to a small part of the hospital; for example, where a ward is without power for several hours. The BCM risk mitigation should be proportional to the magnitude of the incident.

As different components of the EMM system (e.g. software, device hardware, network hardware, back-up hardware) may be supplied by different vendors, it is critical that BCM includes all providers to ensure end-to-end coverage of business continuity. It is essential to coordinate these separate providers and articulate the responsibilities of different vendors to ensure around-the-clock EMM system continuity (see Box 9.7).

Access to the EMM system on a 24-hour, 7-days a week basis is critical to the hospital's operation. In contrast to other systems, like the PAS and diagnostic results systems (where there may be alternative means of sourcing the necessary information in the event that these systems are unavailable), the EMM system is the only complete source of medication management information in the hospital once implemented.

Technical component 13.0: Business continuity

Technical component 13.0.1: Planning and protocols

Consideration of BCM requirements should help to:

- understand the environment, vulnerabilities and criticalities of the hospital in implementing the EMM system
- identify the nature and source of potential disruption events by considering the technical components in the chain that provide the EMM system service, such as the
 - EMM system application and host server environment
 - data centre or computer environment where the EMM system resides
 - ICT network and the level of redundancy within the network at all points between the host-server environment and the EMM system devices within wards
 - back-up generator power supplies within wards and the devices supported; for example, printers that are capable of printing EMM system-derived medication charts when parts of the hospital's network have failed
 - downtime of other key systems interfaced to the EMM system; for example, where PAS has to provide the admission event to the EMM system before inpatient prescribing can take place, or the unavailability of lab results at the point of prescribing
- understand the consequence of each potential source of disruption in terms of its impact on the EMM system
- implement strategies to mitigate each risk
- recognise that disruptions may occur that have not been considered in the business continuity plan risk assessment.

The following approach to BCM should be considered:

1. *Commencement* – gain senior management support to develop and identify policy and strategy for business continuity, aligned to the hospital's existing business continuity strategies.
2. *Analyse risk and vulnerability* – determine critical success factors and identify critical processes or assets.
3. *Analyse business impact* – determine the maximum time that the business can operate without an element of the EMM system.

4. *Define response strategies* — develop strategies for emergency, continuity and recovery situations, and determine disaster recovery, failover and redundancy design requirements. Disaster recovery protocols must be regularly validated, updated and distributed to ensure that staff are aware of their responsibilities. Staff also need to know who to contact if the system fails.
5. *Develop resource and interdependency requirements* — consider what else depends on the successful use of the plan, and who or what is required to deliver the plan.
6. *Develop continuity plans* — produce a set of easy steps, including a list of supporting documents and equipment required to follow the steps.
7. *Develop a communications strategy* — inform staff and external stakeholders of the current status or potential disruptions.
8. *Schedule training, maintenance and testing of plans* — develop a regular training schedule that tests the staff's understanding and use of the plans.

The Australian standard for business continuity management is available for purchase at: <http://infostore.saiglobal.com/Store2/Details.aspx?ProductID=1409610>.

Box 9.8 Example response strategy

Response strategy design options for the EMM system server and application environment may include:

- a failover solution that automatically switches to a secondary stand-by EMM system database, server or network if the primary system fails or is temporarily shut down; failover occurs automatically and requires little more than the user to reconnect to the EMM system
- 'hot', 'warm', or 'cold' recovery sites that result in varying degrees of interruption or temporary delay in processing while the EMM system is recovered
- alternative workarounds (e.g. where copies of each updated medication chart are stored elsewhere for printing in the case of power outage or loss of the EMM system) to account for scenarios where the EMM system is available but the network infrastructure (or parts of it) is unavailable.

Technical component 13.0.2: Periodic failover testing

The BCM protocols should be periodically tested to ensure that the EMM system can recover within the expected timeframe and with full data recovery. The timing of these tests should be determined by ICT services and the EMM operation multi-disciplinary team. All staff should be aware in advance that the testing is to occur and staff should provide feedback on the effectiveness of the protocols to allow for future refinement.

Technical component 13.0.3: Offline medication charts

The EMM system must be capable of rapidly printing up-to-date copies of every active medication chart, at any time, including when there is a loss of connectivity between the EMM system workstations and the EMM system data server (e.g. the EMM system is offline).

It should be possible to instigate this function from any stand-alone workstation, but there should be at least one workstation per ward dedicated to this function. The dedicated workstation must be directly connected (i.e. not through the network) to a printer that can rapidly print high volumes (e.g. a high page-per-minute laser printer). In addition, the dedicated workstations must be connected to uninterruptible power supplies to ensure continued operation if power is lost. Software design should allow a 'one-touch, print-all' option, as well as the option of printing individual charts.

Protocols should be in place that govern who is responsible for ensuring the medication charts are quickly printed, how these paper medication charts are distributed throughout the wards and how to ensure the correct medication charts reach the correct patients (see Box 9.9). Different protocols may be required to manage failures that occur during different times of the day (e.g. before or after a medication round).

For example, responsibility for the decision to print EMM system-derived medication charts should be assigned to a senior officer, such as the nursing coordinator (or nominated member of the operations multi-disciplinary team during business hours) who can check to ensure that the interruption is a sustained outage and not merely a 'hiccup'. This senior officer should liaise and communicate with ICT services.

When the senior officer decides that the outage is of sufficient duration that printing EMM system-derived medication charts is needed, they can then advise the work areas of what to do next. Responsibility for printing the EMM system-derived medication charts should transfer to the work areas, and should be supported by training and regular practice sessions (see *Technical component 13.0.2*).

Once the EMM system is back online, there must be clear protocols for how amendments to the medication charts that were recorded on paper are reconciled with the medication record last updated in the EMM system.

Box 9.9 Offline medication charts

It is essential that the workstations dedicated to printing the medication charts when the EMM system is offline have the most up-to-date version of each medication chart in a format that can be easily and quickly printed. To achieve this, during normal operation, the EMM system should automatically generate a single document for each active medication chart (i.e. in PDF format or similar) and then distribute this to the dedicated workstation in the relevant ward.

Each time the medication chart is modified, the EMM system should automatically replace the existing PDF version with the newest version.

For additional system redundancy, all the offline medication chart workstations should hold copies of the medication charts for all wards. This would still allow printing of all medication charts in situations where the dedicated workstation for one or more wards is non-functional.

Workstations dedicated to printing medication charts when the EMM system is offline should be connected to fail-safe power points (supported by back-up generators or uninterruptible power supplies) and mobile devices must have adequate battery life.



Section B

EMM organisational considerations

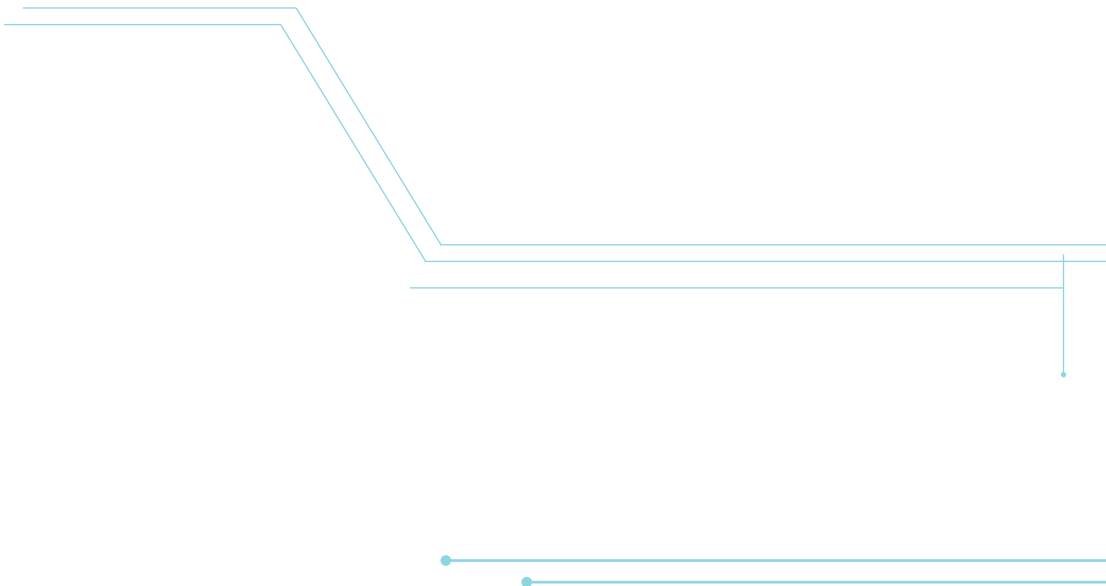
This section of the guide covers:

Chapter 10 Principal stakeholders and key users

Chapter 11 Governance

Chapter 12 Change management

Chapter 13 Sustainability of the EMM system.



Principal stakeholders and key users

Hospital project teams considering implementing an electronic medication management (EMM) system must appreciate from the outset that substantial financial, human and technical resources will be required. The extent of the change management required must be clearly understood by the hospital executive and senior stakeholders, and the EMM system implementation must be fully supported by this leadership team.

This chapter summarises the key considerations for each of the hospital's senior stakeholders and decision makers, and the clinicians that will implement and use the EMM system.

10.1 Principal stakeholders and decision makers

This section highlights the key issues and messages to be considered by the principal stakeholders and decision makers, which include the:

- chief executive officer (CEO)
- director of medical services / medical superintendent / medical champions
- director of pharmacy
- director of nursing and midwifery
- chief information officer (CIO)
- drug and therapeutics committee (DTC).

10.1.1 Chief executive officer

Given the size and complexity of an EMM system implementation, the CEO must:

- be familiar with the rationale for the proposed EMM system and why it is important for the organisation, and be adept at communicating and reinforcing key EMM system messages
- be convinced that the proposed project costs are realistic and affordable – information and communications technology (ICT)-related projects have a tendency to underestimate true costs, and a lack of funds will compromise both the safety and efficacy of an EMM system implementation
- assess the ICT infrastructure costs separately, as this infrastructure will be used for other hospital applications – EMM systems incur substantial infrastructure costs for mobile wireless devices or other equivalent bedside access, and high-availability infrastructure is required to ensure around-the-clock availability of the electronic medication charts. Separate business cases for the EMM system and ICT infrastructure should be considered so that the shared infrastructure costs do not distort the EMM system business case
- ensure that the proposed governance model has appropriate representation from senior medical, pharmacy, nursing, ICT, finance, and safety and quality staff, and that the individuals nominated can ensure a high quality and successful EMM system implementation within their areas of responsibility.

The CEO should:

- give serious consideration to chairing the EMM system project board given the high project costs, technical complexities and the organisation-wide human factors associated with implementing an EMM system. There may be occasions when the CEO is called upon to provide authority and resolve conflict
- visit other hospitals that have implemented EMM systems to understand both the technical magnitude of the task and the human challenges of implementation
- understand the implications of project recommendations to turn-off aspects of electronic medication decision support
- understand the massive organisational impact associated with implementing EMM
- commit resources to ongoing improvements in medication safety using EMM and adequately fund the ongoing maintenance of the EMM system.

Overall, the CEO must be satisfied that the scope of the proposed EMM system project is well conceived, well constructed and achievable within the organisation's capabilities, resources and other priorities.

10.1.2 Director of medical services / medical superintendent / medical champions

One of the biggest challenges associated with EMM system implementation is gaining and maintaining the support of the hospital's senior medical staff. Senior medical staff are role models for junior medical staff, and need to encourage and support the use of the EMM system. The director of medical services or medical champions will play a critical role in advocating the use of EMM system among the senior medical staff.

The director of medical services or medical champions must:

- nominate additional medical staff or champions to participate in EMM system governance structures with appropriate reporting back to the director of medical services or medical champions
- undertake EMM system training, and be familiar with EMM system concepts and issues as they relate to medical staff
- ensure all medical staff undertake the scheduled training in EMM system use, and identify strategies for training of agency and locum medical staff. This will be particularly challenging for private hospitals, because the visiting medical officers (VMOs) are not employees of the hospital.

The director of medical services or medical champions should:

- be a member of the EMM system project board
- visit other hospitals that have implemented EMM systems to understand the opportunities and challenges from the perspective of the medical staff
- attend EMM information sessions and product demonstrations where the audience includes medical staff
- be an early adopter of the EMM system within the hospital
- consider engaging a doctor to train medical staff
- identify strategies that encourage medical staff participation
- ensure that the mobile devices selected (e.g. computers on wheels) enable appropriate bedside access for prescribers, and for VMOs remote access to the EMM (due to the limited availability of on-site junior doctors in private hospitals).

Key messages for the director of medical services or medical champions in engaging with medical staff include:

- the importance of medication safety and reducing medication errors – international and Australian research shows that medication errors are the second most common type of medical incident reported in hospitals, with omission or overdose of medication being the most frequent medication errors⁷⁵
- the need for improvement – demonstrated by the type and extent of existing safety and quality issues, highlighted by local hospital incident data
- the benefits of EMM systems, which
 - help to reduce medication errors and associated clinical risks^{76,77} through legible, abbreviation-free and auditable medication orders
 - align discharge summaries with patient medicines information in the discharge summary provided to general practitioners
 - make patients' previous medication records (including medicines on admission and discharge medicines) available for repeat admissions and patients that frequently visit hospital, reducing the time required to prescribe these medicines
- prescribing medicines electronically may take longer than paper-based prescribing, but this time should be offset against the time saved in other areas, such as no longer having to rewrite medication charts or locate paper charts. This time saved downstream across the multi-disciplinary team is substantial
- selling the 'whole package' of EMM, which includes easy-to-use EMM that is highly integrated with other hospital systems, and supported by a robust and accessible technology infrastructure.

10.1.3 Director of pharmacy

Pharmacists are experts in the safe use of medicines, and substantial pharmacy input and resources will be required at all stages of implementation and ongoing operations of an EMM system. The director of pharmacy is a key stakeholder and decision maker, and should consider taking a proactive leadership role.

The director of pharmacy must:

- nominate senior pharmacists to participate in EMM system governance structures with appropriate reporting back to the director of pharmacy
- undertake EMM system training, and be familiar with EMM system concepts and issues as they relate to pharmacy
- ensure that the work required of pharmacists is resourced appropriately, as pharmacy bears a large share of the work associated with the implementation and ongoing operations of an EMM system (through mainstreaming EMM capabilities within the pharmacy service that reduced dependencies on individual pharmacists). Part-time secondment of pharmacists to EMM project roles must be avoided due to the potential conflict between a pharmacist's EMM system project duties and operational pharmacy duties

75 Roughead LK, Semple S. *Medication Safety in Acute Care in Australia*. Literature review, Sansom Institute, University of South Australia, prepared for the Australian Commission on Safety and Quality in Health Care, Sydney, 2008.

76 Franklin BD, O'Grady K, Donyai P, Jacklin A, Barber N. The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study. *Quality and Safety in Health Care* 2007;16:279–284.

77 Westbrook J, Lo C, Reckmann M, Runciman W, Braithwaite J, Day R. The effectiveness of an electronic medication management system to reduce prescribing errors in hospital. *Health Informatics Conference 2010 Proceedings* 2010;18:96–100.

- ensure that the mobile devices selected (e.g. computers on wheels) enable appropriate bedside pharmacy review.

The director of pharmacy should:

- be a member of the EMM system project board
- visit other hospitals that have implemented EMM systems to understand the opportunities and challenges from a pharmacy perspective
- attend EMM information sessions and product demonstrations to provide leadership and expert pharmacy advice
- identify strategies that encourage pharmacist participation
- ensure the EMM system addresses medication management requirements
- ensure there is a clearly defined objective within the proposed scope of the EMM system project to integrate the EMM system with other systems in use within the hospital pharmacy. The lack of integration (to date) between an EMM system (primarily used for prescribing, pharmacy review and administration of medicines) and the back-end pharmacy system used for dispensing and stock control has, in some cases, increased the workload of hospital pharmacists and has the potential to increase the risk of medication error
- probably not assume the role of project sponsor, as an EMM system represents substantial multi-disciplinary organisational change and there is a risk that the EMM project may be seen by the hospital as a 'pharmacy project'
- ensure there is ongoing funding to adequately support the maintenance and upkeep of the EMM system so that it remains relevant and up to date.

10.1.4 Director of nursing and midwifery

Nurses and midwives represent the largest staff group to use the EMM system. As such, the director of nursing and midwifery is a key stakeholder and decision maker, and there are a number of nursing and midwifery-specific issues that require consideration.

The director of nursing and midwifery must:

- nominate senior nursing staff to participate in EMM system governance structures with appropriate reporting back to the director of nursing and midwifery
- undertake EMM system training, and be familiar with EMM system concepts and issues as they relate to nursing and midwifery
- ensure there is EMM system access in areas where medicines are stored, and be satisfied that there are sufficient devices in clinical areas to meet the requirements of nursing and midwifery, including around-the-clock access to medication charts
- ensure that the mobile devices selected (e.g. computers on wheels) enable appropriate bedside access for medicines administration and device storage.

The director of nursing and midwifery should:

- be a member of the EMM system project board
- visit other hospitals that have implemented EMM systems and understand the opportunities and challenges from a nursing and midwifery perspective
- attend EMM information sessions and product demonstrations where the audience includes nursing and midwifery staff

- consider making nurses and midwives available to provide the EMM system training to other nurses and midwives, and identify strategies for training agency nursing and midwifery staff
- identify strategies that encourage nursing and midwifery staff participation.

10.1.5 Chief information officer

The implementation of an EMM system requires substantial additional ICT infrastructure in most hospitals, and the CIO is a critical stakeholder in ensuring the EMM system is successful.

The size and complexity of the EMM system is significant and must be incorporated into the hospital's ICT strategic thinking. This includes technical infrastructure and high-end server availability options, the application architecture and software solution mix, interoperability, and interfacing. In many hospitals, the EMM system will be the first solution requiring high availability and around-the-clock support arrangements.

The EMM system will require point-of-care and bedside access in all clinical areas, which is likely to require extensive additional network, wireless and power supply infrastructure, and a significant increase in the numbers of mobile and bedside devices (such as wireless computers on wheels or 'infotainment' systems) in most hospitals.

The EMM system will replace the paper medication charts, requiring high-availability solutions that ensure the system remains operational, along with business continuity procedures that enable medicines to be prescribed, dispensed and administered in the event of a system or infrastructure component failure.

In Australia, there are two common approaches to implementing an EMM system:

- as a separate EMM software product that is integrated with or interfaced to other key hospital systems (such as pathology and patient administration)
- as part of a comprehensive clinical system that may also include other functions such as orders and results reporting, and clinical documentation.

The choice of EMM system will be highly influenced by the hospital's current or planned application architecture. Before procurement, the EMM team must make strategic decisions regarding the degree of integration required between the EMM system and other clinical systems, so the application provides a high-quality clinician user experience and supports efficient clinical workflow.

The choice of EMM system will influence, and be influenced by, the hospital's choices in relation to interoperability with other clinical applications to ensure that all the systems, including EMM, meet the wider clinical and business requirements of the hospital.

The CIO must:

- actively participate in the initial stages of EMM system implementation planning to ensure that the ICT infrastructure is sufficient to meet the needs of an EMM system, and the choice of EMM system aligns with the hospital's strategic intent for applications architecture
- be a member of the EMM system project board, given the size and complexity of the technical requirements of EMM system. If this is not possible, the CIO must ensure a senior member of ICT services is a member of the EMM system project board and other governance structures, with appropriate reporting back to the CIO

- consider preparing an ICT infrastructure business case that is separate to the EMM system business case — the cost of the ICT infrastructure required to support an EMM system will be substantial, but will also be used for other hospital applications, so the shared infrastructure costs should not distort the EMM system business case
- consider bringing forward the implementation of ICT infrastructure dependencies so the required infrastructure does not become an obstacle to EMM system implementation. The size and complexity of the required ICT infrastructure is likely to warrant several projects that are managed separately from the EMM system project while maintaining reporting mechanisms between projects (e.g. equipping the hospital with the required ICT infrastructure is sufficiently complex to be a project in its own right). Other parallel projects might include high-availability infrastructure or business continuity planning solutions, and the implementation of bedside devices such as computers on wheels or infotainment systems
- consider other aspects of implementing an EMM system, including the availability of adequate education and training facilities, establishing the required server environments (production, training, testing and development), using quality of service in maintaining EMM system performance, and around-the-clock support arrangements.

10.1.6 Drug and therapeutics committee

The DTC or equivalent group within the hospital must play an integral and active role in all stages of the EMM system implementation and ongoing operations processes, with input from relevant clinician groups.

The DTC (with input from appropriate clinicians) must:

- review the EMM system's functional specifications and business requirements
- review and approve any changes or additions to standard order sets and order lists, public hospital formulary items, policies and protocols, EMM system alerts or their configuration, or other system configurations that may impact the safe use of medicines
- determine the degree to which individual alerts and groups of alerts are activated in the EMM system
- approve the selection, and oversee the ongoing use, of third-party medicines reference information sources and clinical decision support systems used by the EMM system so they remain consistent with other information sources within the hospital.

10.2 Key users

This section highlights the main issues that require consideration from the perspective of the key users involved in the EMM system implementation. These are users who:

- prescribe medicines (mainly medical officers)
- review and supply medication orders (pharmacists)
- administer medicines (mainly nurses and midwives).

10.2.1 Prescribers

The active engagement and participation of prescribers is critical to the success of EMM. Past experiences in Australia suggest that prescribers must:

- undertake EMM system training and understand the rationale for changes to their workflow on moving from paper-based prescribing to electronic prescribing
- be involved in selecting clinical decision support tools to be used in the EMM system, the alert activation level and configuration of alerts; a balance is required between too many alerts (resulting in alert fatigue) and the need for essential alerts to ensure safe use of medicines
- be conscious of the potential for introducing errors when selecting medicines, strengths, doses, forms, routes and frequencies, and ensure that the final medication order reflects the prescriber's intention before confirming the order.

Prescribers should:

- be involved in the specification, selection, user acceptance testing and evaluation of the EMM system, and provide feedback on the required functionality and usability
- take advantage of the improved access to clinical decision support tools (such as medicines reference information and dosing calculators) at the time of prescribing medicines and incorporate these tools into their prescribing workflow
- review and acknowledge prescribing alerts and modify prescribing behaviour accordingly
- be involved in developing standard order sets, and specialty or therapeutic-specific order lists
- record an indication or reason for each medication order to ensure other clinical users are aware of the intent of the order and, where appropriate, record additional clinical information that may help other clinicians understand how the medicine should be managed
- not prescribe on paper medication charts in wards where the EMM system is fully implemented, unless required to do so due to lack of EMM system functionality for certain drugs or administration regimens (e.g. where medicines are not currently supported by the EMM system, such as complex variable dose medicines or fluids for infusion). The existence of both paper and electronic medication charts for a single patient can lead to confusion and increases the risk of medication errors. Prescribers must adhere to hospital prescribing policies such as those detailed in Box 16.4.

10.2.2 Pharmacists

Pharmacists have considerable experience and knowledge of medicines, and their expertise is essential to the successful implementation and use of an EMM system. The Australian experience suggests that pharmacists must:

- undertake the EMM system training and understand the rationale for changes to their workflow on moving from paper medication charts to an EMM system
- be involved in configuring the interfaces between the pharmacy dispensing system and the EMM system, to ensure they work seamlessly, minimise the risk of introducing medication errors, and maximise the efficiency and benefits of the EMM system to the pharmacy service

- ensure that the public hospital formulary in the EMM system and the pharmacy dispensing system is equivalent, if these two systems are not fully integrated. Pharmacists must ensure that the public hospital formulary in both systems is kept up to date to ensure prescriber access to all available medicines, and ensure that consistency of interpretation of medication orders is maintained between the two systems.

Pharmacists should:

- be involved in the specification, selection, user acceptance testing and evaluation of the EMM system, and provide feedback on the required functionality and usability
- be involved in selecting clinical decision support tools to be used in the EMM system, the alert activation level and configuration of alerts; a balance is required between too many alerts (resulting in alert fatigue) and the need for essential alerts to ensure safe use of medicines
- be involved in developing the baseline indicators for evaluating the effectiveness and safety of the EMM system
- record clinical and supply information when reviewing medication orders to ensure other clinical users have the information they need to manage the medication orders
- be responsible for updating and maintaining the public hospital formulary, standard order sets and order lists, and managing clinical decision support-related databases in the EMM system.

10.2.3 Nurses and midwives

Nurses and midwives are responsible for ensuring that medication orders are administered as required. This means administering the correct medicine to the correct patient at the correct time, and in the correct form, dose and route. Australian experience and knowledge suggests that nurses and midwives must:

- undertake the EMM system training and understand the rationale for changes to their workflow on moving from paper medication charts to an EMM system
- ensure timely recording of administration of medicines in the EMM system, and reasons for overdue, withheld, missed or rescheduled medicines
- ensure that witnessing and checking of specific medicines in the EMM system occurs in accordance with legislative and hospital policy requirements
- ensure that administered medicines are recorded in close proximity to the patient, preferably at the bedside or point of care. Medicine administration must be managed as a single process using a single device that can be accessed at the bedside, and must not be recorded in, for example, medication storerooms
- avoid transcribing medication orders from the bedside device onto scrap paper (as an aide-memoire) for collection of the medicine from a medication room. It is preferable that the medication room device is used to access the patient's medication record so that the transcription is avoided.

Nurses and midwives should:

- be involved in the specification, selection, user acceptance testing and evaluation of the EMM system, and provide feedback on the required functionality and usability
- be familiar with the policies and protocols for managing medicines that may continue to be managed on paper medication charts; for example, where variable dose medicines such as warfarin continue to be managed on a paper medication chart, the existence of the paper medication chart must be appropriately recorded in the EMM system, but the EMM system will advise the nurse or midwife to refer to the paper medication chart
- take advantage of the improved access to clinical decision support tools (such as medicines reference information and dosing calculators) at the time of administration of medicines and incorporate these tools into nursing and midwifery workflow
- record clinical notes regarding administration of medicines in the EMM system to assist other clinicians in their medication management decisions (e.g. if a patient is 'nil by mouth').

10.2.4 Shared user responsibilities

All EMM system users share common responsibilities to ensure the safe and effective operation of the EMM system. These responsibilities include:

- reporting any perceived issues or risks in relation to use of the EMM system
- maintaining client confidentiality when using the EMM system
- ensuring user identification and password information remain confidential to prevent unauthorised access to the EMM system
- being familiar with the business continuity management plans and what to do in the event of an EMM system failure
- understanding the risks associated with multiple medication charts and abiding by the policies for the use of both electronic and paper medication charts (i.e. which medicines or circumstances permit the use of paper medication charts)
- adhering to the protocols for storing and charging EMM devices when not in use
- quickly reporting faulty equipment to the hospital department responsible for the maintenance of devices.

Governance

Robust project governance is critical to successfully implementing an electronic medication management (EMM) system. This section describes the roles of the various groups involved in EMM project governance and management.

Although many of the elements described in this section may seem obvious to organisations experienced in managing complex information and communications technology (ICT) and redesign projects, it is included here for completeness particularly for those organisations with less experience in managing projects of the scope and complexity of an EMM system.

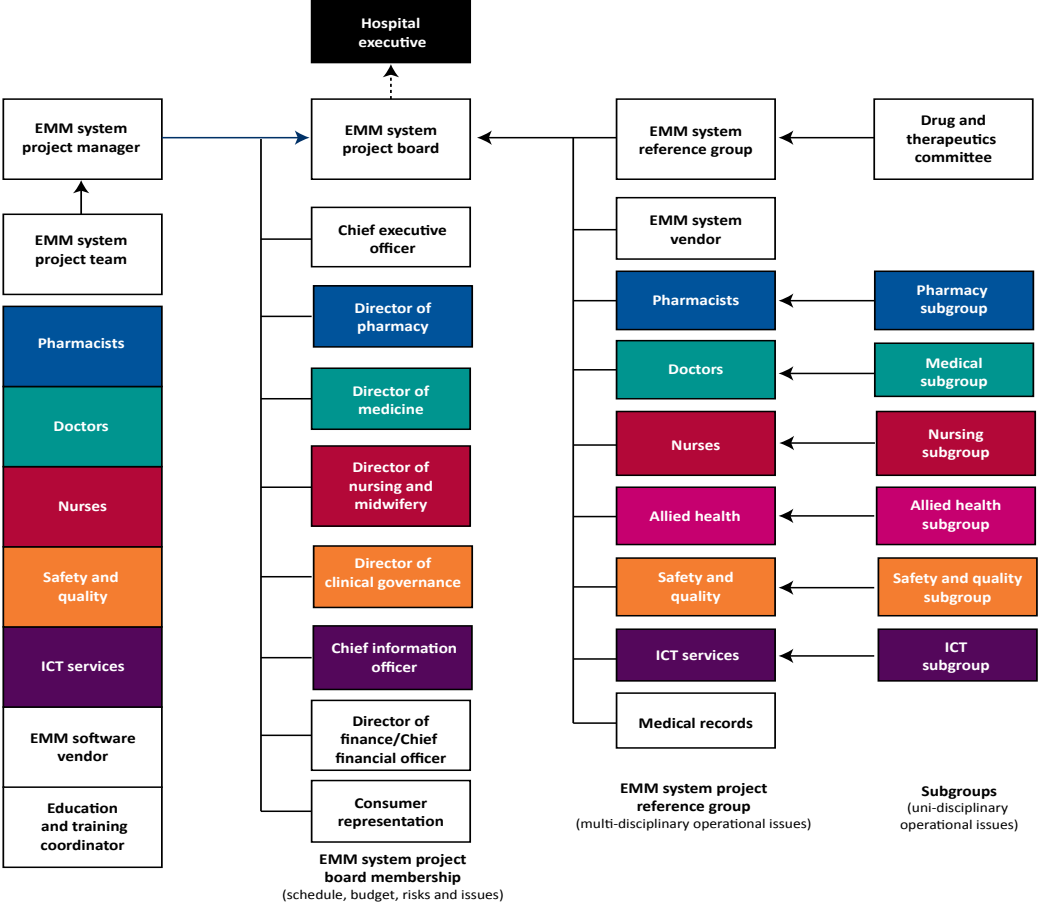
The importance of effective project governance cannot be underestimated if the required outcomes in a complex, multi-disciplinary, whole-of-hospital project such as an EMM system implementation are to be achieved. The ICT infrastructure requirements for an EMM system add further complexity to the project, with substantial additional costs and dependencies that require careful management and oversight.

Good project governance provides strong leadership, clarity in decision making, and transparency in roles and responsibilities to ensure successful implementation of EMM. The EMM system project governance should reflect the size, complexity and cost of the EMM system project, including multi-disciplinary representation from medical, nursing and pharmacy staff, consumer representation and appropriate ICT representation to manage technical infrastructures.

A suitable EMM system governance structure may consist of four operating levels:

1. The EMM system **project board** focuses on the project schedule, budget, risks and issues. This group has overall responsibility for the time, quality and financial aspects of the EMM system project.
2. The EMM system **project team** undertakes the day-to-day operations of the project and is responsible for carrying out the directions of the project manager. The project team, or members of it, should have an awareness of all aspects of the EMM system project.
3. The EMM system **reference group** focuses on multi-disciplinary aspects of the implementation. This group has responsibility for all operational aspects of the EMM system project and ensures that individual components come together in the overall solution, including education and training, process mapping, communications, safety and quality, and interfaces to other systems.
4. **Subgroups and working groups** tackle the specialty details. For example, the pharmacy subgroup focuses on establishing the public hospital formulary, integrating the EMM system with dispensing and stock control functions, and the pharmacy review workflows. The ICT subgroup considers wireless and mobile device infrastructure, high-availability solution options, and transition to support. The drug and therapeutics committee is a critical working group that will advise on all aspects of medicines policy and medication management processes within the EMM project.

Figure 11.1 shows a typical EMM system project governance structure. Smaller hospitals might collapse this structure by combining the work of the reference group and the subgroups or working groups.



EMM = electronic medication management; ICT = information and communications technology

Figure 11.1 Typical EMM system project governance structure

11.1 Project sponsor

The project sponsor is the person primarily responsible for delivering the EMM system. Choosing the right project sponsor is critical to the successful implementation of an EMM system. EMM is largely about medicines and their management, and while the director of pharmacy might be a good choice of project sponsor, it is important that the EMM project is clearly communicated as a whole-of-hospital project and not perceived as a pharmacy or ICT-driven project. Other candidates that should also be considered include the:

- CEO – given the breadth, complexity and costs associated with EMM system implementation, the CEO would send a strong message to the hospital of the importance of EMM, and demonstrate top-level commitment to achieving a successful implementation
- medical director or medical superintendent – a large resource and time cost in implementing an EMM system rests with junior medical staff in public hospitals, so choosing a senior member of the medical staff as project sponsor may help engage and maintain medical staff support
- director of safety and quality – EMM is a safety and quality initiative that could be led by the hospital's safety and quality unit, providing impartial sponsorship and a strong voice for patient safety and quality.

Regardless of the project sponsor's background, it is essential that the EMM project is fully supported by the CEO, the senior medical staff, the director of pharmacy and the director of nursing and midwifery.

11.2 Project board

The EMM project board should consist of, at a minimum, the project sponsor and a small number of principal stakeholders representing prescribers, pharmacists and nurses, as well as finance, ICT services and consumers. The main focus of the project board should be the oversight of the EMM system project schedule (and project tracking against the schedule) to identify and manage:

- critical milestones and timeframes
- project risks and related risk mitigation strategies
- issues management
- project budget, including actual expenditure and estimates to project completion.

The project board is responsible for approving any variations to the EMM project schedule or budget, and should report through the hospital's executive reporting structure so there is a high degree of visibility of the EMM project by the executive. EMM project board meeting minutes should be brief, and action or outcome focused.

The project board should avoid becoming involved in the operational detail of the EMM project – this is the role of the project team and reference group.

11.3 Project manager

A strong emphasis on project management is required to implement the EMM system in a hospital to an agreed timeframe and agreed budget. Due to the project complexity, an experienced and appropriately resourced project manager role that reflects the EMM

scope and complexity is essential. Hospital EMM governance should avoid engaging in part-time project management arrangements, particularly where the project manager has other operational duties.

Selecting the right project manager is critical to perceptions of project ownership within the multi-disciplinary stakeholder community. The project manager should be a specialist project manager, and ideally, an experienced and interested clinician such as a doctor, pharmacist, nurse or health informatics professional. It is necessary to take into account the skills, experience, local knowledge and seniority of the available candidates, and the composition and experience of the wider EMM project team. An EMM system affects all clinicians involved in medication management, and it is important that the EMM project is not dominated by any one clinical profession. It is the project manager's role to ensure all stakeholders within the multi-disciplinary team are engaged, and their specific concerns and issues are addressed. The project manager must also ensure that the required ICT infrastructure is adequately considered, including the timeline associated with infrastructure dependencies within EMM project plans.

11.4 Project team

The size and composition of the project team should reflect the hospital's complexity. The project team for a small independent hospital will be staffed differently to one implementing EMM in a chain of hospitals, or across a state or territory. The project team needs to be multi-disciplinary and should include members from some or all of the following areas:

- pharmacy
- nursing and midwifery
- senior medical staff (should be an early adopter or clinical champion)
- junior medical staff
- education and training
- safety and quality
- ICT services
- the EMM system software vendor.

Box 11.1 Project team resources

EMM project team members should ideally commit full time to the project, but in most cases they will have to balance the EMM project work with the competing interests of their usual 'day jobs'. A successful EMM implementation is one where team members are full time and encouraging people to try and balance their other roles will not achieve this.

It is critical that the project team has multi-disciplinary representation and, as incentives for staff to become involved, the hospital must provide quarantined time for work on EMM project activities. In some cases, the hospital should consider full-time remunerated positions. The expense associated with these incentives should be included in the project scoping and business case costing.

Where a junior medical staff representative is unable to participate as a project team member due to medical staff rotations, it is essential that junior medical staff participate through the EMM project reference group structures.

The project team members should be accountable directly to the project manager, and some team members may also have professional accountability to others. Wherever possible, the majority of the EMM project team members should be full time, fully funded and have previous implementation experience. The use of part-time project team members should be discouraged, as the team members' other commitments could mean there is less time available for the EMM project.

The project team should meet at regular intervals, preferably weekly, to discuss the EMM system schedule, risks and issues so that there is a common understanding among the team members. Project team members need to understand not only their own areas of responsibility and activities, but also the relationships and interdependencies of other work being undertaken within the EMM project schedule. Individual discussions between project team members should also occur outside of the project team meeting. The focus of the project team meetings should include:

- the EMM project schedule and activities running late
- critical path activities
- risks and issues.

It is recommended that each member of the project team provides weekly status reports to the project manager. Status reports should focus on:

- the overall status of the team member's allocated responsibilities and activities
- the achievements of the team member during the period
- allocated activities that are running late
- activities to be completed during the next period
- changes to risks and issues assigned to the team member (including new risks and issues).

The status reports should be circulated in advance of the project team meeting to provide background information to the meeting. The detail in the status reports should not detract from the main focus of the project team meeting. The requirements of any staged implementation, go-live support and ongoing operational management of the EMM system should be considered at the time of project team set-up, and the project team should be staffed appropriately.

11.5 Reference group and specialty subgroups

Apart from the project board and the project team, other groups that may be established to support the work of the EMM project include the reference group and specialty subgroups.

A reference group is a multi-disciplinary operational group within the EMM governance structure, responsible for review and oversight of the operational detail associated with implementing an EMM system. Membership should reflect key stakeholders and user groups, including:

- the clinical professions that will use the EMM system, such as medical staff, pharmacists, nurses and midwives, and allied health

- the hospital's safety and quality unit to recognise the importance of monitoring and maintaining safe medication practice
- medical records staff, to ensure that patient administration system processes support the EMM system, and that EMM system outputs comply with hospital clinical documentation policies and jurisdictional records management legislation
- ICT services to establish appropriate mobile and desktop infrastructure, the central EMM system infrastructure and the required EMM system environments (e.g. production, training, testing)
- the EMM system software vendor to provide EMM system-specific advice and guidance, including experiences of previous implementations.

The reference group should consult specialty subgroups as required (where the size of the hospital requires subgroups). Specialty subgroups should develop the single-discipline detail required by an EMM system. For example, the medical subgroup may focus on prescribing issues, the usefulness of the EMM alerts and access to diagnostic results at the point of prescribing. The pharmacy subgroup may focus on issues such as back-end pharmacy dispensing issues, building the local public hospital formulary and the pharmacy review process. The chair of each subgroup should be a member of the reference group.

The reference group will consider how the work of the specialty subgroups affects each other. For example, the medical and pharmacy subgroups might discuss:

- how the local public hospital formulary developed by the pharmacy subgroup affects the medical staff's ability to prescribe
- how incorrect prescribing by medical staff will affect the pharmacy review process
- how discharge medicines identified by the pharmacists as requiring medical staff review are brought to the attention of the medical staff
- how the discharge medicines in a discharge summary reflect medicines that were dispensed and reconciled.

11.6 Project management

Implementing an EMM system is a large and complex project that requires careful management and coordination. Consideration must be given to the formal project management methodology, timeframes for various components of the project schedule, risk management and project reporting.

11.6.1 Role of the project management office

Some larger hospitals may have a well-established project management office (PMO) that provides support and compliance monitoring for all projects. Where a PMO already exists, the EMM system project manager should seek guidance from the PMO on what is expected in terms of project standards, use of project management methodology templates, and project reporting requirements and tools. The PMO may also require a standard reporting template for project board reporting.

The PMO staff should understand the size and complexity of the EMM system project and the dependent projects that will need to be sequenced, coordinated and managed if the EMM system is to be successful. These projects include:

- ICT technical infrastructure projects such as acquiring devices (fixed, mobile, computers on wheels, infotainment systems) and wireless networks, or other fixed

- telecommunications infrastructure that support point-of-care and bedside access
- implementing high-availability infrastructure requirements or other business continuity solutions
- acquiring and deploying the required EMM system server environments
- implementing any dependent and supporting systems (e.g. results reporting, clinical information systems, electronic medical records).

The PMO has an independent and ongoing quality assurance role in the EMM system project, and its representation on the EMM project board or project team should be considered. Other roles of the PMO include providing advice and guidance on:

- developing the EMM system business case
- the hospital's preferred or mandated project management methodology
- the hospital's requirements for project governance and reporting
- preferred or mandated project controls.

Where a PMO does not exist, the project sponsor will need to consider these issues and identify how they will be addressed (e.g. seeking external advice to develop the business case or provide a quality assurance function).

11.6.2 Project management methodology

A formal project management methodology should be adopted to implement an EMM system. A range of project management methodologies are available and some hospitals may have standardised a particular methodology. For example, PRINCE2⁷⁸ and PMBOK are widely used project management methodologies and PRINCE2 is used extensively in public sector projects. The remainder of this section considers project management using PRINCE2.

It is important to match the use of the methodology to the project size and risk. For example, the key project management controls used in PRINCE2 would include:

- project initiation document
- project brief
- project approach
- project team structure (roles and responsibilities)
- project communication plans
- quality plans
- plans for each stage of the EMM system implementation, such as
 - business case
 - procurement
 - EMM system build
 - lead EMM system implementation
 - evaluation
 - EMM rollout
 - post-implementation review
- authorisation to proceed to next stage report

78 www.prince2.com (accessed 4 March 2010)

- end-stage report
- exception reports
- lessons learned
- project closure report.

11.6.3 EMM project schedule

When putting together the EMM project schedule, hospital project teams may need to consider timeframes for:

- establishing the project governance structure and assembling the project team
- business case development and funding approval
- procurement, product selection and acquisition of the EMM system (see Section 15.3)
- contract negotiation
- project initiation, start up and the implementation planning study
- any customised software development required, including interfaces to key hospital systems – the more customisation required, the greater the time required by the EMM system software vendor to deliver the new software
- user acceptance and interface testing – these are likely to take considerable time, which will increase with the extent of software customisation
- EMM system lead implementation and subsequent evaluation, and the speed at which the remaining EMM system rollout can be achieved
- any ICT infrastructure deployment required before EMM system implementation (e.g. wireless networks, bedside access to the EMM system via computers on wheels or infotainment systems, infrastructure that supports business continuity planning so the EMM system is available around the clock)
- any other activities required during implementation planning (see Chapter 4), implementation and go-live (see Chapter 18).

11.6.4 Risks and issues management

Project risks are situations that affect the quality, cost or time of the EMM project – some examples are listed in Box 11.2. Risks need to be proactively managed by identifying mitigation strategies and associated timeframes for each risk. Risks should be routinely managed by the project team member responsible and discussed at project team meetings. Risks are categorised as high, medium or low impact – the project manager should report high-impact risks to the project board.

Box 11.2 Potential EMM project risks

- Lack of executive-level sponsorship.
- Lack of clinical 'champions' and commitment from senior clinicians.
- Insufficient planning
 - financial – trying to implement EMM 'on the cheap'
 - technical – lack of sufficient devices at the point of care (e.g. at the bedside)
 - human – failure to engage senior stakeholders and insufficient project team resources.
- Inadequate change management.
- Failure to adequately engage with and involve end users
 - not relieving busy clinicians of some routine duties so they can properly contribute to the project
 - not addressing resistance to change and issues raised by staff.
- Insufficient project team resources
 - team size too small to cover all aspects of the EMM project
 - lack of multi-disciplinary skills
 - part-time project manager juggling the EMM implementation with other operational commitments.
- Insufficient time or resources allocated to training, particularly for medical staff.
- Lack of information and communications technology (ICT) involvement or funding resulting in inadequate technology infrastructure for clinicians' operational needs.
- Inadequate or non-existent interfaces between the EMM system and other key systems such as
 - patient administration systems (e.g. for patient identification)
 - diagnostic result systems (e.g. for medicine to diagnostic result checking and medication-related diagnostic test ordering)
 - pharmacy dispensing systems (e.g. to avoid transcription errors)
 - discharge summary systems (e.g. for information transfer on discharge medicines).
- Lack of business continuity planning to support around-the-clock access to the electronic medication charts.
- Protracted lead implementation requiring the use of both electronic and paper-based medication charts.
- Failure to perform implementation and post-implementation assessment and remediation.

Adapted from Victorian Hospitals Electronic Prescribing and Decision Support (VHEPADS) Group. *Electronic Medication Management: A Report for Victorian Drug Usage Advisory Committee, VDUAC, Melbourne, 2003.*

Project issues are events that may affect the delivery of the project. They may be categorised as high, medium and low impact – the project manager should report high-impact issues to the project board. Project issues should be routinely managed by individual project team members responsible for the issue and discussed at project team meetings.

Examples of project issues associated with implementing an EMM system are:

- push-back from medical staff due to the additional time needed to use an EMM system
- poor system performance affecting uptake and use by clinicians
- lack of integration between the EMM system and other key hospital systems, requiring workarounds
- a protracted implementation that fails to achieve the required critical mass within a reasonable timeframe.

11.6.5 Project reporting

Project reporting depends on the hospital's overarching governance structures as well as EMM project-specific governance. The following examples of project reporting are provided for illustrative purposes only:

- The project manager should regularly report to the project board on
 - the EMM project schedule, including milestones achieved
 - status of tasks (completed, running late, not started, due)
 - project expenditure, including project budget, expenditure variations and forecast expenditure to project completion
 - high impact project risks and issues.
- The project board should report regularly through the hospital's executive reporting structures, focusing on aspects of the EMM system implementation that are relevant to the executive.
- The project sponsor and project manager should attend key hospital management meetings whenever possible, and provide status reports on the EMM project.
- Each member of the project team should provide status reports at predefined intervals on their activities, risks and issues; these reports should be circulated before the regular project team meetings.

Change management

Implementing an electronic medication management (EMM) system involves substantial organisational and transformational change, including changes to the way that multi-disciplinary teams operate. The failure of information and communications technology (ICT) system implementations overseas due to poor change management is well documented in the literature.^{79, 80} The experience of Australian EMM system implementations also shows that change management is critical, and must be appropriately resourced and communicated to ensure success. See Box 12.1 for more information.

Change management addresses the human factors associated with implementing an EMM system and includes:

- assessing and segmenting stakeholders, and developing strategies to address stakeholder issues and concerns
- developing targeted communication strategies (not 'one size fits all') to inform stakeholders of the rationale for implementing EMM (e.g. improved safety and quality of care)
- conducting change readiness assessments to monitor the responses of stakeholders and changes in the hospital culture as EMM is implemented (e.g. changes in the understanding and support for safety and quality in the use of medicines)
- addressing stakeholder concerns
- identifying champions and change agents within the hospital.

Investment in an appropriate 'gestation period' for EMM system implementation is essential. Stakeholders must be well informed about the project objectives, implementation planning and timing, and expected benefits of the implementation before deciding on a go-live date.

Box 12.1 Change management

Hospital project teams may wish to consider engaging professional change management support from commercial organisations with a track record of implementing major transformational change within healthcare settings.

Where this occurs, it is important that the change support involves skills transfer to the hospital clinicians, so that the clinicians become the change agents. In this way, change management skills are retained within the hospital.

If professional change management support is not engaged, the EMM team should at least consider employing a proven change management methodology such as the eight-stage process outlined by John Kotter in his 1995 book, *Leading Change*. See www.mindtools.com/pages/article/newPPM_82.htm for an overview.

79 Littlejohns P, Wyatt JC, Garvican L. Evaluating computerised health information systems: hard lessons still to be learnt. *British Medical Journal* 2003;326:860.

80 Lorenzi N, Riley RT. Managing change: an overview. *Journal of the American Medical Informatics Association* 2000;7(2):116–124.

12.1 Stakeholder assessment

Stakeholder assessment is a key change management strategy that ensures a thorough understanding of stakeholders, their perceptions and their impact on the EMM project. Table 12.1 includes a worked example.

Table 12.1 Example stakeholder assessment

Stakeholder	Level of stake in project	Potential impact on project	What does the project expect the stakeholder to provide?	Perceived attitudes or risks	Stakeholder management strategy	Responsibility
Senior medical staff	Medium	Critical	Use of EMM system Active encouragement and support for EMM system use by junior medical staff, particularly in public hospitals	Risk of not using and influencing uptake, and use by junior medical staff	Identify clinical champions to make the case with their peers Involve CEO in negotiating required project outcome Ensure a fast and efficient EMM prescribing process Emphasise downstream benefits including time to discharge prescriptions and summaries	Director of medicine CEO EMM system vendor Project team

CEO = chief executive officer; EMM = electronic medication management

12.2 Targeted engagement strategies

To successfully engage with stakeholders, the project team needs to understand how users perceive the EMM project, and how best to engage users within the project. Key questions that can help the project team understand the stakeholders are shown in Box 12.2.

Box 12.2 Stakeholder assessment

- What interest do stakeholders have in the outcome of the EMM system? Is it positive or negative?
- What do users expect from the EMM system?
- What motivates users and why?
- What information do users require from the project team?
- How do users want to receive information? What is the best way of communicating EMM project messages to them?
- What is their current opinion of the EMM project? Is it based on good information?
- Who influences their general opinions, and who influences their specific opinion of EMM? Do some of these influencers therefore become important stakeholders in their own right?
- If users are unlikely to be positive, what will be required to gain their support for the EMM project?

Adapted from www.mindtools.com/pages/article/newPPM_07.htm

To answer these questions, the project team should talk to EMM stakeholders directly – asking stakeholders their opinion is often the first step in building a successful relationship with them.

The stakeholder assessment should be summarised on a stakeholder map (see Figure 12.1). A good way of doing this is by colour-coding stakeholders, showing advocates and supporters in green, blockers and critics in red, and others who are neutral in orange.

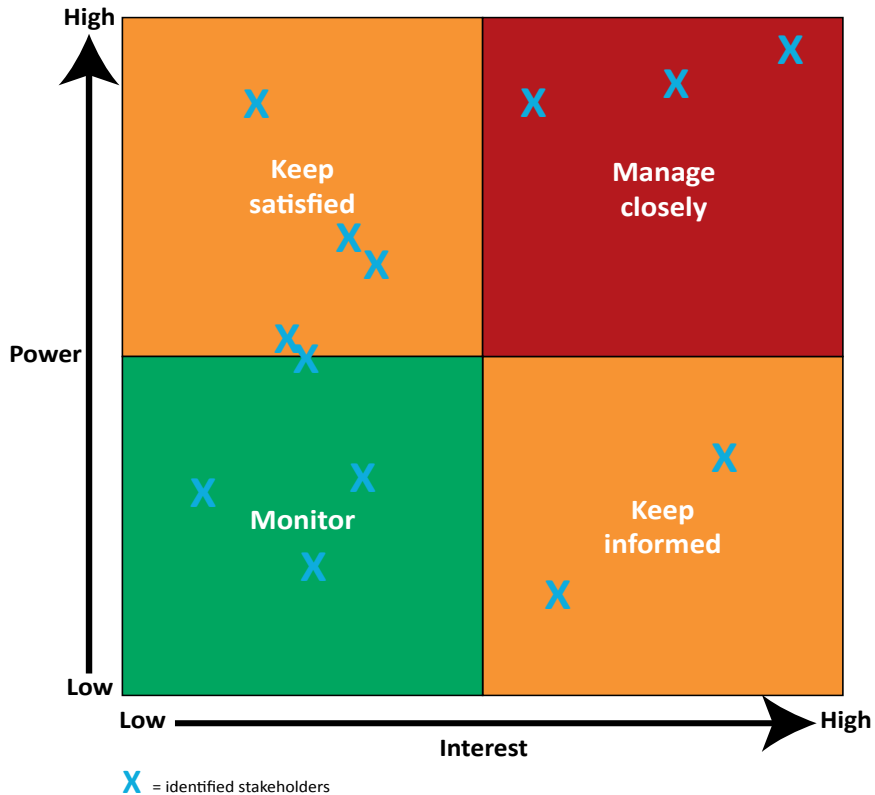


Figure 12.1 Example stakeholder map

The position of a stakeholder on the grid will determine the actions required to engage them:

- High power, high interest – these are the stakeholders that must be fully engaged, and the project team needs to make the greatest efforts in satisfying these stakeholders.
- High power, low interest – the project team needs to undertake enough work with these stakeholders to keep them satisfied, but not so much that they become bored with the EMM project messages.
- Low power, high interest – keep these stakeholders adequately informed, and communicate regularly to ensure there are no major issues arising.
- Low power, low interest – monitor these stakeholders, but do not bore them with excessive communication.

The project manager will need to develop targeted strategies, including communication materials, in response to the stakeholder analysis.

12.3 Change readiness assessments

Change readiness refers to a hospital's ability and willingness to change. This can be assessed in a variety of ways, but should focus primarily on the questions in Box 12.3.

Box 12.3 Change readiness assessment

- Have key stakeholders accepted the vision for EMM and how will it change the way in which the hospital generally, and medication management specifically, operate?
- Do stakeholders understand the need to change if EMM is to be successful?
- Do stakeholders feel compelled to offer support to the implementation of an EMM system?
- Will they openly sponsor EMM?
- Are the hospital's goals and resources aligned to support and manage EMM?
- Will policies and practices inhibit or support EMM?
- How will stakeholders respond to the proposed changes?
- Is there likely to be widespread support or opposition to EMM?
- Are stakeholders likely to understand and commit to EMM?
- Are there any cultural or organisational barriers to implementing an EMM system?

Adapted from
www.opm.gov/egov/documents/MPG/MPG-2_Information_Change_Management_Best_Practices2.pdf#6
(accessed 28 March 2010)

Change readiness assessments (including assessment of organisational culture), in the form of staff surveys, should be conducted periodically as part of the EMM system implementation.

The EMM governance structures will need to take appropriate action to improve the level of organisational readiness for EMM, informed by the outcomes of the change readiness assessment. For example, the change readiness assessment may indicate a poor understanding of EMM concepts that might require enhanced EMM communication activities such as newsletters, product demonstrations and awareness sessions. Conducting change readiness assessments periodically during the implementation process should demonstrate increasing readiness for implementation as the time for go-live approaches.

12.4 Addressing stakeholder concerns

It is essential that stakeholder issues or concerns are addressed quickly. Concerns should be formally logged, along with the person or groups responsible for addressing the issue, and the response provided. The project manager should contact the stakeholder to ensure that the stakeholder is satisfied with the response. If the stakeholder is not satisfied, the issue or concern should be addressed by escalation through the EMM governance structures as appropriate.

12.5 Identifying champions and change agents

Clinical champions and change agents are essential to ensure EMM sponsorship within the hospital, within any lead implementation and in each clinical unit as the EMM system is implemented. Clinical champions need to represent each of the clinical professions that will use the EMM system, including senior medical staff, junior medical staff, pharmacists, nurses and midwives.

Clinical champions must have the ability to 'sell' the benefits of EMM to their peers. There are two types of champion:

1. Senior stakeholders that take up the leadership challenges associated with the implementation of the EMM system (e.g. senior medical staff within early adopter clinical units or lead implementations). These champions are role models for the EMM system implementation.
2. Ward-based champions that have undergone additional education and training. They are the first point of contact for ward staff during education, training and implementation of the EMM system.

Although it may be sufficient to have pharmacist, nurse or midwife clinical champions that have a hospital-wide role, medical staff champions are recommended within each of the clinical units. This is because the Australian sites that have implemented EMM systems found that medical staff were the most difficult to engage to use the EMM system (see Box 12.4).

Box 12.4 Sponsorship and buy-in

The Australian sites that have implemented EMM systems found that medical staff were the most difficult to engage to use the EMM system. The process was made easier when there was strong senior medical support. These role models helped drive adoption of the EMM system by other medical staff.

This buy-in was achieved by the senior medical champions communicating the benefits of the EMM system to other medical staff, and appreciating the challenges associated with medical staff rostering and workload.

Sustainability of the EMM system

Electronic medication management (EMM) is not a 'set and forget' system. Once implemented, its maintenance becomes part of ongoing hospital operations. The ongoing operation of the EMM system requires a dedicated team and resources to ensure that the system remains up to date, functional and safe. This chapter outlines the requirements for the continuous operation of the EMM system, including:

- ongoing resourcing, evaluation, refinement and maintenance
- consolidation of education and training
- ongoing vendor relationship management and support
- benefits realisation.

13.1 Ongoing resourcing

A multi-disciplinary team, including clinicians, information and communications technology (ICT) services and drug and therapeutics committee representatives should be responsible for the ongoing operations of the EMM system to ensure that it continues to support the changing medication management practices of the hospital and to manage changes to the way the EMM system operates.

Australian hospitals that have implemented EMM consider the following resource requirements for the ongoing maintenance of the EMM:

- one 1.0 full-time equivalent (FTE) staff member for system management, issue management, enhancement requests, software upgrades, vendor management and making EMM data available for reporting
- two 1.0 FTE trainers for ongoing refresher training, training in new features, opportunistic training and training of new staff
- one 1.0 FTE maintenance pharmacist to maintain the EMM medication content
- one 0.5 FTE staff member for medication safety and quality initiatives
- one 0.5 FTE staff member for reporting.

Clearly defined roles and responsibilities, and governance accountability are required to ensure the effective ongoing sustainability of the EMM system.

13.2 Ongoing evaluation of the EMM system

It is essential that a continuous quality improvement process is implemented and embedded within the culture of the organisation. Feedback loops are critical to ensure that clinician issues are fed back to the EMM support team for follow-up action.

Opportunities for improved medication safety should be identified, investigative actions undertaken, EMM data analysed and the results presented for clinical review. Strategies for implementing any proposed changes to medication management practice should be agreed to, implemented, and then subsequently reviewed and refined.

The EMM system should have the capacity to capture data on system use for evaluation purposes. For example:

- the extent to which alerts are presented and how clinicians respond to them
- the frequency of use of standard order sets
- the extent of compliance with hospital medication policies
- the preferences of clinical staff in navigating the EMM system
- the timeliness of EMM activities (e.g. medication reconciliation on admission, pharmacy reviews, countersigning telephone orders, discharge medicine orders).

In addition, the EMM system should enable the generation of reports to:

- monitor the usage behaviour of clinicians using the EMM system (e.g. identify patterns in usage)
- identify and diagnose recurrent issues or risks (including potential system workarounds)
- audit and evaluate the root cause of reported incidents
- provide other data to support ongoing evaluation of the EMM system against the defined baseline indicators (see Section 16.7.3).

Reviewing this information allows constant refinement of the EMM system and the way it supports safe medication management, identifies additional targeted training (e.g. those that do not use the system as intended and frequently resort to workarounds). Review also allows communications to be tailored towards addressing key EMM system issues or highlighting examples of significant improvements in medication management.

13.3 Continuous adaptation

To ensure ongoing user acceptance, the EMM system should be continually adapted to meet the needs of the hospital. This may require changes to the EMM configuration, software or supporting infrastructure, with different groups responsible, depending on the nature of the change (see Table 13.1).

Table 13.1 Potential adaptations of the EMM system

Change	Example	Responsibility
Software configuration	Changing onscreen information display, adding clinical decision support alerts, generating new standard order sets or lists	Depends on the change – may be pharmacy, drug and therapeutics committee or software vendor
Software development	Adding new functionality, such as support for prescribing fluids for infusion	Software vendor, with guidance from EMM governance unit
Supporting infrastructure	Increasing network bandwidth to improve response rates, provision of additional devices	ICT services

EMM = electronic medication management; ICT = information and communications technology

The changing needs of EMM users may be identified through ongoing monitoring of EMM system data, frequent staff feedback sessions or surveys, or one-off feedback forms. Where a significant change to the EMM system is proposed by many users, the actions and timelines associated with making this change should be communicated to all EMM users.

13.4 Ongoing database configuration and maintenance

A number of EMM system functions require ongoing maintenance to ensure up-to-date information (see Box 13.1). Databases in third-party supporting systems may also need to be synchronised with changes made to the EMM system. Maintaining these databases is a critical ongoing requirement and must be supported by appropriate resources.

Functions that need ongoing maintenance include:

- EMM system user access (see also *Functional component 1.0.1*)
- public hospital formulary (see also *Functional component 2.3*)
- inclusion of new drugs and incorporation of monthly Pharmaceutical Benefits Scheme (PBS) updates
- standard order sets and order lists (see also *Functional component 2.2*)
- policies and protocols (see also *Functional component 3.3*)
- alerts and clinical decision support (see also *Functional component 3.0*)
- medicines reference information (see also *Functional component 3.2.1*)
- changes to interfaces between patient administration systems (see also *Functional component 1.0.10*) and pathology results (see also *Functional component 1.0.8*)
- EMM reporting requirements.

Configuration changes that require taking the EMM system offline should be done at times that are the least disruptive to patient care (usually at night). If the required offline time is 15 minutes or less (e.g. monthly medicines reference information updates), afternoon nursing handover sessions may be a useful time to make the change, as these are not usually busy medication round or administration times. While the EMM system is offline, protocols for the use of paper medication charts may need to be considered, depending on the duration of the planned downtime (see Box 16.4 for more information). Training in these protocols should be incorporated in the training plans for all staff.

Box 13.1 Ongoing maintenance of EMM system databases

The following examples highlight the requirement for ongoing maintenance of EMM system (and related) databases to ensure safe use of medicines:

- Each time a **new medicine** is added to the local public hospital formulary, order sets or 'quick lists' may need to be created or modified, specific alerts or rules may need to be configured, and – if a restricted medicine – additional authentication and recording requirements for administration need to be configured and tested.
- Each time a **new user** is added to the system, the specific EMM system access rights of the user need to be configured and tested.
- Each time **new medicines reference information** is released, the medicines reference information database in the EMM system needs to be updated.
- Each time a **new hospital policy regarding medicine use** is released, the policies and protocols governing its use in the EMM system must also be configured (i.e. restrictions to prescribing of 'last line' antibiotics).

The above requirements apply equally to changes to existing database entries or configurations.

13.5 EMM software upgrades

The EMM software will generally require upgrading for two main reasons: as part of a routine software enhancements and known 'bug' fixing service periodically released by the EMM system vendor; or to introduce completely new EMM functionality.

Any upgrades to the EMM software must be fully and extensively tested in a separate test environment before being implemented in the live production environment, following the user acceptance testing process in this guide. System users should be made aware in advance of any system outages, and the timing of these outages should be scheduled to minimise the impact of safe medication management (e.g. at night). While the EMM system is offline, protocols for the use of paper medication charts should be put in place where the duration of the planned outage requires this (see Box 16.4 for more information) in line with the business continuity planning section of this guide.

A back-up of the live system environment should be made before the upgrade and the protocol for rollback of the system should be clear in case any issues arise during the upgrade.

13.6 Consolidating education and training

Ongoing education and training is essential. Irrespective of the quality of the initial training, it is unlikely that users will gain a full appreciation of all the functionality within the EMM system during a single training session (or series of sessions). This section outlines considerations for consolidating education and training to ensure system users are sufficiently equipped to use the EMM system to its full potential.

13.6.1 Periodic refresher training

Periodic refresher training should be held to allow users to consolidate their understanding of the overall functionalities of the EMM system. If possible, this should be held at regular intervals (e.g. the first Monday of every month), so that users become aware of its availability and can make time to attend. All periodic training should be conducted in a dedicated training environment that exactly mirrors the live system environment. This ensures that no minor differences between the two systems lead to confusion for users.

13.6.2 Targeted training for specific issues and users

Targeted training should be held for specific issues (commonly identified as problematic) or for specific users (who may require additional training in some or all of the EMM functions).

The requirement for additional training, either for specific issues or users, may be identified through ongoing monitoring of EMM system data or staff feedback sessions. For example, when reviewing the EMM system data, particular processes may be identified that many people have difficulty with. A specific training session may then be provided for all or a subgroup of users to address the issue. Similarly, monitoring may identify particular users who are having difficulty with one or more processes, and specific one-on-one training could be provided.

In both cases, it is important to provide training to prevent users adopting unsafe system workarounds, which may be perpetuated to other users and undermine the overall safety of the EMM system.

13.7 Ongoing vendor support

Following the implementation of any EMM system, ongoing vendor support is required to ensure the EMM system functions as specified and to respond to requests for system enhancements.

13.8 Benefits measurement

Benefits measurement is an ongoing process that should be continually monitored in line with the benefits register (refer to Table 16.5). The realisation of benefits should be regularly communicated to EMM users to ensure continued understanding and compliance with the safe use of the EMM system.

Section C

The EMM implementation project

This section describes the implementation process and identifies five stages for EMM system implementation:

Chapter 14 The EMM system implementation process

Chapter 15 Stage 1 – Project initiation (including business case and EMM solution selection)

Chapter 16 Stage 2 – Implementation planning

Chapter 17 Stage 3 – EMM system build and configuration

Chapter 18 Stage 4 – Implementation and go-live activities

Chapter 19 Stage 5 – Post-implementation review.

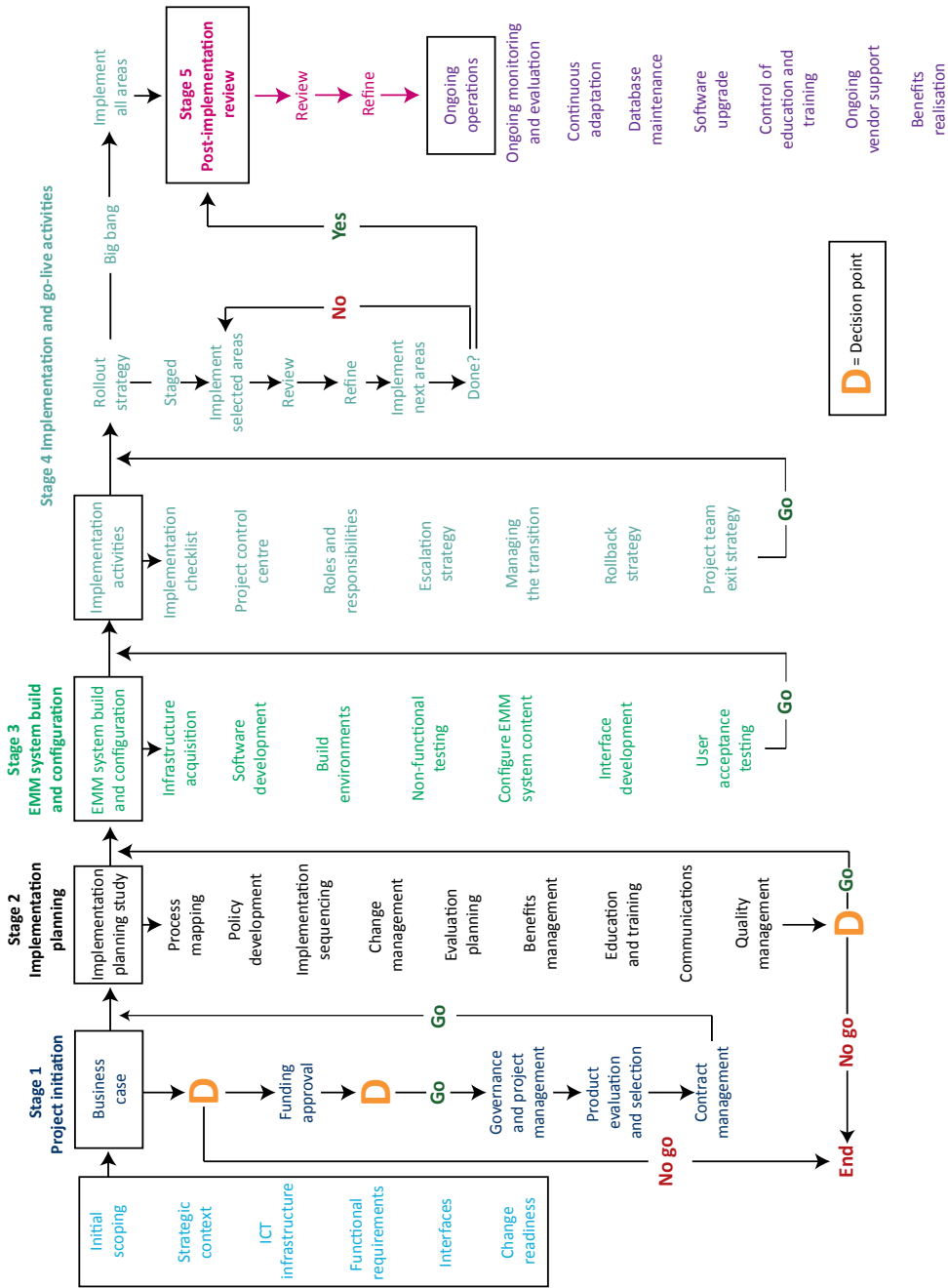
The EMM system implementation process

The electronic medication management (EMM) system implementation process consists of five stages:

- Stage 1 – Project initiation
- Stage 2 – Implementation planning
- Stage 3 – EMM system build and configuration
- Stage 4 – Implementation and go-live activities
- Stage 5 – Post-implementation review

Each of these stages, their components and critical decision points are represented in Figure 14.1. Detailed guidance on each of these stages is provided in this section.

Although hospital project teams that are already planning, procuring or implementing EMM systems might proceed directly to the most appropriate chapter, reviewing earlier chapters will identify opportunities to improve planning, procurement and implementation for EMM systems that are already under way.



EMM = electronic medication management; ICT = information and communications technology

Figure 14.1 EMM system implementation process flow

Stage 1 – Project initiation

Before any electronic medication management (EMM) product selection or implementation decisions are made, the scope of the proposed EMM project must be fully appreciated and accepted by the hospital executive, including the time required, the likely financial costs and the organisational impact of introducing an EMM system.

This chapter covers:

- the two-stage EMM business case development
- funding approval
- governance and project management
- product evaluation and selection
- contract management.

15.1 Developing the EMM business case

The chief executive officer (CEO) must be satisfied that a comprehensive business case has been made for implementing an EMM system. This business case should consider the strategic, clinical and economic justification for the project, as well as outline project management requirements. An indication of the types of issues to be considered in the business case, including a needs analysis and EMM system options, are shown in Table 15.1.

Hospital project teams should consider adopting a two-stage approach to developing the EMM system business case.⁸¹

1. The first-stage business case will be broad and provide an early indication of the size, complexity and costs of implementing and supporting an EMM system. This provides options that can be approved in principle.
2. The more detailed second stage provides the basis for selecting the most cost-effective option.

The cost of the information and communications technology (ICT) infrastructure required to support the EMM system will be substantial. As this infrastructure will also be used for other hospital applications, separate business cases for the EMM system and the ICT infrastructure should be considered, so that the shared infrastructure costs do not distort the EMM system business case.

At the end of the first and second passes, a formal business case for EMM system implementation should be developed and submitted for approval. Some hospital project teams will use a standard business case template that contains guidance on the required content. Alternatively, templates are freely available online from government agencies.⁸²

81 Australian Government Department of Finance and Deregulation (DFD). *ICT Business Case Guide Development and Review*, DFD, Canberra, 2008.

82 For example, Victorian Department of Treasury and Finance (DTF). *Investment Lifecycle Guidelines: Business Case*, DTF, Melbourne, 2008. www.lifecycleguidance.dtf.vic.gov.au/admin/library/attachments/ILG%20Business%20Case%20v1.0%20web.pdf [accessed 14 April 2010]

It would be useful to request in-confidence access to EMM business cases developed by other hospitals and jurisdictions that have implemented EMM; however, organisational or commercial sensitivities might prevent the release of business cases. It would also be useful to speak directly with the person that negotiated the EMM business case approval process to understand the challenges they faced and use their experiences to inform your own business case content.

Table 15.1 **Developing a business case**

Issue	Intent	First pass	Second pass
Needs analysis			
1. Preparation	Address critical questions and financials	Review the rationale, assumptions, benefits and risks (see Box 11.2 for example project risks) of an EMM system in broad terms	Review the initial first-pass business case
2. Demonstrate strategic alignment	Identify broad policy and service delivery objectives the initiative would support	Clarify alignment with policy and service delivery	Incorporate strategic alignment in performance indicators, costs, schedules and risks
3. Clarify demand	Create an early understanding of the end-user demand that might be met	Assess demand sources and characteristics, particularly around end users	Specify demand in more detail
4. Establish benefits and KPIs	Identify tangible and intangible benefits, KPIs	Analyse demand in broad terms, quantify and qualify benefits as far as possible (see Section 16.8) Create an initial statement of success	Rigorously examine benefits Revise statement of success Develop benefit realisation plans
5. Clarify ICT gaps	Identify gaps in ICT requirements	Identify usable components of the existing ICT environment and identify gaps that must be addressed to meet the initial statement of success	Analyse relevant ICT environments in more detail and identify gaps in relation to the revised statement of success
EMM system options			
6. Prepare EMM system options analysis	Consider recent experience with similar projects in Australia	Consider a range of options, particularly in relation to improvements to ICT infrastructure, that could deliver an EMM system Make initial enquiries to industry for broad cost information (request for information) and prepare shortlist of options	Focus on options selected in first pass and draw on tender quality information from industry
7. Identify practical EMM system options	Articulate options in broad terms only (if at all)	Prepare high-level review of options that could deliver the EMM system Consider demand and value to identify the most promising options	Analyse options selected in first pass in detail
8. Clarify option schedules and governance	Identify length of delivery and potential financial implications	Show timing of benefits by quarter and clarify governance requirements	Develop a realistic project schedule for each option Define formal governance and reporting mechanisms

continued

Issue	Intent	First pass	Second pass
9. Identify risks and mitigations	Discuss risks generally and subjectively, based on experience and site visits to other EMM sites	Conduct brief, formal assessment of initial scope and technical design Prepare risk management plan	Develop a detailed risk assessment and management plan for each option Develop a detailed technical and architecture report backed by feasibility studies, proof of concepts or formal market approaches Develop capacity and project-management plans
10. Develop cost estimates	Estimate costs and economic viability	Provide initial estimate including basic net present value calculations for each option	Develop cost spreadsheets with detailed estimates and cost data for specific items based on formal market testing Clarify economic viability using net present value calculations and any other ratios or techniques for each option

EMM = electronic medication management; ICT = information and communication technology; KPI = key performance indicator

15.1.1 First-stage business case

Due to the magnitude of the change required to safely implement an EMM system, the EMM team should first conduct an 'overview' business case to ensure a thorough understanding of the requirements for EMM, including costs, timeframes and risks. This should be done before developing a full business case.

The first-stage business case should include broad consultation with stakeholders, and substantial input from pharmacists, clinicians and ICT services. It can be developed inhouse or commissioned from an external organisation. If an external organisation is used, it is essential that senior stakeholders within the hospital have strong ownership of the scope and content of the business case.

The EMM-specific elements to be considered in the first-stage business case include:

- the case for change (i.e. the rationale for implementing EMM)
- the expected benefits from implementing the EMM system
- the medication components that are within the scope of the EMM implementation (e.g. all inpatient wards, general wards only, intensive care or high-dependency units, outpatients, emergency)
- how the medication components that are not in scope will be addressed
- the strategic context for the EMM system
- the EMM information technology infrastructure needs of the hospital
- the functionality expected within the EMM system, including integration or interfaces with existing and planned systems (this can be done in broad terms)
- organisational change readiness assessment and change management requirements
- governance and project management structures required to support the EMM system implementation, including support from senior clinicians and executives
- staff resources required to implement the EMM system, including clinicians, ICT

- services, project management and change management specialists
- education and training requirements
- ongoing EMM support requirements, including maintaining and upgrading the EMM system
- legislative and policy requirements.

This guide contains advice on all these elements. Once the first-stage business case is complete, compare the requirements for the EMM system implementation with the hospital's existing capabilities and its capacity to implement an EMM system.

15.1.2 Second-stage business case

The second-stage business case follows executive approval or in-principle approval of the first-stage business case.

Ensure that the following elements are considered in the second-stage business case:

- State the case for medication safety strongly at the start of the business case.
- Substantiate the case for change with national and international evidence.
- Be succinct and avoid repetition. If necessary, supplement the case for change with a more substantial explanation as an appendix, so as not to overwhelm the intended audience with detailed analysis.
- Apply medication safety evidence to the hospital activity statistics to estimate adverse drug events, readmission rates and likely deaths associated with medication errors. Make medication safety directly relevant to your hospital.
- Consider other system benefits as a result of implementing EMM, such as greater compliance with hospital medication protocols and downstream benefits based on expected workflows (e.g. any additional time required to prescribe medicines on admission in intake wards is offset by the time saved by not rewriting medication charts in receiving wards).
- Consider how EMM supports new models of care (e.g. prescribing by other health professions, different roles and responsibilities in the workforce as anticipated by the National Health Workforce Strategy).
- Consider financial benefits. The case for change will focus on patient safety and this correlates to efficiency gains that support greater throughput by avoiding adverse drug events and decreasing length of stay. Other financial benefits include improved prescribing practice and greater PBS compliance and reimbursement. Refer to international literature and estimate potential cost reductions using your hospital's drug expenditure. Estimates and costs should be for the proposed life of the EMM system (typically seven years; five years in some jurisdictions).
- Apply sensitivity analysis to understand the tipping points in the business case.
- Ensure all staffing resources are costed appropriately and for the required duration. Do not underestimate the magnitude of the change required to implement EMM and the ongoing business-as-usual costs of supporting EMM.
- Ensure ICT infrastructure costs are identified, costed and funded, including point-of-care and wireless devices, around-the-clock service and business continuity requirements. These elements can be included within the EMM business case, but it is better to cross-reference the EMM business case to other business cases where this critical shared investment is either already funded or the case has been made.

Do not assume that the ICT infrastructure will be available, and make any external dependencies very clear.

15.2 Obtaining funding approval

To obtain EMM system funding approval, the EMM project sponsor (see Section 11.1) must ensure that the project has clearly defined scope and objectives that are based on the contributions and needs of key stakeholders.

A preliminary procurement strategy should be developed that sets out:

- the procurement objectives (what is to be procured)
- a procurement timeline
- an analysis of the market's capability to meet the procurement objectives
- options for engaging the market (consideration may be given to tendering approach or type of contract that may be offered, where a market approach has been identified)
- the ability and capacity within the organisation to manage the procurement process.

The project sponsor should ensure that preliminary risk, stakeholder and change management plans have been developed. The funding request should be supported by a completed business case, procurement strategy and change management plan.

15.3 Procurement, product evaluation and selection

In some hospitals, EMM system procurement will be governed by state or territory procurement policies. The EMM team should seek advice from their local procurement or purchasing unit before developing an EMM system procurement plan.

It is essential to assess the EMM market to determine the solution options that are available before developing the procurement plan. The Australian EMM market has relatively few commercial solutions, and the options available to the hospital may be substantially influenced by the hospital's strategic business or ICT plans.

Understanding the range of functions within the available EMM options before commencing procurement will:

- enable hospital project teams to assess their procurement options in light of their strategic business or ICT plans, including the viability of EMM procurement and the number of suitable EMM solutions that are available
- ensure that the hospital's EMM specifications do not unintentionally preclude potential EMM solutions. Give careful consideration to the allocation of mandatory categories in EMM requirements to ensure the procurement process is viable.

15.3.1 Project procurement plan

Before developing a detailed procurement plan, an appropriate governance structure should be in place to ensure that the responsibility for any procurement decision lies with an accountable person, and that appropriate steps are taken to allow scrutiny of the process. Some hospitals may require the appointment of a probity auditor for the duration of the procurement.

A procurement plan should be developed to manage the following activities:

- identifying the procurement need
- selecting the most appropriate procurement method
- accurately stating functional and technical specifications
- preparing tender documentation
- rigorously assessing responses
- negotiating the final contract
- managing the ongoing contract.

15.3.2 Procurement considerations

Before developing a request for tender (RFT), the hospital must clearly define the type of EMM system required; the functional, technical and usability specifications; and the tender evaluation criteria.

Type of system

In Australia, there are two common approaches to implementing an EMM system:

- as a separate EMM software product that is integrated with or interfaced to other key hospital systems (such as pathology and patient administration)
- as part of a comprehensive clinical system that may also include other functions such as orders and results reporting, and clinical documentation.

The approach taken will be influenced by the hospital's strategy and application architecture. This is a critical decision for the hospital and is a priority for the chief information officer (CIO) (see Section 10.1.5). Hospital project teams embarking on an EMM system procurement process must first seek the advice of the CIO and must be very clear as to the preferred approach.

EMM system specifications and user requirements

The time and resources required to develop detailed specifications for the EMM system must not be underestimated, and should be informed by a multi-disciplinary group of clinicians, ICT professionals, the drug and therapeutics committee (DTC) and the hospital executive. The EMM system specifications must be approved by the project team and project sponsor before being incorporated into the tender documentation (see Section 15.3.3), and will be used to evaluate tender submission compliance with user requirements for the EMM system.

The functional and technical specifications for the EMM system must include aspects associated with the EMM software and the supporting hardware requirements (e.g. wireless networks, data servers, hardware devices). A guide to the functional and technical specifications identified through Australian-hospital experience and extensive consultation with experts in medication safety, as well as a review of Australian and international literature, is presented in Chapter 9.

The National Health Service (NHS) in the United Kingdom has published comprehensive functional specifications for ePrescribing systems used in hospitals and many of these overlap with those identified for EMM systems in Australia.⁸³ Hospital project teams

⁸³ NHS. *ePrescribing Functional Specification for NHS Trusts*, NHS, London, 2007.

wishing to develop detailed and comprehensive functional specifications should refer to the NHS document.

An Australian study by Ryan⁸⁴ evaluated the functionality of 11 commercial EMM systems against a defined set of criteria, although this study did not seek to compare the systems against one another.

Specifying the acceptable usability (e.g. minimum response times, ease of access to common functions) of the EMM system is also critical for a successful implementation. The usability specifications should not be restricted to the EMM software, as support hardware may be the cause of unacceptable usability (e.g. insufficient wireless network bandwidth may reduce system response times to unacceptable levels).

EMM software must be designed with inherent usability. Hospital project teams evaluating EMM systems should consider good design principles identified in the literature⁸⁵ and evaluate known usability issues.⁸⁶ Chapter 9 contains many examples of requirements that support EMM.

Tender evaluation plan

An evaluation plan must be prepared before the tender is issued and the evaluation criteria should be specified in the RFT. The plan should detail the:

- processes and principles to be followed when evaluating tender responses
- responsibilities of the evaluation panel
- evaluation schedule and the conduct of site visits
- conduct of general vendor product demonstrations, and EMM system and technical demonstrations to test compliance with specifications
- tender evaluation scores and weightings that will be used to formally evaluate the tender (including the assessment of vendor credentials)
- outcomes required of the tender process in terms of value for money, quality and preferred contract period
- probity and reporting requirements.

Local procurement policies and protocols will be in place to manage tenders and these policies should be adhered to when preparing the tender evaluation plan. Information about evaluation planning (see Section 13.2) and benefits management planning (see Section 13.8) can be used to support the EMM system tender evaluation plan.

Evaluation panel

The EMM system tender evaluation panel should be multi-disciplinary and include the EMM project manager, an independent probity adviser and representatives of the following groups:

- the EMM project team
- pharmacists (e.g. the chair of the pharmacy subgroup)

84 Ryan M. Australian electronic medication management policy and systems. *Journal of Pharmacy Practice and Research* 2007;37:49–55.

85 www.asktog.com/basics/firstPrinciples.html

86 Koppel R, Metlay J, Cohen A, Abaluck B, Localio R, Kimmel S, Strom B. Role of computerised physician order entry systems in facilitating medication errors. *Journal of the American Medical Association* 2005;293:1197–1203.

- medical staff (e.g. the chair of the medical subgroup)
- nurses and midwives (e.g. the chair of the nursing and midwifery subgroup)
- ICT services
- safety and quality
- finance and purchasing.

15.3.3 Tender documentation

The EMM system tender documentation is developed by the project team, with assistance from procurement. EMM system project teams should check with their procurement sections for specific guidance regarding the content of tender documentation. In the absence of other guidance, use the checklist in Box 15.1. The project manager should ensure that the tender documentation has been produced in line with local procurement policies and approved for release.

Box 15.1 Sample tender documentation checklist

Conditions of tender

General conditions

- ☐ Invitation
- ☐ Enquiries by respondents
- ☐ Language and currency
- ☐ Affirmative action
- ☐ Inconsistencies

Submission preparation

- ☐ Respondents to inform themselves
- ☐ Respondents to meet costs

Submission lodgement

- ☐ Lodgement of submissions
- ☐ Copies
- ☐ Validity period

Managing submissions

- ☐ Improper assistance or collusive tendering
- ☐ Confidentiality
- ☐ Disclosure of information

Evaluation process

- ☐ Compliance
- ☐ Content and format requirements
- ☐ Conditions of articipation
- ☐ Essential requirements
- ☐ Preferred respondent

Statement of requirement

- ☐ Introduction
- ☐ Background
- ☐ Context
- ☐ Objectives
- ☐ Requirement
- ☐ Essential requirements
- ☐ Optional requirements
- ☐ Timeframes
- ☐ Reporting
- ☐ Communications
- ☐ Confidentiality

Evaluation process

- ☐ Evaluation method
- ☐ Submission evaluation criteria

15.3.4 Tender evaluation

The tender evaluation panel will assess the tenders in accordance with the evaluation methodology specified in the tender evaluation plan. This evaluation should consider compliance of the tender with mandatory requirements, qualitative evaluation and value for money.

Mandatory criteria

Mandatory criteria include:

- compliance with the requirements set out in the RFT document (including ensuring that tenders are complete and were lodged correctly)
- compliance with and acceptance of the conditions of contract
- demonstration of the tenderer's ability to meet all mandatory conditions of the tender and specifications.

Failure to meet any of the mandatory requirements may result in the tenderer being eliminated from further consideration. Give careful consideration to the allocation of mandatory categories in EMM requirements to ensure the procurement process is viable.

Qualitative criteria

Compliant tenders should be evaluated against a set of weighted, qualitative (e.g. non-price) evaluation criteria. The tender evaluation panel will assess and score the tenderer's ability to satisfy these evaluation criteria and provide a numeric basis to compare tenders. Table 15.2 provides an example of a tender evaluation scoring approach.

Table 15.2 Example tender evaluation scoring approach

Score	Definition
0	Fail
1	Poor – not demonstrated
2	Unsatisfactory – marginal
3	Satisfactory – expectations met
4	Very good – expectations marginally exceeded
5	Excellent – expectations exceeded

Examples of qualitative criteria that may be considered in an EMM system tender evaluation are shown in Table 15.3. The example qualitative criteria in the Table reflect the view of attendees of the workshop to review the revised guide (attendees had either implemented EMM or were planning to do so). The actual evaluation criteria to be used and their corresponding weights should be developed by the EMM project team in consultation with stakeholders.

Table 15.3 Example tender evaluation criteria

Evaluation criteria	Weighting (%)	Range in weightings (%)
Demonstrated experience of implementing an EMM system in large and complex hospitals	15	5–15
EMM system software demonstrated to be applicable to the Australian context and meets specifications	10	8–30
EMM system implementation methodology of the respondent	8	0–8
Skills and experience of the proposed team	10	0–10
Support for workflow	10	10–12.5
Usability (including test scripts)	10	8–12.5
Integration with other systems (e.g. pathology and diagnostic results, pharmacy, patient administration system)	5	0–10
Complete medication management cycle (including medicines on admission, restarting admission medicines on discharge, integration with discharge summaries, ongoing use of medicines in ambulatory settings, administration of medicines, and medication order review and supply)	10	5–15
Extent and integration of clinical decision support	5	5–10
Conformance to technical specifications	5	5–15
Satisfactory references	5	0–5
Adherence and commitment to NEHTA standards	5	5–15
Other value-added elements in the tender proposal	2	0–2.5
Total score (out of 100%)	100	

EMM = electronic medication management; NEHTA = National E-Health Transition Authority

Value for money

Value for money should be assessed using weighted scoring comparisons and the price detailed in the tender response. Other major factors to be considered include the quality of the proposed solution, and how well it meets or exceeds the specification; the whole-of-life costs; and the capacity and experience of the tenderer to deliver the proposed solution, as specified, on time and on budget.

Evaluation report

When the evaluation process is completed, the project manager should prepare an evaluation report, which will provide (as a minimum):

- details of the tender and tender evaluation approach
- details of the tenders received
- relative ranking of the tenders
- any key issues that still need to be addressed
- purchase recommendations for the preferred tender or tenders
- rationale used to select the preferred EMM system supplier.

15.3.5 Product evaluation and selection

The hospital should develop scripted product scenarios that reflect the intended use of the EMM system as part of the product evaluation (for further information, see Section 16.3 on business process mapping and Section 17.4 on developing test scenarios and scripts). The scenarios should include:

- processes that consider the entire EMM system from prescribing, through review and supply, to administration
- processes that consider the management of complex and high-risk medicines such as warfarin
- product demonstrations that reflect the broad multi-disciplinary requirements of the EMM system and assess the overall usability of the EMM system
- processes that demonstrate interoperability between the EMM system and other key systems.

An example scenario is shown in Table 15.4.

Table 15.4 Example scripted product scenarios

Scenario	Action	Requirement identification no. ^a	Linked requirement
Jane Doe, date of birth 09/10/1956, female, presents to the emergency department complaining of leg pain. Jane has been a smoker for 30 years and has chronic airway limitation and hypertension.	Create a new medication chart record for Jane Doe that includes a list of medicines taken before admission.		
Jane advises that she is taking Tritace (ramipril) 5 mg mane, clarithromycin 250 mg bd (for chronic bronchitis) and Ventolin 2 puffs when required for shortness of breath. These medicines should be continued during hospitalisation.	Record the medications on admission to hospital, and demonstrate how some medicines are ceased and how some medicines are continued on the electronic medication chart. Enter the medicines Jane is taking as listed, demonstrating the ability to convert a drug entered by trade name to the generic once selected.	19	Only accepted Australian generic names of all drugs and medication are to be used, as well as Australian units of measurement to indicate drug dosage. Physicians and nurse practitioners must still have the ability to select a drug based on trade name, but this will convert to the generic name once selected.
On prompting, Jane advises that she is also taking St John's wort.	Using search function, locate St John's wort and add this to the patient's list of medicines on admission.	47	Search function should be provided to help staff efficiently locate the correct medication name.
Jane indicates that she is also allergic to penicillin. She had urticaria and wheezing after taking oral penicillin 20 years ago. She is on a gluten-free diet because of concern about gluten sensitivity.	Attempt to close the medication record, and show how the system alerts the user to record allergy status and does not allow the user to close the record without first doing this. Record Jane's penicillin allergy in the system.	33	Record the following: <ul style="list-style-type: none"> • details for allergies or adverse drug reactions <ul style="list-style-type: none"> – known – drug (or the class/family) – reaction – date – recorded by – nil known – unknown. Other requirements: <ul style="list-style-type: none"> • perform reverse allergy checking • code the allergy to belong to a whole family • medication chart cannot be closed if allergy status is not completed, unless it is impossible (e.g. unconscious, psychotic – this information must be collected as soon as is practicable). The system must be able to receive information about the patient's known allergy status.

continued

Scenario	Action	Requirement identification no. ^a	Linked requirement
Jane is sent for an ultrasound, which confirms she has deep vein thrombosis of her right leg. Dr Edward Goode considers initiating a heparin infusion and oral warfarin. (Note: a heparin infusion is not usually first-line therapy for deep vein thrombosis.)	Show how Jane's allergy appears to users of the system.	6	Create, amend and view patient details in the EMM system for the following information: <ul style="list-style-type: none"> • allergies, or none known • adverse drug events • other relevant drug history (e.g. if the patient is on a medication clinical trial).
	Point out where Jane's name, date of birth and gender appears on the screen.	9	Display patient name, date of birth and gender on every screen view.
	Dr Edward Goode searches the drug reference database to check the half-life of heparin.	25	Australian drug reference databases, searchable by generic and trade name, should be accessible within the system interface.
Dr Edward Goode initiates an intravenous heparin infusion and oral warfarin, doses to be adjusted daily depending on blood test results.	The system should demonstrate an alert to notify the prescriber about interactions relating to this patient's allergies and history, and the proposed additional drugs.	20	Clinical decision support such as alerts should be available.

continued

Table 15.4 continued

Scenario	Action	Requirement identification no. ^a	Linked requirement
		39	At the time of entry of a medication order, the system should alert the clinician to the following potential patient safety issues: <ul style="list-style-type: none"> • known allergies and cross-allergies (additional alert if attempts are made to prescribe a drug the patient is allergic to) • drug interactions. Vendor to outline what drug interactions would be included as part of the proposed system, the evidence base for the alerts and customisation available to reduce 'alert fatigue'. At a minimum, drug–drug, drug–allergy and dose–range alerts are required.
		34	Allergies and ADR records for patient must be displayed with medication data and cross-referenced so that a clinical advisory is displayed if the patient is prescribed a medication to which they have an allergy or ADR recorded (or a medication within the same or similar family/class). Current allergy details for a patient should be displayed on all patient-centric views.
		12	Create infusion/additive chart that can be viewed or printed.
During the night Jane develops a cough and 39 °C fever. By telephone order, the doctor prescribes Panadeine Forte 2 tablets (paracetamol and codeine).	Display an infusion chart.		
	Demonstrate how a verbal order is recorded within the system.	43	The ability for nursing staff to take a verbal order from a doctor. This would currently require a second nursing witness and electronic signature. Availability for EMM system to prompt if medical officer has not reviewed and electronically signed within 24 h. Verbal orders to a pharmacist do not require a second witness.

continued

Scenario	Action	Requirement identification no. ^a	Linked requirement
<p>The opportunity arises for Jane to participate in a clinical trial for a drug to treat deep vein thrombosis. She is switched from heparin and warfarin to the new drug, SR1234A; however, the new drug is not in the drug list within the EMM system.</p>	<p>Display a medication list including the following drugs, including as much of the dosage details as possible:</p> <ul style="list-style-type: none"> • atenolol 50 mg po daily • atorvastatin 80 mg po nocte • gentamicin 5 mg/kg IV daily e.g. 480 mg IV daily (dose amount and interval may change depending on levels and renal function) • metoclopramide 10–20 mg po/IV/IM TDS • paracetamol 1 g po every 4–6 h (maximum 4 g in 24 h) • perindopril 2.5 mg po daily • ramipril 10 mg po daily • sodium chloride with potassium (30 mmol KCl in 1000 mL sodium chloride 0.9%). If going through a peripheral line, administer at 5–10 mmol/h; if going through a central line, 10–20 mmol/h. (Rates greater than 20 mmol/h require continuous electrocardiogram monitoring and should only take place in ICUs, critical care units or EDs) • vancomycin 1 g IV every 12 h. Maximum rate 10 mg/min (dose and frequency may change depending on the patient's renal function) • warfarin 5 mg po daily (dose dependent on INR results). 	27	<p>Assist clinicians by providing easy access to basic medication lists.</p> <p>For example:</p> <ul style="list-style-type: none"> • atenolol 50 mg po daily • atorvastatin 80 mg po nocte.
	<p>Show how the system accommodates drugs that are not listed in the drug database, and how new drugs are added. Prescribe SR1234A.</p>	52	<p>The system must accommodate drugs that are not listed in the drug database (e.g. trial drugs).</p>

continued

Table 15.4 continued

Scenario	Action	Requirement identification no. ^a	Linked requirement
New drug SR1234A needs to be protected from light. At ACT Health, this alert is described as 'Non-PVC Light Sensitive'.	Show how the system alerts nurses to the need to protect the new drug (SR1234A) from light before and during administration.	63	Nursing administration prompts/alerts (e.g. protect from light, non-PVC giving set required). Administrator must be able control the level of alerts (both administration and prescribing) to avoid excessive alerts and alert fatigue.
Jane responds well to the new treatment and is ready to go home.	View and show print preview of Jane's medication chart. Demonstrate how both medicines on the electronic medication chart and medicines ceased on admission are made available to create a discharge prescription. Create a PBS-compliant discharge prescription for Jane.	11 18	Create medication chart and/or medication view that can be printed. Must be compatible with a legal prescription format (e.g. PBS prescriptions). Create a discharge prescription view for each patient that contains the following as an example: <ul style="list-style-type: none"> • subset of patient demographic details • admitting specialist • admission date • admission diagnosis • discharge date and time • discharge to • discharge diagnosis • Patient Administration System episode number • allergies • medicines on admission • medicines on discharge (including medicines changed during admission and medicines required on discharge) • author's name (electronic signature), designation and date/time of completion. The discharge prescription must be able to combine with the discharge summary.
		70	Ability to generate a PBS prescription.

ADR = adverse drug reaction; bd = twice daily; ED = emergency department; ICU = intensive care unit; IM = intramuscular; IV = intravenous; kg = kilogram; mane = in the morning; mg = milligram; mL = millilitre; mmol = millimole; nocte = at night; PBS = Pharmaceutical Benefits Scheme; po = oral; TDS = three times daily
^a Relates to the tender specifications
Adapted with permission from ACT Health

The EMM product demonstrations should reflect the detailed requirements of specific clinical groups. For example:

- Pharmacists need to establish standard order sets and order lists, establish the public hospital formulary, configure workflow in relation to pharmacy review, create to-do lists and reminders, and understand interaction of the EMM system with any third-party dispensing and stock-control systems.
- Medical staff need to understand the prescribing process, access quick prescribing features such as standard order sets and order lists, understand the extent and nature of prompts and alerts (and how they can be turned off), access diagnostic test results when prescribing, prescribe discharge medicines and generate discharge summaries (where integrated with the EMM system).
- Nurses and midwives need to administer medicines, order nurse-initiated medicines, countersign for controlled medicines or complex variable dose medicines, undertake telephone orders, and understand the utility and constraints of mobile devices.

Many EMM systems originate overseas and do not contain Australian drug information. There are often significant differences between overseas drug names and licensing, which may require extensive EMM system customisation and quality assurance in developing Australian content for drug catalogues and drug information sources. These aspects need to be costed in the EMM business case and scheduled as implementation tasks.

Along with functionality requirements, the user experience (the way in which the EMM system supports access and use of EMM functions) is vital for user acceptance. For this reason, any system should be extensively tested by users to ensure the proposed solution supports clinician workflow before selecting the final product and engaging a vendor. Particular attention should be given to the workflow support available for highly repetitive or frequently used EMM functions, such as prescribing and administration.

If deficiencies are identified in the proposed EMM solution, they should be flagged as needing improvement and incorporated within the EMM contract. It is better to identify these issues up-front as part of the EMM product selection, rather than find the EMM product is a poor fit later on – resulting in clinician push-back, expensive and time-consuming software enhancements and re-implementation later.

Box 15.2 User interface evaluation

Where possible, the user interface should be independently evaluated by experts in human-computer interaction to ensure the EMM system is as user-friendly as possible and that usability issues do not make the system unsafe.

15.4 Contract management

EMM system vendor contracts should be managed in line with the contract management plan, with regular meetings and performance monitoring throughout the life of the contract.

15.4.1 Contract management plan

A contract management plan should be developed that clearly articulates how the EMM system vendor contract will be managed.⁸⁷ This plan should include:

- a brief description of the goods or services being provided
- contact details of key personnel associated with the contract
- a list of documents associated with the contract and their location
- transitional arrangements
- communications channels
- performance evaluation measures
- reporting requirements
- identification of risks associated with the contract and risk mitigation activities
- contract operation details, including
 - conflict and dispute resolution process
 - incentives for the vendor to meet deadlines and performance measures, and the penalties for failing
 - management of contract variations
 - payment timing and conditions, including commencement of support arrangements
- a list of contract milestones
- the contract review process.

15.4.2 Contract management meetings

Regular contract management meetings should be held between the project manager and the EMM system vendor to review delivery against the contract, including the early identification and resolution of contractual issues.

15.4.3 Monitoring vendor performance

The project manager should undertake regular contractor performance monitoring to evaluate supplier performance, manage risk, develop vendor capability, manage problems and ensure agreed outcomes are delivered. Vendor performance monitoring should occur during the contract implementation and at regular intervals throughout the life of the contract.

The project manager should evaluate the procurement process by collecting the knowledge gained during the procurement process, and ascertaining whether stakeholder needs and expectations have been fulfilled. These activities should ensure that:

- value for money has been achieved
- the procurement outcomes match or exceed the original objectives
- the vendor performance is satisfactory (as measured against contracted evaluation measures)
- significant lessons learned are captured and disseminated.

⁸⁷ Government procurers will also need to consider the Government Information Technology and Communications (GITC) contracting framework: www.gitc.finance.gov.au (accessed 25 February 2010)

Stage 2 – Implementation planning

This chapter outlines the considerations for electronic medication management (EMM) system implementation planning, which should consist of:

- the implementation planning study (IPS)
- business process mapping and redesign
- EMM system policy development
- implementation sequence planning
- change management planning
- evaluation planning
- benefits management planning
- education and training planning
- communications planning
- quality management.

Box 16.1 External support for implementation

Due to the complexity and scale of implementing EMM systems, some of the initial Australian implementation sites have suggested engaging a specialist systems integrator to manage the technical and interfacing aspects of the EMM system implementation.

16.1 The implementation planning study

The IPS should represent a joint-effort approach, reflecting the EMM system vendor's implementation approach and responsibility to deliver the system, as well as the hospital's implementation tasks. Through the IPS, the vendor demonstrates a thorough understanding of the hospital environment, and the EMM project team becomes familiar with the vendor's implementation methodology, the selected EMM software and the vendor's project team.

The detailed plans developed during the IPS may require changes to the contractual payment schedule so that payments are more closely aligned to the project milestones defined in the IPS.

The IPS is likely to include the items in Box 16.2. If engaging the EMM system vendor to undertake the IPS is too costly, it may be undertaken 'inhouse'.

Box 16.2 Implementation planning study (IPS) checklist

Typical IPS components comprise:

- ☐ the scope of the EMM implementation (e.g. all areas of the hospital or inpatient areas only)
- ☐ electronic medication reconciliation
- ☐ accessing the Pharmaceutical Benefits Scheme
- ☐ a detailed EMM system implementation plan, including
 - all implementation tasks
 - software development activities
 - configuration and build activities
 - any lead EMM system implementation
 - EMM system rollout plans
- ☐ resources required from the vendor and the hospital
- ☐ project structures — governance, relationships, escalation processes
- ☐ project controls, including
 - scope and change management
 - configuration management
 - quality management
 - risk management
 - issue management
- ☐ technical infrastructure requirements, including the number of environments (e.g. production, test, training, development) and an environment management plan
- ☐ capacity requirements (e.g. numbers of users, user concurrency, data capacity)
- ☐ a gap analysis of the functional requirements and a plan to fill the gaps through software development
- ☐ an analysis of the interfaces required and a plan to deliver the interfaces
- ☐ project team EMM system training
- ☐ the strategic context that diagrammatically illustrates and describes the relationships between EMM and other systems
- ☐ the business context that diagrammatically illustrates and describes the end-to-end scope of EMM, the scope of the EMM system implementation and how EMM will be managed at the boundaries to ensure medication safety
- ☐ goal-state process mapping
- ☐ EMM system acceptance criteria
- ☐ a traceability framework
- ☐ EMM system education, and a training strategy and plan
- ☐ a data migration strategy and plan (if required)
- ☐ a testing strategy and plan, including
 - user acceptance testing
 - non-functional testing

continued

- interface testing
- integration (end-to-end) testing
- stress and volume testing
- ☐ a software installation plan
- ☐ operational support and transition to support plan
- ☐ go-live support
- ☐ a list of all project deliverables
- ☐ contract payment milestones
- ☐ service level agreements with EMM vendors and information and communications technology service providers
- ☐ legislative and policy requirements
- ☐ a responsibility matrix.

16.2 Implementation scope

Chapter 6 of this guide identifies the strategic and business context for EMM. The business context is repeated here for convenience.

The business context of the EMM implementation needs to be clearly defined. Consider each care location or setting within the hospital to ensure that all areas where medicines are prescribed, dispensed or administered are included, such as:

- general wards
- intensive care or high-dependency units
- specialist areas such as chemotherapy and renal dialysis
- emergency department
- outpatients
- rehabilitation
- mental health
- operating theatres
- day procedure units
- diagnostic imaging
- hospital-provided community services
- any other areas of the hospital.

Before implementing an EMM system, the EMM governance and project teams must consider each aspect of medication management within the hospital, as well as how to maintain the medication continuum and ensure patient safety as patients move between different areas of the hospital. This must include an end-to-end medications process map that clearly indicates what will happen at the boundaries of each service delivery area. This will ensure that medication safety issues are thoroughly addressed in EMM planning, and that the EMM system supports streamlined and integrated workflow across the hospital.

If an area of medication use is not within the scope of the EMM system, the rationale for this decision should be fully explained and documented, as well as how the 'gap' in the medication continuum will be addressed to ensure medication safety.

The EMM implementation plan includes a template to help identify and manage medicines in relation to the proposed boundaries associated with a hospital's EMM scope.

16.3 Business process mapping and redesign

Business process mapping is an important first step in understanding how the selected EMM system will be used. Completing current-state process mapping early in the EMM project will provide a useful checklist to inform the EMM system tender requirements and the IPS.

The EMM system vendor may have a methodology for process mapping, and can facilitate future-state process mapping sessions and advise on the options available within the EMM system software. Process mapping will raise many issues that will require consideration, including multi-disciplinary consideration through the project team structures.

The benefits of process mapping include:

- a clear, concise, visual method of describing the current and future EMM processes that supports multi-disciplinary review
- superior tender documentation and specification requirements based on a detailed review and analysis of current and future redesigned processes
- a mechanism for sharing knowledge and understanding of current and proposed EMM system processes, including use in EMM project communications, and EMM system education and training
- a checklist to ensure all current processes are mapped to one or more proposed new EMM system processes
- assurance that the proposed scope of EMM addresses medication safety and can realistically support workflows. Some hospital project teams substantially reworked their EMM implementation approach because the original solution failed to sufficiently address workflow.

16.3.1 Current-state process maps

For the current-state process maps, the project team should identify the required data sources (e.g. episodic datasets, medication charts, formularies, pick-lists, and current risk and incident reporting) and the need for standardisation of data sources, especially where multiple hospitals will be sharing a common EMM system build.

The project team should develop a holistic set of process maps that document the current end-to-end processes and the interactions between prescribing, medication review, dispensing and administration of medicines, including:

- recording of medicines on admission and patients' medication history
- recording of allergies and adverse drug reactions
- prescribing of new medication orders
- prescriber review of medication orders (e.g. every seven days)

- requirements of complex, high-risk and variable-dose medicines (e.g. warfarin)
- requirements of specialised medicines (e.g. palliative care, chemotherapy and acute pain)
- supply of medicines from imprest
- supply of medicines from pharmacy
- pharmacy review of medication orders
- clinician processes for editing and correcting medication orders
- clinician processes for documenting clinical notes
- administration of medicines, including variations (e.g. patch on/patch off, fasting, future dose withholding)
- administration of Schedule 8 medicines
- mechanisms for reporting medication errors
- processes for clinical decision support and medicines reference information
- discharge medicines prescribing, review and supply
- reconciliation and management of patient medicines information recorded in the discharge summary
- inpatient and ambulatory care medication management.

The project team must validate the process maps with clinicians through multi-disciplinary validation sessions. For each process map, document the issues and risks, and ensure these are addressed in the future-state process mapping.

16.3.2 Future-state process maps

The development of future-state process maps should involve the selected EMM system vendor, as the choice of EMM system software may influence the process redesign. The future-state EMM processes should incorporate new or modified processes as a result of implementing an EMM system that will improve the way medicines are managed and provide the maximum benefit for users of an EMM system.

Once the preferred EMM system vendor has been selected, the following activities should be considered:

- Visit other hospitals that have implemented the selected EMM system to understand how it was done.
- Refer to current-state process maps to identify potential improvements to current processes.
- Identify how all aspects of the current-state process maps translate to one or more future-state process maps.
- Identify where it may not be possible to directly map current-state processes to future-state maps and outline potential risks, alternative processes or workarounds.
- Liaise with the selected EMM system vendor to develop the future-state process maps so that the process maps relate to how the selected EMM system will be implemented.
- Test acceptance of the future-state process maps with clinicians, including through multi-disciplinary validation sessions.
- Use the process maps to inform improvements to current process and EMM system project communications, and education and training materials.

For each future-state process map, highlight the areas that have changed. It may be useful to summarise the changes in stop/start/continue charts that can be used as part of the communication strategy. Stop/start/continue charts are widely available in the public domain and an example is included in the implementation plan.

Box 7.1 of this guide includes a real-life scenario from an Australian hospital that illustrates why process mapping should be a critical part of EMM implementation planning.

16.4 Policy development

Implementing an EMM system will challenge existing hospital policies and provide an opportunity for the hospital to review its medication policies. Policies should include:

- the new EMM system process, including roles and responsibilities
- the way the EMM system is expected to be used and the hospital's expectations of staff in using the system (e.g. medication orders must not be transcribed on non-approved documents, such as scrap paper, even as an aide-memoire)
- the circumstances in which paper medication charts are acceptable (e.g. where complex, variable-dose medicines or fluids for infusion are not yet included in the EMM system; where the EMM implementation is staged; or on transfer of the patient to another hospital) (see Box 16.4)
- how the medication continuum is supported where EMM addresses only part of the hospital's medication management requirements, or where more than one EMM system is in place
- the process for transcribing patient medicines information onto other clinical documentation (e.g. discharge summaries where these are not integrated).

Box 16.3 EMM system policy development

The first Australian EMM system implementation sites have highlighted the need for clearly articulated policies on the use of the EMM system that are endorsed by the hospital executive.

Such policies were seen as being necessary for managing push-back from clinicians and for preventing the continued use of paper charts in areas where EMM had already been implemented (see Box 16.4).

For example, to ensure accuracy and alignment of discharge medicines to the discharge summary, a policy is required that states that any changes to discharge medicines after the discharge prescription has been generated must be updated in the EMM system before the discharge summary is finalised.

Box 16.4 Policy for the operation of paper medication charts versus electronic medication charts

One of the key policies required when implementing an EMM system defines the rules and circumstances under which paper medication charts and electronic medication charts are used. The policy must define:

- when the use of a paper medication chart is acceptable (e.g. where the medicines are not currently supported by the EMM system, such as complex, variable-dose medicines or fluids for infusion)
- which form of the medication chart takes precedence under which circumstances
- the protocol for cross-referencing one type of medication chart within another (e.g. where a paper medication chart must be used for specific medicines, the existence of the paper medication chart must be recorded in the EMM system. Similarly the presence of other medicines in the EMM system must be recorded on the paper medication chart)
- the process and person responsible for ceasing a paper medication chart and creating an electronic medication chart when a patient is transferred from a paper chart ward to an electronic chart ward (and vice versa) where a staged implementation is planned
- the protocol for reconciling the paper medication chart and electronic medication chart, and the persons responsible, when the system is returned to normal operation following a temporary interruption to the functioning of the EMM system (i.e. power or network failure – see also *Technical component 13.0.3*)

16.5 Avoiding the pitfalls

Some organisations implementing EMM have identified implementation problems and the unintended occurrence of new types of errors. To avoid these problems, prevention strategies that address the workflow, business and cultural issues must be put into place as part of implementation planning. Prevention strategies should be reinforced through education, training and communications before EMM system implementation. New issues should be solved as they occur during the implementation process.

For each identified pitfall, devise prevention strategies and allocate implementation responsibilities and subsequent monitoring activities to individual members of the project team. Some of the pitfalls and potential strategies are identified in Table 16.1.

Table 16.1 Potential pitfalls and prevention strategies

Potential pitfall	Prevention strategies
Electronic prescribing takes longer	<p>Emphasise the safety benefits and reiterate the evidence identified in the case for change</p> <p>Emphasise the downstream benefits to the clinical team, including time saved by not rewriting the medication chart</p> <p>Emphasise time saved in discharge prescribing and reconciliation with the discharge summary</p> <p>Note that studies and experience suggest that the time required will reduce with experience</p> <p>Appreciate that good design and streamlined access are required for all prescribers, but may be particularly challenging for VMOs in private hospitals who visit less frequently</p>
Missed medication doses	<p>Ensure the EMM system supports workflow</p> <p>Ensure appropriate point-of-care access at the bedside and medication stores, and actively discourage transcribing of medicines through medication policy, education and training</p>
Wrong medication prescribed	<p>Ensure EMM system design includes:</p> <ul style="list-style-type: none"> • specialty or clinician pick-lists based on frequency of prescribing habits • use of Tall Man lettering for medicines <p>Consider additional validation requirements for prescribing certain medicines</p> <p>Consider grouping medicines to limit the possibility of mis-selection</p>
Alert fatigue resulting in important medication interactions being overlooked	<p>Carefully manage the introduction of alerts and ensure they reflect the priorities of the DTC</p> <p>Consider whether alerts for commonly used medication combinations by specific prescribers can be downgraded (although this may not be a feature of existing EMM systems)</p>
Wrong dose	Consider whether default doses are appropriate for some or all medicines
Double dosing	Ensure the EMM system checks and manages duplicate medication orders

DTC = drug and therapeutics committee; EMM = electronic medication management; VMO = visiting medical officer

A recent study of an EMM implementation in the United Kingdom identifies a number of pitfalls.⁸⁸

16.6 Implementation sequence planning

Sufficient time is required to properly implement an EMM system, but not too much time that project fatigue occurs and momentum is lost. The objective should be to obtain a critical mass of clinicians using the EMM system within a reasonable timeframe.

There are two approaches to rolling out an EMM system:

- Lead implementation, where the EMM system is implemented in one area first, followed by a sequential implementation rollout based on wards or groups of wards, conducted over 12 months.
- 'Big bang', where the entire hospital transfers from paper-based to electronic medication charts at one time, avoiding the challenge of maintaining two systems.

⁸⁸ www.ehi.co.uk/insight/analysis/763/e-prescribing:-safer-than-paper (accessed 21 February 2012)

Each approach has its merits. Lead implementation allows for communicating information about the EMM system, and testing of the system build and concepts in a measured way before a full-scale implementation. This means that hardware purchases can be staged and implementation timeframes may be more flexible. However, lead implementation also provides greater opportunity for procrastination.

The 'big bang' approach requires greater surety about prior EMM system planning and a more substantial EMM system build prior to go-live, but has the potential to deliver the benefits of the EMM system much earlier, with less opportunity for procrastination.

The preferred approach will be influenced by:

- the skills and experience of the EMM system vendor
- the capacity of the hospital and the project team to deliver results
- the extent of organisational commitment, particularly the chief executive officer (CEO) and the senior medical staff.

Irrespective of the preferred approach, rapid EMM system deployment should be considered because of:

- the risks to patient safety from maintaining both electronic and paper medication charts
- the need to achieve a critical mass with EMM so that clinicians do not have to work in different ways in different parts of the hospital (with some wards using EMM, while others use paper medication charts)
- the desire to capitalise quickly on the successes of lead implementations and minimise the opportunity for procrastination
- the need to prevent project fatigue.

Where lead implementation is preferred, consideration should be given to which ward(s) to implement first and the factors involved in selecting the lead wards. Initial Australian hospital EMM system implementations have selected their lead wards based on:

- low levels of patient transfers (to minimise reconciliation between electronic and paper medication charts)
- areas of the hospital where there are strong clinical champions prepared to embrace EMM, particularly among prescribers such as senior medical staff
- clinical specialties where medication management represents a greater component of the care provision (e.g. aged care)
- areas of the hospital that already have wireless networks and sufficient numbers of mobile devices or 'infotainment' systems in place, or where this equipment can be installed relatively easily.

An important factor is where the emergency department (ED) fits within the implementation rollout. Some hospital project teams see the ED as a significant challenge and have scheduled the ED implementation last. However, others recognise that many admissions come via the ED, and capturing patient medicines information in the EMM system at this early stage means that medication charts will already be electronic by the time the patients are transferred to their receiving inpatient wards. This reduces workload in the receiving wards by avoiding the duplication of effort where paper medication charts would need to be entered into the EMM system. It also reduces errors resulting from transcription.

If the ED is within the scope of the EMM implementation, the project team needs to consider whether the medicines for all patients attending the ED are in scope or only those patients who are admitted. This is an important issue that will substantially affect how EMM is implemented in EDs and how medication continuity is addressed.

The view of Australian hospital project teams that have already implemented EMM is that once the stakeholders are satisfied with the initial implementation in lead wards, the EMM system should be rolled out to the rest of the hospital within a reasonable timeframe. A suggested reasonable implementation timeframe is provided in Figure 16.1.

Implementation stages	Project month														
	1	→	12	13	14	15	16	17	18	19	20	21	22	n	Ongoing
EMM system build and configuration															
Implementation in lead ward (Ward 0)															
Evaluation of lead ward implementation															
Refinement of approach based on lead ward evaluation															
Implementation of Ward 1															
Implementation of Ward 2															
Implementation of Ward 3															
Implementation of Ward n															
Post-implementation review															
Ongoing operations															

Figure 16.1 Example of staging an EMM system implementation

16.7 Evaluation planning

Evaluation planning is important to measure and communicate the successes and failures associated with the EMM system implementation, provide an opportunity for clinical staff feedback and refinement of the EMM system, and assess performance and utility against the proposed future state.

Evaluation planning is even more important where a lead implementation is intended, so that the lessons are learned before full-scale implementation rollout. Where the EMM system is to be implemented in several hospitals, the lessons of the first site are learned before implementation at subsequent sites.

Evaluation may be undertaken by members of the project team, people unconnected to the EMM system implementation within the hospital, or contracted out to an independent organisation with a track record of evaluating clinical systems.

Evaluation should include the following components:

- evaluation framework
- expected outcomes
- baseline indicators
- evaluation activities
- implementation checkpoint and milestone reviews
- post-implementation review (PIR).

EMM system evaluation formalises the refinement process and allows continuous quality improvement as the system becomes embedded within the hospital's operations.

16.7.1 The evaluation framework

The evaluation framework defines all the activities, sequences and timeframes associated with the EMM evaluation including:

- expected outcomes of implementing the EMM system and indicators demonstrating that the expected outcomes are being achieved
- baseline indicators, potential data sources, how the data is to be collected, and the frequency and timing of data collection
- evaluation activities, including the type of activity (e.g. anecdotal evidence, surveys, EMM system-generated statistical reports or observational studies), the method of data capture, and the frequency and timing of the evaluation activity (e.g. baseline, on completion of lead implementation, monthly during implementation and post-implementation)
- opportunities for analytical and predictive capabilities.

An example of how to set out an evaluation framework is shown in Table 16.2. Some of the expected outcomes and baseline indicators for evaluation may have been identified in the initial scoping study, business case, or product evaluation and selection stages. Additional guidance can be found in Chapter 15 and Section 16.7.

Table 16.2 Example evaluation framework

Expected outcome	Indicator	Sub-indicators	Measure(s)	Potential data sources	Activity for data collection	Time points for measurement
Improved quality and safety in medicines use	Reduced AMEs	Prescribing errors by number, type, severity, patient volume, bed-days, total LOS	Number of prescribing errors by type and severity Number of patients Number of bed days Total LOS	Medication charts Hospital issue and risk reporting (sentinel events) Review of medication incidents and AMEs	Audit of medication charts for a defined time period Review of sentinel events	Pre-implementation Post-implementation Ongoing monitoring
	Increased adherence to guidelines	Administration and other errors				

AME = adverse medicine event, LOS = length of stay

16.7.2 Expected outcomes

Clearly defining the expected outcomes from implementing the EMM system will ensure the evaluation framework and evaluation activities are designed to measure the expected outcomes. This should be done at the local site level and inform the development of the baseline measures for ongoing monitoring of EMM system performance.

Expected outcomes are the broad results of implementing an EMM system. Examples include:

- improved accuracy and legibility of medication orders
- reductions in
 - reported prescribing errors
 - reported dispensing errors
 - reported medication administration errors
 - pharmacist-prevented prescribing errors
 - nursing or pharmacist clarification of prescriber's requirements or intent
- increased use of online medicines reference information
- increased capacity for pharmacy review.

16.7.3 Baseline indicators

Baseline indicators must be defined and measured before implementing the EMM system. The NSW Therapeutic Advisory Group has developed indicators for quality use of medicines in Australian hospitals⁸⁹ that should also be considered when developing indicators for evaluating the success of the EMM system implementation.

89 www.ciap.health.nsw.gov.au/nswtag/QUMIndicators.html (accessed 16 April 2010)

An audit should be conducted of the extent to which the paper medication chart complies with best practice over a defined period prior to implementing EMM. The Australian Commission on Safety and Quality in Health Care's National Inpatient Medication Chart (NIMC) audit tool⁹⁰ is useful for establishing baseline measures. Examples of indicators for paper-based medication charts and their expected changes under an EMM system are shown in Table 16.3.

Table 16.3 Indicators for paper-based charts and expected changes when using an EMM system

Paper-based chart indicator	Expected indicator changes in an EMM system
Whether error-prone abbreviations were present in the medication order	Error-prone abbreviations will not be configured in the EMM system, so this indicator will be 100%
Whether the patient's medical indication was documented	Where recording of the patient's indication is not mandatory, a report from the EMM system of the number of medication orders without indication recorded, sorted by prescriber, by specialty or by class of medicine, is to be used for follow-up education and training
Whether the medication order was clearly legible	Legibility will not be an issue in the EMM system, so this indicator will be 100%
Whether the prescriber and pharmacist had initialled the medication order	Prescriber signatures will be defaulted within the EMM system and a report will indicate the extent to which pharmacists have reviewed medication orders
Whether the nurse or midwife had initialled administration of the medicine	The signature of nurses and midwives administering medicines will be defaulted within the EMM system
Whether the non-administering codes were used correctly	Correct use of non-administering codes will need to be checked against other information, such as progress notes in the medical record, in a post-implementation case note audit for patients
Whether allergies and adverse drug reactions were recorded	The EMM system can make recording allergy and adverse drug reaction information mandatory at the time of prescribing, so this indicator would be 100%. Where recording of the indication is not mandatory at the time of prescribing, a report from the EMM system of the number of patients without allergy and adverse drug reaction information recorded is to be used for follow-up education and training
Whether the number of medication charts identified was correct	The number of paper medication charts recorded in the EMM system is to be validated against the number of paper medication charts in the medical record
Whether telephone orders were validated or countersigned by the prescriber	Prescribers will ideally access the EMM system remotely, so telephone orders will no longer be required The extent to which telephone orders are validated or countersigned by the prescriber will depend on the EMM system workflow facilities and whether the system supports telephone orders without subsequent validation or countersigning
Whether the patient medicines information in the discharge summary reflected medicines on admission, medicines prescribed during the admission and medicines on discharge, and listed reasons for any changes between admission and discharge	Alignment of patient medicines information in the EMM system and the discharge summary requires a case note audit, unless the EMM system is sufficiently integrated with discharge summary production

EMM = electronic medication management

An audit of the number, type and severity of medication-related errors reported through the hospital's risk or incident reporting mechanisms should also be conducted. However, it is important to recognise the limitations of this source, given that the pharmacy rectifies most prescribing errors before they become reportable issues.

The frequency with which pharmacists and nurses contact the prescriber to clarify medication orders should be established. Before EMM system implementation, baseline indicators should be measured through an audit over a defined period in which pharmacists record data for all medication orders they intervened in and categorise the type of intervention (clarification, modification to existing medication order, change of medicine). After EMM system implementation, the same categories should be used to generate a report on how pharmacists intervened electronically and how data from the report compared with the baseline audit. Reports can also be generated on how the system has influenced prescriber behaviour (e.g. how many alerts were generated, how many alerts were ignored or whether alert numbers varied depending upon the EMM system pathway chosen by the prescriber).

To determine whether the EMM system increases or decreases the capacity of pharmacists to conduct pharmacy reviews, an analysis of the volume of pharmacist reviews before implementation of the EMM system should be undertaken. This includes ensuring activity data on pharmacy reviews are available before EMM system implementation and comparing the baseline data with the EMM system reports on pharmacy reviews.

Use of existing online medicines reference information sources should be measured before these resources are integrated with the EMM system. Activity data on the use of medicines reference information resources should be available before implementation of the EMM system and again, baseline data should be compared with EMM system reports.

16.7.4 Evaluation activities

Evaluation activities should focus on the areas of perceived risk and the areas of expected benefit for the EMM project. These might include:

- measuring the expected benefits of implementing the EMM system
- examining the utility and usability of the EMM software, and identifying ways to improve the user experience or provide additional benefit
- optimising the business process flows to better support the work of clinical staff
- assessing the quality and format of the EMM system training, the training schedule and training facilities
- evaluating the numbers, location and types of devices that were provided for the EMM system, including satisfaction with wireless network performance and identifying any blackspots
- reviewing satisfaction with the EMM system operating performance
- assessing the user experience of the EMM system implementation schedule, the communication channels and the extent to which clinicians felt involved with the EMM system implementation.

Evaluation will use a range of quantitative and qualitative techniques, including:

- primary and secondary data collection and analysis (as per the baseline indicator measurements described in Section 16.7.3)

- surveys of EMM system users regarding the utility of the system, the extent to which it improves clinical practice, and user views on its benefits and costs. Electronic survey tools could be used to deploy and report on survey data
- workshops or focus groups with stakeholders that explore the results of the surveys in more detail, including benefits, costs, issues and potential resolutions
- access to information sourced from the EMM system, such as
 - the frequency that EMM clinical decision support alerts are accepted or overridden
 - EMM system usage durations (e.g. length of prescribing sessions)
 - user pathways and preferences (e.g. use of prescribing pathways such as standard order sets or order lists, or access to non-formulary items).

Post-evaluation of the EMM system should be undertaken after it is embedded in operational practice and sufficient time has elapsed to ensure stakeholders are familiar with the system. However, evaluation should be done before stakeholders forget their user experience, become familiar with the benefits of the EMM system and forget the medication management processes that were in place before the EMM system was implemented.

16.7.5 Checkpoint and milestone reviews

Where EMM system implementation is staggered, periodic checkpoint and milestone reviews should be instituted to ensure the implementation continues to be relevant and appropriate, continues to learn from earlier implementations, and that timelines are maintained.

16.7.6 Post-implementation review planning

On completion of the EMM system implementation, a formal PIR (see Chapter 19) should occur to assess whether the EMM deliverables defined in the business case have been achieved. The PIR also provides information to inform future system implementations. Specific questions the PIR will address in relation to seven key success factors are shown in Table 16.4.

Table 16.4 Examples of potential evaluation areas and core questions

Evaluation area	Core evaluation question
Service delivery	Is the EMM system delivering the anticipated benefits and levels of service?
Affordability	Did the procurement project meet the approved budget?
Sustainability	Did the EMM project meet its social, economic and environmental objectives? Are negative impacts being managed?
Governance	Were the issues raised through governance addressed?
Risk management	Was the risk management process effective?
Stakeholder management	Are stakeholders satisfied with the outcomes of the project and the level of consultation?
Change management	Has the change management process been effective? Are there issues that should be considered more carefully in the future?

EMM = electronic medication management

16.8 Benefits management planning

Benefits management is an important part of any project and must be appropriately resourced during implementation and throughout the ongoing operation. This is particularly true for EMM because of the challenges associated with determining the true economic benefit of safe electronic prescribing and medication management. It is highly unlikely that the EMM system business case can be justified purely in cost terms, as the majority of direct benefits are qualitative and very few benefits will be significantly cash releasing. It is important that the broader benefits of implementing an EMM system are identified and, wherever possible, measured to justify the hospital's investment in EMM.

A benefits register should be used to log all the benefits identified at the outset (in the business case). The information on each benefit should include:

- a description of the anticipated benefit
- baseline measures and indicators to evaluate the benefit against
- estimates of the most likely value of the benefits, and estimates of the 'best case' and 'worst case' scenarios
- the people responsible for measuring the benefit and the people that are the beneficiaries.

As the EMM system implementation progresses, additional benefits will be identified and these should be added to the benefits register. An example benefits register is shown in Table 16.5.

Table 16.5 Example benefits register

Benefit	Baseline measure	Likely value	Worst case	Best case	Responsibility and beneficiary group
Reduction in prescribing errors	Baseline measure to be collected before go-live for a one-month period ^a	20% reduction	0%	40%	R = Pharmacy B = Medical
Reduction in administration errors	Baseline measure before go-live from incident reporting system	2% reduction	0%	10%	R = Pharmacy B = Nursing and midwifery
Elimination of time required rewriting medication charts	Average time required to rewrite medication chart	10 minutes per chart	No time saving for patients on few or no medications	30 minutes for patients on complex medication regimes	R = EMM system B = Medical
Restarting admission medications on discharge	Baseline measure to be collected before go-live for a one-month period	80% of discharges	No change	All discharges	R = EMM system B = Medical
Populating the discharge medication script from the current medications list and admission medications list	Average time required to generate the discharge script	80% of discharges	No change	All discharges	R = EMM system B = Medical

B = beneficiary; EMM = electronic medication management; R = measurement responsibility

a The hospital's incident reporting system as an information source may be limited, recognising that most prescribing errors are identified and prevented by pharmacy before they become reportable

Baseline measurements are required before EMM system implementation, and benefits measurement should be ongoing throughout the system implementation and for a sufficient time afterwards to ensure all the benefits are identified. It is likely that some benefits will not be realised until the EMM system is entrenched within the operational workflow of the hospital, clinicians are using the EMM system fully, and a continuous process of EMM system review and improvement has been established.

It may also be useful to draw up a table of benefits for each stakeholder group to help target the case for EMM to different groups (Table 16.6).

Table 16.6 Example benefits table by stakeholder group

Stakeholder group	EMM functional area	Benefit
Patients	Medication reconciliation	<ul style="list-style-type: none"> Improved medication safety during inpatient stay by documenting GP/ community medicines in EMM system with medicines stopped, changed or continued Improved medication safety post-discharge through medication reconciliation on discharge, including recommencing medicines stopped or changed on admission (where appropriate)
	Prescribing	<ul style="list-style-type: none"> Improved medication safety during inpatient stay through clinical decision support Reduced opportunity for medication errors through clearly documented and legible prescribed medicines
	Administration	<ul style="list-style-type: none"> Reduced opportunity for administration errors through clearly documented and legible administration record Reduced opportunity for administration errors through clinical decision support
	Consumer medicines information	<ul style="list-style-type: none"> Improved consumer understanding of medicines on discharge, the indication and the reasons for changes to medicines Greater opportunity for consumer compliance with their medicines regime Reduced opportunity for over-medication because generic substitutions are identified
Prescribers	Prescribing	<ul style="list-style-type: none"> Reduced prescribing time, and improved medicines safety and continuity by having previous medicines already available for stop/change/continue Reduced prescribing time through the use of pick-lists and protocol-based prescribing Improved medication safety through clinical decision support for prescribing decisions Reduced prescribing time because reviewing the electronic medication chart no longer requires the prescribed medicines to be re-prescribed Reduced prescribing time because discharge medicines are brought forward from the medicines on admission list and the current medication chart for discharge prescribing Reduced prescribing time because discharge medicines automatically populate the discharge summary
Nurses and midwives	Administration	Etc.

EMM = electronic medication management; GP = general practitioner

16.9 Education and training

Significant investment in education and training is critical to the successful implementation and ongoing operation of an EMM system. Education contextualises EMM, while training is mainly concerned with how to use the EMM system. The following sections primarily relate to pre-go-live education and training that is required to support a successful EMM system implementation. The requirements for ongoing training are outlined in Section 13.6.

16.9.1 Education planning and materials

Most people that are affected by the implementation of information systems only understand the new system in terms of its effect on them, and often have little knowledge or understanding of the system overall. An EMM system will fundamentally change the way hospitals operate and it is important that users of an EMM system understand not only their part in the EMM process, but the overall process and how their work affects other EMM system users.

Education material provides an understanding of:

- the importance of EMM for the hospital (the vision for EMM)
- the scope of the EMM system implementation, including its staging and timeframes
- the medication management cycle and importance of 'closing the loop'
- the processes that will change as a result of implementing an EMM system
- the expected benefits
- the challenges associated with EMM system implementation
- how the learner can be involved and participate in the EMM system implementation.

Education material can be made available in many formats including:

- one-on-one or small group sessions
- presentations at clinical meetings or 'grand rounds'
- EMM product overviews and demonstrations
- poster displays and fact sheets
- interactive online materials.

EMM system vendors may provide education and training materials that may be sufficiently developed to be used unchanged. However, most hospital project teams will want to contextualise the education and training material so that it:

- includes the vision for EMM in the hospital
- includes an overview of the overall EMM system implementation
- includes information on why EMM is important, citing literature on the extent and impact of medication errors and highlighting local hospital audit results, where possible, to personalise the education materials
- clearly defines the benefits of an EMM system including accuracy, legibility, transparency and auditability, ease of access, and safety and quality. The improvement of legibility may be demonstrated by direct comparison of the electronic and paper medication chart

- couches any perceived disadvantages (e.g. any additional time cost to prescribers) as a net gain; for example, time saved in rewriting medication charts, in bringing forward medication orders from earlier episodes, in preparing discharge medicines, in calculating body mass index-related dosages
- explains how drug–drug interaction and other clinical decision support warnings will be handled initially to minimise the impact on prescribers
- includes real-life case studies (from clinician and client perspectives)
- recognises the inevitability of EMM and encourages active participation in the change process.

16.9.2 Training and materials

All users of the EMM system must be sufficiently trained in all types of devices used in the system before working on a ward that operates EMM. The primary goal of training is to provide information about the system and build staff capability, but it also builds user confidence in the system (i.e. reveals and allays user concerns), and enables further development and tailoring of the system based on participant feedback.

Training requires significant resources and time. Some considerations include:

- scheduling broad education sessions before EMM system-specific training, including basic computer competencies training
- ensuring training materials are available to support the training sessions, including any materials that the vendor supplies and possibly modifying these materials to reflect local requirements
- providing and booking training facilities, particularly where the training rooms are a shared resource that needs to be booked in advance (see Section 16.9.4)
- timing the training to occur close to the go-live date to ensure the information remains current (see Section 16.9.5)
- tailoring training to different roles and considering the differences in time required to train different stakeholder groups (see Section 16.9.3)
- adapting the skills and experience of the trainers, including using generic trainers alongside domain experts (pharmacists providing training to pharmacists, nurses providing training to nurses and midwives, etc. Pharmacists may also be considered for providing training to medical staff because of their medication domain knowledge)
- providing flexible one-on-one training for medical specialists, including sessions at the start and the end of the day
- making use of expert EMM system users and clinical champions to support initial implementations within ward areas and providing additional training to this group
- engaging with medical staffing and medical education to determine how best to train the large number of junior medical staff in public hospitals; the opportunistic use of prescheduled induction education sessions and grand rounds provide a good forum for pre-training education and awareness sessions (these sessions are often well attended and lunch is sometimes provided)
- options for training night duty staff, including night-time training sessions, rostering daytime training, and any specific costs associated with providing this training

- options for training private specialists, including in their consulting rooms
- options for training agency staff, including contractual arrangements where agencies train their own staff in accordance with the hospital's defined requirements
- providing a drop-in or information room.

It is essential to provide a 'sandpit' area – a separate environment within the EMM system that is identical to the proposed live environment – where stakeholders can consolidate their training and experiment with using the EMM system before going live. Consolidation training is crucial to a smooth transition to EMM and mechanisms must be in place to ensure EMM system learners access the sandpit.

Australian sites that have already implemented EMM systems found that it is not always possible to fully train agency and locum staff before they use the EMM system. Recognising that these staff may only work on a single occasion at the hospital, shortened training should be tailored to reflect their needs and access to EMM experts on the ward should be made available.

Endorsement of user EMM system competence should be a requirement before allowing staff to practise in an EMM-equipped ward. Ideally, this endorsement would become part of staff credentials within hospitals. User competence may be assessed using defined scenarios that the clinicians are required to step through in the EMM system with the assessor.

Box 16.5 EMM systems are only a tool

EMM systems are used as a tool to assist in medication management; they do not remove the requirement for good clinical judgement. Previous implementations have reported adverse medicine events resulting from the inclusion or omission of directions in an EMM system; for example, a clinician administering a medicine to a patient on direction from the EMM system, despite knowing the medicine had already been given. In these cases, common sense should prevail.

16.9.3 Role-based tailored training courses

Education and training materials and their delivery should align to the future-state EMM processes that have been identified and be based on clinical process flows and clinical scenarios.

Education and training delivery should be tailored specifically to each group of clinical staff that will use the EMM system, to maximise the learning experience of each staff group. This includes education and training for:

- all staff that will use the EMM system, to paint the big picture about how EMM will be used within the hospital
- public hospital prescribers
- private hospital prescribers (taking into account the limited time that these specialists spend in the hospital)

- pharmacists (for review and supply of medication orders, and medication reconciliation)
- nurses and midwives, and others administering medicines.

Education and training delivery will inevitably be time constrained, so prioritising content will be important. Consideration should be given to:

- pre-training awareness materials that provide an overview of key EMM functions to familiarise people with basic concepts before they attend the training sessions, such as
 - poster displays with annotated screenshots and key EMM system use messages
 - fact sheets
 - quick reference guides or pocket guides
- consolidation training following the formal EMM system training, including access to a sandpit to practise using the EMM system prior to go-live or whenever users feel that they need further practice between formal training sessions.

16.9.4 Dedicated training time and space

Scheduling adequate time for education and training is essential and has been a major challenge for Australian EMM sites to date. Sufficient training is necessary for all staff using the EMM system and it is particularly important to ensure that medical staff are allocated time to attend training.

Ward-based training is not a substitute for classroom training because of the inherent distractions of the clinical environment. However, opportunistic consolidation or refresher training on the wards may be a useful addition to classroom training.

The availability of sufficient dedicated training facilities is important due to the competing demands on shared training resources and the disruption to the 'business as usual' education and training requirements of the hospital. In addition, the availability of dedicated training facilities provides the opportunity for impromptu training of new staff.

16.9.5 Timing of the training

The sequencing of education and training is important and will influence the implementation rollout schedule. Specifically:

- frequent education and awareness sessions may occur well in advance of the formal training sessions to ensure awareness and understanding of the proposed EMM system
- formal training in the use of the EMM system should occur shortly before the intended go-live date, but allow sufficient time for consolidation training practice using a sandpit environment
- scheduling EMM system training too far in advance will reduce knowledge retention and require additional refresher training
- the capacity of the training facilities, including the availability of trainers, could constrain the implementation rollout, particularly where a 'big bang' implementation approach is preferred.

16.10 Project communications

Communication is an essential change management tool for EMM system implementation. The hospital's intent to implement an EMM system must be communicated clearly and early to all hospital staff, and include details such as the expected benefits, implementation timeframes and implementation sequence. Communication planning should include the:

- communications plan
- communication tools
- delivery methods.

The communications messages used during EMM system implementation must be consistent with those used in the education and training materials.

16.10.1 The communications plan

A communications plan describes the overall goals, objectives, outcomes and schedule for EMM communications, including the:

- target audience(s)
- key messages to be addressed through communications
- types of communication mode or tools to be used at each stage
- timing of communication materials
- frequency of communications.

See Table 16.7 for an example communications plan template.

Table 16.7 Example communications plan template

Target audience	Communication type ^a	Stakeholder (primary or secondary)	Responsibility	Key message	Communication mode ^b	Timing ^c	Frequency ^d
All staff	Project announcement	Both	Project team	EMM is coming soon	Posters	3 months before go-live	Once
All clinical staff	Project announcement	Primary	Project clinicians	Medication safety	Posters, CEO newsletter	3 months before go-live	Once
Prescribers	Project update	Primary	Lead medical staff	Medication safety	Grand rounds	2 months before go-live	Monthly

CEO = chief executive officer; EMM = electronic medication management

a For example, project update, project announcement

b For example, email, phone, face to face, meetings

c Project stage or data range during which communication applies

d Frequency of contact; for example, once, daily weekly, fortnightly, monthly

16.10.2 Communication tools

Consideration should be given to the types of communication tools to be used, including:

- EMM project branding and identity for all communication and education materials
- EMM project newsletters and status reports, emails and personalised letters
- posters and flyers
- promotional materials such as pens, mousepads and stickers
- EMM system awareness materials
- EMM system product demonstrations
- annotated EMM system screenshots.

For each communication tool, the purpose, target audience, frequency and cost of deployment should be considered.

Change readiness assessments should measure the effectiveness of the communication strategies, and the communication tools and delivery mechanisms may need to be refined in light of these findings.

16.11 Quality management

Formal sign-off for key project documentation is essential to ensure the documents have received the appropriate level of quality assurance, ownership and approval. Formal sign-off is an often neglected task and must be taken seriously. Adopting a project management methodology such as PRINCE2, PMBOK or even a well-developed inhouse methodology will help obtain the right levels of sign-off within the EMM system project. The EMM system project documents that should be formally signed off are outlined in Box 16.6.

Box 16.6 Quality management and project delivery sign-off checklist

- ☐ EMM business case
- ☐ EMM system functional and technical specifications
- ☐ Tender documentation before its release
- ☐ Contract with selected EMM system vendor
- ☐ Implementation planning study
- ☐ All project control documents described in Section 11.6.2
- ☐ Software development and enhancement specifications
- ☐ EMM system interface specifications
- ☐ Change control requests
- ☐ Any EMM process maps that have been developed
- ☐ New software that has been configured, tested and determined as fit for purpose
- ☐ Any EMM system build documentation
- ☐ User acceptance testing strategy and plans
- ☐ User acceptance test scripts
- ☐ Education plan and training materials
- ☐ EMM communications plan and tools
- ☐ Scope and content of the evaluation activities, such as lead site evaluation
- ☐ Post-implementation review
- ☐ Ongoing governance arrangements for EMM on completion of implementation rollout
- ☐ Service level agreements between the EMM project and third parties such as technical and user support

All changes to the scope or functionality of the EMM system should be managed through a formal change control process that includes:

- definition of the proposed change
- the case for change
- time and cost impacts of the proposed change
- the approvals process.

Stage 3 – EMM system build and configuration

This chapter outlines electronic medication management (EMM) system build and configuration activities. These should include:

- acquiring technical infrastructure and business continuity management (BCM) planning
- developing any software that may be required
- building the technical environments
- non-functional testing
- configuring the EMM system content
- developing interfaces to key systems
- conducting user acceptance testing.

17.1 Acquiring technical infrastructure and planning business continuity management

Acquiring the EMM system technical infrastructure and BCM planning is a project in its own right, and ideally should be managed separately by information and communications technology (ICT) services with clear reporting lines to the EMM project manager, as other crucial components of the EMM system depend on infrastructure and BCM. Further details on the EMM hardware infrastructure requirements are provided in Section 9.4 and requirements for BCM planning are outlined in Section 9.5.

The technical infrastructure may include:

- central server infrastructure supporting the various EMM system environments, including development, test, training and production (live) environments. Some hospital ICT services may require additional environments
- duplication of the central server environment in another location and in a configuration that minimises downtime during planned and unexpected outages. All points of failure in the system should be identified, and either duplicated or linked to a BCM plan to deal with potential failure (e.g. dual power supplies to air-conditioning, servers, switches, etc.)
- desktop and point-of-care solutions (e.g. wireless networks, portable computers, computers on wheels, bedside devices or infotainment systems)
- robust telecommunications and wireless infrastructure
- access and authentication requirements that support clinical workflow (e.g. swipe cards, biometrics, proximity devices or bedside devices linked to the patient to ensure correct patient identification automatically)
- sufficient dedicated printers and power points, including multi-tray printers where PBS scripts are used
- active-directory facilities for user log-on, single sign-on options and inactivity time-out requirements.

17.2 Software development

The selected EMM software should be capable of supporting the future-state environment and processes identified during business process mapping. However, additional EMM software may be required to ensure that the system performs all of the functions identified by the hospital. Software vendors need to be engaged before and during the business process mapping to advise on what is currently possible with the EMM software, what can be readily developed and where the costs (time and money) of developing additional functionality exceed the likely benefits. It is essential that hospital project teams select a vendor who is responsive to tailoring the EMM software to their local specifications, where required.

Software development introduces additional risk for the EMM system implementation, requiring additional hospital resources to contribute to specification development, review and sign-off; undertake user acceptance testing, including developing test scripts for the new software; and provide ongoing maintenance.

If inhouse solution components are developed, the hospital must ensure there are adequate resources available to maintain the solution in line with releases of the EMM software.

17.3 Building the technical environments

Building the EMM technical environments will be an ICT services task in conjunction with the EMM system vendor. However, some of the business owners of the EMM environments will be EMM project team members for configuration and testing.

The hospital's ICT services will determine how many EMM environments are required, but typically there will be:

- a configuration and development environment
- a testing environment (for user acceptance testing and interface testing)
- a training environment (and training datasets)
- a production (live operational) environment.

Additional staging environments may also be required.

The management and synchronisation of these environments (in line with software releases, configuration changes and training refresh needs) requires substantial resourcing that must be factored into the EMM project budget and timeframes.

17.4 Non-functional testing

Non-functional tests of the EMM technology infrastructure ensure the infrastructure meets the technical business requirements. The specific non-functional testing required will be determined by the technology infrastructure mix.

All EMM system implementations will need to undertake:

- EMM system capacity testing to ensure there is capacity for the proposed number of users
- EMM system performance testing to ensure system response times are in line with those specified

- EMM system availability testing if there are resilient technical features that can be tested
- peripheral device testing, including regular printers and specialised printers, such as those for prescriptions and dispensing labels, and wireless infrastructure
- organisational infrastructure capacity testing and identification of constraints that might affect the performance of the EMM.

Where high-availability EMM technical infrastructure is used, testing the load-balancing and replication failover aspects of the infrastructure will also be required.

The non-functional testing should be managed through a formal process of:

- developing test scripts (in line with the technical requirements identified in the business case and technical requirements procurement)
- running the test cases
- recording the outcome of the test cases
- undertaking remedial action to address test case failures
- repeating the test cases until successful.

The traceability matrix (see Section 17.7.6) should indicate, for each of the technical requirements identified in the business case, that the non-functional testing has validated the original requirement, or that the original requirement has been modified and the change in requirement has been documented.

17.5 Configuration of EMM system content

Configuring EMM system content requires considerable investment of time and resources. Configuration will normally be the responsibility of clinical staff, often pharmacists, as part of the project team.

Table 17.1 outlines the EMM system content that needs to be configured and a reference to the relevant components outlined in Chapter 9.

Table 17.1 Configuration of EMM content

Content	Reference
Configuration of user access to EMM system	<i>Functional component 1.0.1</i>
Creation of standard order sets and order lists	<i>Functional component 2.2</i>
Configuration of the local public hospital formulary	<i>Functional component 2.3</i>
Establishment of local policies, protocols and guidance	<i>Functional component 3.3</i>
Configuration of EMM system clinical decision support tools and alerts	<i>Functional component 3.1</i>
Configuration of access to medicines reference information	<i>Functional component 3.2.1</i>

EMM = electronic medication management

17.6 Developing interfaces to key support systems

Although the majority of the EMM system's functional and technical components are likely to be already available within the selected EMM system, interfaces may be required between the EMM system and other hospital systems (see Section 9.3, *Technical component 10.0*) – particularly where a best-of-breed strategy has been adopted. These may include:

- patient administration systems (PASs)
- pathology results reporting systems
- pharmacy dispensing systems
- allergy and alert information sources
- medication reconciliation system (where a stand-alone system is used)
- discharge summary systems
- other clinical information systems where a best-of-breed strategy is adopted (e.g. decision support systems for antimicrobial stewardship programs⁹¹).

Although the EMM system vendor will play a lead role in interface testing, the application mix within hospitals is likely to require inhouse resources to test (and sometimes develop) inhouse applications.

Interface development and testing can be a lengthy and expensive process that needs sufficient planning and resourcing to ensure these activities are completed well in advance of implementation rollout.

17.7 User acceptance testing

User acceptance testing (UAT) ensures the EMM system is fit for purpose and the software is stable with no major defects. The process has formal and informal stages, which begin after software development, and EMM system build and configuration are complete. UAT represents the last stage of the EMM system build phase that tests whether the system will operate successfully when implemented in the real clinical setting. The test environment must be identical to the anticipated EMM production (live) environment.

UAT involves:

- developing a set of test scripts or cases (see Section 17.7.1) based on the original business requirements, written as a set of sequenced actions that align to the use of the selected EMM software
- defining the acceptance criteria for sign-off of the UAT process
- trialling the test scripts or cases through a formal process that determines whether the EMM software has passed or failed the test script, as well as break testing to identify other defects
- managing defects to ensure that failed scripts are brought to successful conclusions
- recording all test scripts and results in a traceability matrix.

The informal UAT process involves 'dry running' the test scripts and break testing. The formal UAT process may include several iterations, interspersed with defect resolution by the EMM system vendor. Professional testers are often employed to manage the

91 Antimicrobial stewardship is an institutional program that optimises the use of antimicrobials.

UAT process. It is recommended that the UAT testing be undertaken by clinical staff (prescribers, pharmacists, nurses and midwives) that will use the EMM software. Clinicians undertaking UAT should first receive training in the use of the EMM so they are comfortable with the system.

It is essential to define the acceptance criteria before commencing UAT to ensure implementation time pressures do not compromise the process. UAT ensures that the EMM system is fit for purpose on go-live. This means that it may be acceptable to go-live with an EMM system that has known issues or bugs, but only where these do not affect patient safety. However, the impact of these unresolved issues on EMM users needs to be carefully considered by the EMM governance at the appropriate time, including whether the EMM implementation should be delayed until known issues are addressed.

17.7.1 Developing test scripts

Test scripts are a set of instructions or scenarios to be performed on the EMM system to test that the system functions as expected. These will range from basic testing such as retrieving a specific patient's current medication record, to the complex process of ordering medicines and testing the associated clinical decision support functions.

Each test script must be accompanied by:

- test script input data
- a formal and detailed description of the operational activities to be performed, intended to thoroughly exercise the test script
- a formal description of the expected results.

An example of a test script template is provided in Table 17.2 (also see Box 17.1). Some larger hospitals may use specialised test management software that manages the test scripts, linking them to the original business requirement and the outcomes of the UAT process.

It is essential that test scripts are derived from real-life EMM business scenarios and are developed by clinical staff, preferably in conjunction with business analysts. Test scripts should include testing for high-risk prescribing errors such as those identified by Bates et al.⁹² Each of the original business requirements will result in one or more test scripts.

The test scripts cannot be run until the EMM system has been configured and the clinical staff that are developing the test scripts have been trained in, and are familiar with, EMM software functions.

Box 17.1 Test scripts

Detailed examples of test scripts for ePrescribing can be requested from the Certification Commission for Healthcare Information Technology (CCHIT) at www.cchit.org/certify/2011/cchit-certified-2011-eprescribing.

These scripts, although specific to the United States' health system, can provide a starting point for the hospital to build test scripts tailored to the Australian hospital context and the selected EMM system.

92 Bates DW, Cohen M, Leape L, Overhage JM, Shabot M, Sheridan T. Reducing the frequency of errors in medicine using information technology. *Journal of the American Medical Association* 2001;8(4):299–308.

Table 17.2 Example test script template

Test script # 1						
Description: New medication order						
Script reference	Procedure	Expected result	Actual result	Pass/Fail		Criteria and reference
1.01	Select patient	Patient record displayed	Patient record displayed	<input checked="" type="checkbox"/> Pass	<input type="checkbox"/> Fail	Enter patient hospital no.: B99999 (for patient Mr John Dow)
1.02	Select the 'new medication order' function	Prescribing function displayed	Prescribing function displayed	<input checked="" type="checkbox"/> Pass	<input type="checkbox"/> Fail	
1.03	Select the required medicine by typing the first few letters of the medicine until the required medicine is displayed	Medicine requested displayed	Required medicine not in the list	<input type="checkbox"/> Pass	<input checked="" type="checkbox"/> Fail	Enter erythromycin Check content of medicine entries in the database and rerun script

17.7.2 Informal user acceptance testing

An informal or 'dry-run' of UAT is preferable to test the UAT scripts and EMM system configuration before commencing formal UAT. This should ensure that defects identified during the formal UAT process are due to software errors rather than incorrect UAT scripts or incorrect EMM system configuration. Completing an informal UAT process before formal UAT reduces the uncertainty that is associated with the duration and cost of the formal UAT process.

17.7.3 Break testing

Break testing provides an opportunity for the EMM project team to test the system in an informal and unstructured way, the objective being to 'break' the system by identifying defects that may not be found when following a formal business process scenario. For example, break testing might include:

- entering text where numbers are expected
- entering zeroes to ensure division by zero calculation errors are captured
- entering data that is outside the expected range of the required data items
- entering large amounts of text into free text boxes
- completing events out of sequence
- undoing or partially undoing data entry sequences
- using special characters and control codes in data entry fields

- testing whether the EMM system allows medication management practices that are unsafe or result in nonsensical outputs. The National Health Service *Guidelines for Hazard Review of ePrescribing Systems*⁹³ and Institute for Safe Medication Practices' list of high-alert medicines⁹⁴ may assist in developing tests for unsafe medication orders.

Break testing ensures that common defects are identified and resolved before the formal UAT process.

17.7.4 Formal user acceptance testing

The formal UAT process has a defined number of test cycles and defect management cycles. In larger hospitals, this process may be managed by ICT services and is subject to a rigorous process that the EMM project team is unable to influence.

17.7.5 End-to-end testing

End-to-end testing is the final test process to ensure that the configured EMM system operates and interoperates with other key systems correctly, including that:

- demographic, and admission or episodic information entered into patient administration systems is received and processed correctly by the EMM system
- all updates to demographic or episodic information are also updated correctly within the EMM system
- diagnostic results are either correctly accessible from within the EMM system, or correctly and rapidly accessed via the third-party system that manages the diagnostic results
- patient medicines information for the discharge summary is correctly made available (where the discharge summary is integrated) and reflects medicines on admission, medicines prescribed during the admission and medicines on discharge, and lists reasons for any changes between admission and discharge
- medicines reference information is accessible through either integrating the medicines reference information database into the EMM system or through external links
- changes to the public hospital formulary at the dispensing system end are also updated in the EMM system (where the dispensing system is integrated) in real-time
- all external data (such as diagnostic results or demographics) required to trigger clinical decision support alerts, does so (include alert-inducing scenarios in test scripts).

End-to-end testing typically involves technical experts from each of the third-party systems that will interoperate with the EMM system. Each of the test messages that make up the end-to-end test scripts should be monitored as the test messages progress through the EMM system and each of the third-party systems. End-to-end testing is complex and time consuming, and should be resourced properly.

93 NHS. *Guidelines for Hazard Review of ePrescribing Systems*, NHS, London, 2008.

94 www.ismp.org/Tools/highalertmedications.pdf (accessed 16 April 2010)

17.7.6 Traceability matrix

The traceability matrix maps all business and technical requirements articulated in the EMM business case through to the final EMM solution, including any variation in requirement or solution as the EMM system is specified, procured, configured and tested as fit for purpose. The traceability matrix demonstrates that the EMM system that is implemented meets the original requirements. Where the system does not meet the original requirement, the traceability matrix identifies why not, providing transparency of process as the implementation process moves from a conceptual pretender requirement to a production solution using a specific EMM product.

The traceability matrix is updated with the UAT test scripts and the results of the UAT process.

17.7.7 Acceptance and sign-off

Acceptance and sign-off of the UAT process should occur when all major defects have been rectified and a clean run of UAT testing has occurred. The traceability matrix (Section 17.7.6) should reflect the original requirements and how these have changed as the EMM system implementation project has progressed. The traceability matrix represents the current state of the EMM system from a business perspective and is the definitive documentation that links the original business requirement to the configured EMM system that will be implemented.

Sign-off of the traceability matrix indicates that the configured EMM system is fit for purpose and reflects the requirements of all business units. It should be signed off by all major stakeholders.

Stage 4 – Implementation and go-live activities

This chapter brings together the planning activities discussed in previous chapters as a set of implementation and go-live tasks that are required to successfully implement the electronic medication management (EMM) system in a hospital. Many of these activities will need to be completed simultaneously with the EMM project schedule.

This chapter also outlines the plans that are required to manage the period immediately preceding and immediately following go-live, including the:

- implementation checklist
- role of the project control centre
- roles and responsibilities of personnel during the go-live period
- immediate pre and post-go-live tasks to be performed
- escalation strategy
- management of the transition where a staged implementation is preferred
- rollback or project suspension strategy in the event of project issues or system failure
- project team exit strategy and transition to support.

18.1 Implementation checklist

The checklist in Box 18.1 summarises the key EMM system implementation activities required.

Box 18.1 EMM system implementation checklist

EMM governance activities

- ☐ Governance structures are in place and operating effectively
- ☐ EMM project team is established
- ☐ EMM project schedule has been developed and signed off

EMM implementation planning activities

- ☐ Implementation planning study has been completed and signed off
- ☐ Implementation approach ('big bang' or staged) is signed off
- ☐ Change management plan has been developed and signed off
- ☐ Evaluation framework has been developed and signed off
- ☐ Benefits measurements have been identified and signed off
- ☐ Approach to education and training has been developed and signed off
- ☐ Adequate education and training facilities have been identified
- ☐ Communications plan has been developed and signed off

continued

- ☐ Business continuity plans have been developed and signed off
- ☐ Draft go-live plans are developed (to be finalised closer to go-live).

EMM technical infrastructure activities

- ☐ Central technical infrastructure requirements (including high availability, and the number and type of EMM environments) have been agreed to and signed off
- ☐ Central technical infrastructure has been acquired and built
- ☐ Desktop infrastructure requirements (including devices, mobile devices, printers and wireless networks) have been identified and signed off by each clinical area
- ☐ Non-functional requirements have been tested and signed off
- ☐ Desktop infrastructure has been acquired, installed and tested (in line with implementation rollout plans) and signed off
- ☐ Business continuity testing protocols have been developed and trialled

EMM software development activities

- ☐ Changes required for the selected EMM product to meet the business requirements have been identified and signed off
- ☐ Interface specifications between the EMM system and third-party systems have been developed and signed off
- ☐ Any developments to the required software have been undertaken
- ☐ Traceability matrix has been completed and signed off
- ☐ User acceptance testing scripts have been developed and validated as representing the business requirements
- ☐ User acceptance testing has been conducted and EMM production software release signed off
- ☐ Interface testing and end-to-end testing have been conducted and signed off

EMM system content configuration activities

- ☐ Access privileges to the EMM system have been configured and tested
- ☐ Order sets and 'quick lists' have been developed and tested
- ☐ EMM system configured to reflect local rules for managing medicines (i.e. any restrictions or additional requirements)
- ☐ EMM system with Pharmaceutical Benefits Scheme and/or public hospital formulary loaded and reconciled with pharmacy dispensing system formulary (if not integrated)
- ☐ Access to medicines reference information tested

Final go-live activities

- ☐ Sign-off the EMM system as fit for purpose through governance structures
 - confirm key communication materials to be used during the go-live period
 - confirm education and training materials
 - finalise go-live plans

18.2 The project control centre

The project control centre is established immediately before go-live and remains for the duration of the go-live period. The control centre is where all issues are logged, prioritised and managed, and is the central point for information sharing and team updates during the go-live period. It is important to capture all issues, not just the difficult issues, as the type and frequency of presenting issues may reflect a pattern that requires remedial action.

The project control centre will usually be comprised of project team members. However, at go-live, increased resources may be required to support this team, such as clinical champions, the reference group or specialty subgroup members.

The project control centre members must 'walk the floors', be responsive and rectify issues quickly (i.e. not just 'log the job'). The early implementation phase is a critical period for adoption and endorsement of the system, and EMM system users will expect any issues to be fixed quickly.

18.3 Go-live roles and responsibilities

Go-live roles and responsibilities should be defined so there is clarity during the go-live period. Roles and responsibilities will include:

- project manager – overall management of the project control centre and go-live period
- project team – coordinating go-live tasks, logging and managing issues
- go-live support team members – front-line support roles for clinical units during the go-live period (including evening and night shifts for 24-hour cover, maintaining the roster for clinical champions covering the implementation period and support hand-over at the end of shifts)
- EMM system vendor – system and user support
- project board or hospital executive – decision making in the event of rollback or an implementation suspension situation.

18.4 Pre and post-go-live tasks

Detailed go-live planning should include the allocation of tasks to team members and their scheduling to cover clinical areas across all shifts, including the evening and night shifts, and weekends. Absolute clarity is required in task allocation, so that the team invokes confidence in the clinicians using the EMM system for the first time during this critical period. Team members should be highly visible out on the floors supporting the clinical areas.

Technical go-live checklists should ensure that all aspects of the desktop infrastructure are fit for purpose, including:

- all devices are installed and tested to ensure that they operate with the EMM system
- batteries of mobile devices are fully charged, the home location of the device has access to power, and wireless networks are enabled and EMM validated
- network printers are configured and tested

- user access profiles have been established and tested — with all users having successfully logged on to the EMM prior to go-live.

Clinical staff rosters must ensure that all staff have been trained to use the EMM system, and the use of agency staff is minimised wherever possible during the immediate go-live period (unless agency staff have received the same level of education and training as hospital staff). The roster should maximise the support cover of clinical champions and expert users, including providing extra support.

18.5 Escalation strategy

An agreed escalation strategy is essential before commencing go-live so there is clarity regarding responsibilities and decision making. The role of the project board during this period requires careful consideration, including whether it is the project board or the hospital executive that makes the decision in the event that rollback or project suspension is being considered.

18.6 Managing the transition in a staged implementation

Where the EMM system implementation is staged, managing the transition from paper medication charts to electronic medication charts and vice versa is critical. Clinical areas using EMM need to understand what is required when a patient is transferred to a non-EMM clinical area and be aware of the policies governing the use of paper versus electronic medication charts. Some example issues are:

- Will a printed version of the EMM system-derived medication chart become the paper medication chart?
- Is the printed EMM system-derived medication chart transcribed onto the National Inpatient Medication Chart?
- To avoid transcription errors, how is the paper medication chart validated as an accurate copy of the EMM system-derived medication chart?
- What processes need to be put in place to cease medication orders on the EMM system and prevent further medication orders from occurring within the EMM system following the creation of a paper medication chart?

An operational policy (see Box 16.4) is required to underpin these decisions and be reinforced through EMM system education and training, and EMM communications.

18.7 Rollback

In the event of a major failure of the EMM system during the go-live period, a rollback or project suspension strategy is required. The strategy will determine:

- the circumstances in which a rollback or suspension will be considered
- the duration of the failure period before a rollback or suspension decision will be considered
- the decision makers in a potential rollback or suspension situation
- the sequence of events following a rollback or suspension decision.

18.8 Project team exit strategy and transition to support

Go-live planning needs to consider how the project team and go-live support will exit the clinical areas following implementation, including:

- timing of the exit strategy — not so soon that the clinical areas are left exposed, and not so late that the clinical areas become dependent on the project team
- arrangements for ongoing support by clinical champions and expert users
- levels of support that are required, including first-line support resting with clinical champions and expert users, second-line support to the help desk and third-line support to the EMM software vendor
- arrangements for transition of the project team to an ongoing operations multi-disciplinary team (see Chapter 13)
- mechanisms that monitor ongoing support in line with service level agreements.

Stage 5 — Post-implementation review

A post-implementation review (PIR) is the last step in the electronic medication management (EMM) implementation process and represents closure of the feedback loop. A PIR allows the lessons learned from previous projects to be fed back into the process to benefit future projects.

Undertaking a PIR can generate both short-term and long-term gains. Short-term gains include:

- identification of ways to improve the value proposition of the EMM
- identification of ways to help EMM users overcome implementation hurdles that require workarounds
- increase in user morale through the continuous improvement of the EMM system.

Long-term gains may include:

- learning from the implementation experience
- financial benefits from improved project performance
- improved concept criteria and project briefing
- development of more precise design criteria
- improved project decision making.

Undertaking a PIR increases understanding and the quality of information, which can be used to improve the hospital's project decision making. A successfully completed PIR will usually result in a recommended action plan for improvements. This may include:

- changes to medication management processes and workflow
- improvements to the EMM software
- recommendations for refresher education and training
- requests for additional or different devices
- improvements to EMM system response times and performance.

The PIR should commence at an appropriate time after EMM system implementation. The timing of the PIR will vary according to individual implementations, but should allow enough time for the system to be effectively embedded in day-to-day operations, but not too much time that stakeholders forget their user experience, become familiar with the benefits of the EMM system and forget the medication management processes that were in place before EMM system implementation.


The PIR may be completed by the project manager or members of the EMM project team, or may be commissioned from an independent organisation with experience of EMM systems.

There are numerous PIR guidelines and templates in the public domain.⁹⁵

⁹⁵ See, for example, www.treasury.nsw.gov.au/__data/assets/pdf_file/0008/5102/post_implementation_review.pdf

Glossary

administer	To make a decision about giving a patient a medicine. This may include administering the medicine, delaying the administration of the medicine or not administering the medicine.
best-of-breed solutions	Systems that combine the most appropriate individual software packages (usually designed to address one or more components of the process) into a solution that covers the end-to-end process.
big bang implementation	An implementation that goes 'live' in all (or the majority of) hospital wards in a relatively short time period.
clinician	A healthcare professional who is involved in the clinical care of a patient.
electronic medication management (EMM)	The entire electronic medication process from the prescriber's medication order, to the pharmacist's review of the medication order and supply of medicine, to the nurse's documentation of administration of the medicine, and all the processes in between.
gestation period	In this document, the period of time given before implementation of the EMM system for delivery of the communications strategy and other relevant planning to ensure stakeholders are well informed about the project objectives, planning, timing and expected benefits.
go-live	The period during which the planning for implementation is effected (i.e. the transition from 'planning' to 'doing') and the EMM system that has been under development or operating in a limited test mode becomes fully active so that users can access it.
rollback	Returning to the last known functioning process. In the case of the EMM system, this may be back to paper processes in the event of an entire system failure, or to the last known functioning configuration following a failed software upgrade.
sandpit	In this document, an EMM system environment that can be used to 'play' with the system before it goes live to consolidate skills learned during training.
single supplier solution	An end-to-end process covered by a single software package.
usability	The ease of use of the system with respect to access, navigation, familiarity, consistency and intuitiveness.
user interface	The software with which the user interacts with the EMM system.
workaround	A temporary means of bypassing or avoiding a problem without addressing its cause.



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