AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Electronic Medication Management Systems

A guide to safe implementation

3rd edition

Published by the Australian Commission on Safety and Quality in Health Care
Level 5, 255 Elizabeth Street, Sydney NSW 2000

Phone: (02) 9126 3600
Fax: (02) 9126 3613

Email: accreditation@safetyandquality.gov.au
Website: www.safetyandquality.gov.au

ISBN: 978-1-925948-07-3

© Australian Commission on Safety and Quality in Health Care 2019

All material and work produced by the Australian Commission on Safety and Quality in Health Care is protected by copyright. The Commission reserves the right to set out the terms and conditions for the use of such material.

As far as practicable, material for which the copyright is owned by a third party will be clearly labelled. The Australian Commission on Safety and Quality in Health Care has made all reasonable efforts to ensure that this material has been reproduced in this publication with the full consent of the copyright owners.

With the exception of any material protected by a trademark, any content provided by third parties, and where otherwise noted, all material presented in this publication is licensed under a **Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International Licence**.

Enquiries regarding the licence and any use of this publication are welcome and can be sent to communications@safetyandquality.gov.au.

The Commission's preference is that you attribute this publication (and any material sourced from it) using the following citation:

> Australian Commission on Safety and Quality in Health Care. Electronic medication management systems: a guide to safe implementation. 3rd edition. Sydney: ACSQHC; 2019.

Acknowledgements

The principal author of the third edition of this guide was Steve Saunders, Principal Consultant, Closed Loop and Associates. Many individuals and organisations have supported the development of this revision. The involvement and willingness of all concerned to share their experience and expertise is greatly appreciated.

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your healthcare provider on particular healthcare choices.

This document includes the views or recommendations of its authors and third parties. Publication of this document by the Commission does not necessarily reflect the views of the Commission, or indicate a commitment to a particular course of action. The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Version Control

Version	Date
3.0	November 2017
3.1	May 2019

Contents

Preface 6

Acronyms and abbreviations 7

1. Overview 8
   - 1.1 Purpose 8
   - 1.2 Scope 8
   - 1.3 Additions 9

2. How to use the guide 10

Part A
EMM context, standards and technology 12

3. Case for change 14

4. Essential elements of an EMM implementation 16

5. Medication management continuum 18
   - 5.1 Medication management process 19

6. EMM strategic, medication and functional scope 22
   - 6.1 Strategic context 23
   - 6.2 Medication scope 27
   - 6.3 Functional scope 31

7. How EMM supports national medication safety priorities 34
   - 7.1 Quality use of medicines 34
   - 7.2 Medication reconciliation, including best possible medication histories 34
   - 7.3 High-risk medicines 35
   - 7.4 Preventing and controlling healthcare-associated infections 35
   - 7.5 Patient identification 37
   - 7.6 Opportunities to support other safety and quality standards 37

8. EMM national infrastructure and standards 38
   - 8.1 My Health Record system 38
   - 8.2 Healthcare Identifiers Service 39
   - 8.3 National Clinical Terminology Service 40
   - 8.4 Digital supply chain solutions 41
   - 8.5 Secure messaging and clinical exchange specifications 42
   - 8.6 On-screen display of clinical medicines information 42
   - 8.7 On-screen presentation of discharge summaries 44
   - 8.8 Prescription exchange services 45

9. Business requirements for EMM systems 46
   - 9.1 Introduction to the requirements 46
   - 9.2 How to use the requirements 47

Contents

Part B
EMM organisational considerations 48

10. Principal EMM stakeholders and users 50

10.1 Principal stakeholders and decision-makers 50

10.2 Clinicians using EMM 55

11. EMM project governance 60

11.1 Project sponsor 62

11.2 Project board 62

11.3 Project manager 62

11.4 Project team 63

11.5 Reference group and specialty subgroups 64

11.6 Project management 64

12. Organisational change management 68

12.1 Stakeholder assessment 69

12.2 Targeted engagement strategies 70

12.3 Change readiness assessments 71

12.4 Addressing stakeholder concerns 72

12.5 Identifying champions and change agents 72

Part C
EMM implementation project 74

EMM system implementation process 76

13. Stage 1 – project initiation 78

14.1 Developing the EMM business case 78

14.2 Obtaining funding approval 81

14.3 Procurement and product evaluation and selection 82

14.4 Contract management 95

14. Stage 2 – implementation planning 96

15.1 Learning the lessons of Australian implementations 96

15.2 Considering the literature 99

15.3 Implementation planning study 105

15.4 Implementation scope 108

15.5 Business process mapping and redesign 109

15.6 Policy development 113

15.7 Implementation sequence planning 115

15.8 Evaluation planning 116

15.9 Benefits management planning 121

15.10 Education and training 124

15.11 Project communications 127

15.12 Quality management 128

15. Stage 3 – EMM system build and configuration 130

16.1 Acquiring technical infrastructure 130

16.2 Software development 130

16.3 Building the technical environments 131

16.4 Non-functional testing 131

16.5 Configuration of EMM system content 131

16.6 Developing interfaces with third-party systems 132

16.7 User acceptance testing 133

16.8 Ensuring business continuity 135

16. Stage 4 – implementation and go-live activities 136
17.1 Implementation checklist 136
17.2 Project control centre 138
17.3 Go-live roles and responsibilities 138
17.4 Tasks before and after go-live 138
17.5 Escalation strategy 138
17.6 Managing the transition in a staged implementation 139
17.7 Rollback 139
17.8 Project team exit strategy and transition to support 139

17. Stage 5 – post-implementation review 140

18. Business continuity planning 142

Part D
EMM post-implementation 144

19. Operationalising the EMM system 146
20.1 Governance 146
20.2 Resourcing 147
20.3 EMM configuration and maintenance 147
20.4 EMM software upgrades 148
20.5 Education and training 148
20.6 EMM solution provider support 149
20.7 Rehearsing and refining business continuity plans 149

20. Regulation, policy and compliance 150
21.1 Regulation 150
21.2 Policy 152
21.3 Compliance 155

21. Monitoring and evaluation 156
22.1 Benefits measurement 156
22.2 Optimising EMM workflow and medication safety 156

22. Continuous quality improvement and data analytics 158
23.1 Continuous quality improvement 158
23.2 Data analytics 160

Glossary 162

References 163

Contents

Tables

Table 1.1	Stakeholders and relevant sections of this guide to read	11
Table 6.1	Example of a strategic scope analysis	25
Table 6.2	Example of a medication scope analysis	28
Table 6.3	Example of a functional scope analysis	31
Table 12.1	Example of a stakeholder assessment	69
Table 14.1	Developing an EMM business case	79
Table 14.2	Example tender evaluation scoring approach	85
Table 14.3	Example weightings for tender evaluation criteria	86
Table 14.4	Examples of test script scenarios	88
Table 15.1	Potential pitfalls and prevention strategies	98
Table 15.2	Success factors for EMM and e-health record systems	99
Table 15.3	Mitigation strategies for usability, design and functionality issues	100
Table 15.4	Mitigation strategies for unintended adverse consequences of implementing e-health records	102
Table 15.5	Example evaluation framework	117
Table 15.6	Indicators for paper-based charts and expected changes when using an EMM system	118
Table 15.7	Example of a benefits register	121
Table 15.8	Example of a benefits table by stakeholder group	122
Table 15.9	Benefits reported by Australian health service organisations that have implemented EMM	123
Table 15.10	Example of a communications plan template	128
Table 16.1	Example test script template	134

Figures

Figure 5.1	Medication management continuum	18
Figure 5.2	Guiding principles to achieve continuity in medication management	19
Figure 5.3	The medication management process	20
Figure 6.1	Relationship between the strategic, medication and functional scope of EMM systems	22
Figure 6.2	Medication management continuum in a health service system	30
Figure 8.1	Display format for medication orders	43
Figure 8.2	Display format for discharge medicines	44
Figure 11.1	Typical governance structure for an EMM system	61
Figure 12.1	Example stakeholder map	70
Figure 13.1	Process flow for EMM system implementation	76
Figure 23.1	The plan–do–check–act cycle	158

Boxes

Box 3.1	Endorsements of EMM from professional organisations	15
Box 4.1	Safe and successful EMM implementation checklist	17
Box 6.1	Questions to ask if the EMM system is not incorporated into the broad clinical information system	24
Box 11.1	Project team resources	63
Box 11.2	Potential EMM project risks	66
Box 12.1	Change management	68
Box 12.2	Questions for the project team to ask stakeholders	70
Box 12.3	Questions to assess change readiness	71
Box 12.4	Sponsorship and buy-in	72
Box 14.1	Sample documentation checklist for the content of a tender	84
Box 15.1	Australian EMM implementation – lessons learned	96
Box 15.2	Implementation planning study checklist	106
Box 15.3	Scenario: Pharmaceutical Benefits Scheme prescriptions for public health service organisation discharges	112
Box 15.4	EMM system policy development	114
Box 15.5	Quality management and project delivery sign-off checklist	129
Box 17.1	EMM system implementation checklist	136
Box 20.1	Configuration and maintenance of the EMM system	148

Preface

Electronic Medication Management Systems: A guide to safe implementation (3rd edition) has been produced by the Australian Commission on Safety and Quality in Health Care (the Commission) to assist hospitals and health service* organisations to safely implement electronic medication management (EMM) systems.

The guide has been informed by a review of the second edition[1], more recent international literature, the experiences of Australian EMM system implementation sites, and stakeholder consultation, to provide guidance on the activities required for safe and effective EMM system implementation and use. This edition also incorporates feedback from individual health service organisations, and states and territories that have either implemented EMM or progressed their EMM planning since the previous edition of the guide.

This edition of the guide includes additional material about:

- The experiences of recent EMM implementations
- National medication safety priorities
- Medicines-related standards and national infrastructure
- Embedding the Pharmaceutical Benefits Scheme in workflow
- Business continuity planning and operationalising the EMM system
- Policy and compliance, and regulation
- Data management and analytics, and continuous quality improvement.

The use of the guide by health service organisations implementing EMM was first endorsed by state, territory and Australian Government health ministers in November 2011. An implementation plan is also provided on the Commission website as a planning tool for EMM system implementation in health service organisations.

* The term 'health services' has been used throughout the guide to reflect the broader range of inpatient and ambulatory services that are increasingly part of EMM implementations.

Acronyms and abbreviations

Abbreviation	Explanation
Agency	Australian Digital Health Agency
AMS	antimicrobial stewardship
AMT	Australian Medicines Terminology
BCP	business continuity planning
BPMH	best possible medication history
CEO	chief executive officer
CIO	chief information officer
Commission	Australian Commission on Safety and Quality in Health Care
DTC	drug and therapeutics committee
ED	emergency department
EMM	electronic medication management
EMR	electronic medical record
HI Service	Health Identifiers Service
HPI-O	Health Provider Identifier – Organisation
ICT	information and communications technology
ICU	intensive care unit
IPS	implementation planning study
NCTS	National Clinical Terminology Service
PBS	Pharmaceutical Benefits Scheme
RFT	request for tender
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNOMED CT-AU	SNOMED CT Australian release
UAT	user acceptance testing
VMO	visiting medical officer
VTE	venous thromboembolism

1 Overview

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

1.1 Purpose

The guide supports the safe and effective implementation and use of electronic medication management (EMM) systems in Australian health service organisations. The potential for harm because of poorly implemented EMM systems should be recognised and minimised through diligence in product selection, work practice change and end-to-end implementation. The guide should:

- Be relevant for use in all Australian public and private health service organisations
- 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 third edition of the guide builds on the previous editions. It was informed by:

- A scan of the publicly available literature (up to July 2016)[2]
- A review of publicly available tender requirements for EMM systems
- Experience from implementing EMM systems in Australia
- Consultation with stakeholders with experience in medication safety.

Several documents were also used to inform the guide:

- The National Safety and Quality Health Service Standards[3]
- *National Inpatient Medication Chart User Guide*[4]
- The Pharmaceutical Benefit Scheme (PBS) Hospital Medication Chart[5]
- The second edition of the guide[1]
- *National Guidelines for On-Screen Display of Clinical Medicines Information*[6]
- Australia's National Medicines Policy.[7]

The literature scan is available on the website of the Australian Commission on Safety and Quality in Health Care.*

* www.safetyandquality.gov.au

1.3 Additions

The guide incorporates feedback from health service organisations, and states and territories that have progressed EMM implementation since the previous guide. These organisations have either fully implemented EMM or have progressed planning for EMM implementation. Sections of the guide have been updated to reflect the experiences of these more recent EMM implementations. The guide includes additional sections on:

- The experiences of recent EMM implementations
- National medication safety priorities
- Medicines-related standards and national infrastructure
- Embedding the PBS in workflow
- Business continuity planning and operationalising the EMM system
- Policy and compliance, and regulation
- Data management and analytics, and continuous quality improvement.

The original implementation planning template has been substantially revised.

2 How to use the guide

The guide comprises four parts:

A

Electronic medication management (EMM) context, standards and technology – This part of the guide covers why health service organisations should consider moving to an electronic medication management (EMM) system, essential elements for implementing an EMM system and national standards for EMM systems.

B

EMM organisational considerations – This part of the guide covers the organisational aspects of implementing an electronic medication management (EMM) system, including the interrelationship between EMM stakeholders, EMM governance and organisational change management.

C

The EMM implementation project – This part of the guide describes the implementation process, identifies five stages for electronic medication management (EMM) system implementation and details business continuity planning.

D

EMM post-implementation – This part of the guide outlines the requirements for the post-implementation continuous operation and improvement of the EMM system.

Use of the guide will depend on whether an organisation already has an EMM system or is about to start planning for an EMM system. Health service organisations that have already implemented an EMM system and are seeking to consolidate EMM to better support medication safety should refer to Parts A and D. Health service organisations that are starting to plan for their EMM system should read the entire guide.

Not all aspects of EMM implementation will be relevant to all stakeholders. However, the Australian Commission on Safety and Quality in Health Care strongly recommends that the EMM project sponsor, senior stakeholders, the project manager and the project team read the entire guide.

Senior stakeholders include the following:

- 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.

EMM users include:

- Prescribers
- Pharmacists
- Nurses and midwives.

The main issues for senior stakeholders and users are discussed in Chapter 10. Relevant sections for stakeholders who require specific information are listed in Table 1.1.

Table 1.1 Stakeholders and relevant sections of this guide to read

Clinicians	Project governance	Operational governance	Chief information officer and ICT personnel
Case for change (Chapter 3)	Essential elements of an EMM implementation (Chapter 4)	Ongoing quality improvement and innovation (Part D introduction)	Strategic context (Section 6.1)
Business requirements for EMM systems (Chapter 9)	EMM strategic, medication and functional scope (Chapter 6)	Operationalising the EMM system (Chapter 20)	Business requirements for EMM systems (Chapter 9)
Director of medical services, medical superintendent and medical champions (Section 10.1.2)	Principal EMM stakeholders and users (Chapter 10)	Regulation, policy and compliance (Chapter 21)	Chief information officer (Section 10.1.5)
Director of pharmacy (Section 10.1.3)	EMM project governance (Chapter 11)	Monitoring and evaluation (Chapter 22)	EMM project governance (Chapter 11)
Director of nursing and midwifery (Section 10.1.4)	Organisational change management (Chapter 12)	Continuous quality improvement and data analytics (Chapter 23)	Acquiring technical infrastructure (Section 16.1)
Clinical information officers (Section 10.1.6)	Developing the EMM business case (Section 14.1)		Building the technical environments (Section 16.3)
Drug and therapeutics committee (Section 10.1.7)	Implementation sequence planning (Section 15.7)		Non-functional testing (Section 16.4)
Clinicians using EMM (Section 10.2)	Evaluation planning (Section 15.8)		Developing interfaces with third-party systems (Section 16.6)
Reference groups and specialty subgroups (Section 11.5)	Benefits management planning (Section 15.9)		User acceptance testing (Section 16.7)
Identifying champions and change agents (Section 12.5)	Education and training (Section 15.10)		Business continuity planning (Chapter 19)
Business process mapping and redesign (Section 15.5)	Project communications (Section 15.11)		
Training and materials (Section 15.10.2)	Quality management (Section 15.12)		
User acceptance testing (Section 16.7)	Escalation strategy (Section 17.5)		
Responsibilities of EMM users (Section 21.1.2)	Rollback (Section 17.7)		
Policies reflecting clinician responsibility (Section 21.2.3)			

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

2.1 EMM in the Australian context

EMM materials related to the Australian context can be found in the following sections of the guide:

- How EMM supports national medication safety priorities (Chapter 7)
- EMM national infrastructure and standards (Chapter 8)
- Supporting the Pharmaceutical Benefits Scheme (Section 15.5.3).

Part A
EMM context, standards and technology

This part of the guide covers why health service organisations should consider moving to an electronic medication management (EMM) system, essential elements for implementing an EMM system and national standards for EMM systems. It includes:

- Chapter 3, Case for change
- Chapter 4, Essential elements of an EMM implementation
- Chapter 5, Medication management continuum
- Chapter 6, EMM strategic, medication and functional scope
- Chapter 7, How EMM supports national medication safety priorities
- Chapter 8, EMM national infrastructure and standards
- Chapter 9, Business requirements for EMM systems.

3 Case for change

The main reason for implementing an electronic medication management (EMM) system is to improve medication safety. Implementing an EMM system enables safe management of patients' prescriptions.

In 2009, the National Health and Hospitals Reform Commission final report[8] stated that:

- Around 2–3% of hospital admissions are medicine related
- Around 10% of patients attending general practice experience adverse drug events
- Medication error rates are particularly high in elderly people, and during transfer of care between hospital and community settings
- An estimated 52–88% of transfer documents contain an error.

Implementing EMM systems at the point of care will[8]:

- Minimise harm to patients
- Reduce duplication
- Reduce waste
- Increase system-wide efficiency.

The guide provides advice about the activities required for the safe and effective implementation of an EMM system. It includes guidance on the scoping, selection, configuration, implementation and ongoing operation of a safe EMM system. Many Australian health service organisations are planning to implement EMM systems; this guide details the factors that influence safe and successful EMM system implementation and use.

The use of EMM for ordering medicines has been cited as the most promising application of information technology to help reduce serious medication errors.[9] Automating the medication ordering process produces standardised, legible and complete orders.[10] When combined with clinical decision-support systems, it can reduce medication errors.[11]

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.[12]

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 health service organisation systems. Poorly designed applications and failure to appreciate the organisational implications associated with their introduction can introduce unexpected new risks in patient safety.[13]

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

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'.
- **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 e-prescribing 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** 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 **Australian Digital Health Agency** 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 **Institute of Medicine of the National Academies** released the book *Preventing Medication Errors*, which states that '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 paper or oral approaches. Electronic prescribing is safer because it eliminates handwriting and ensures that the essential data elements (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 [computerised 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'.

Source: Edited and reproduced with kind permission from the Tasmanian Department of Human Services

4 Essential elements of an EMM implementation

This chapter identifies priority implementation issues that should be addressed when implementing electronic medication management (EMM). The issues represent the main items that a successful EMM implementation will depend on.

This chapter can help focus executive attention on the critical issues that need to be addressed. The Australian Commission on Safety and Quality in Health Care recommends that the EMM project sponsor, project manager and project team read this entire guide.

A checklist of the essential elements for safe and successful EMM implementation in health service organisations is in Box 4.1.

Box 4.1 Safe and successful EMM implementation checklist

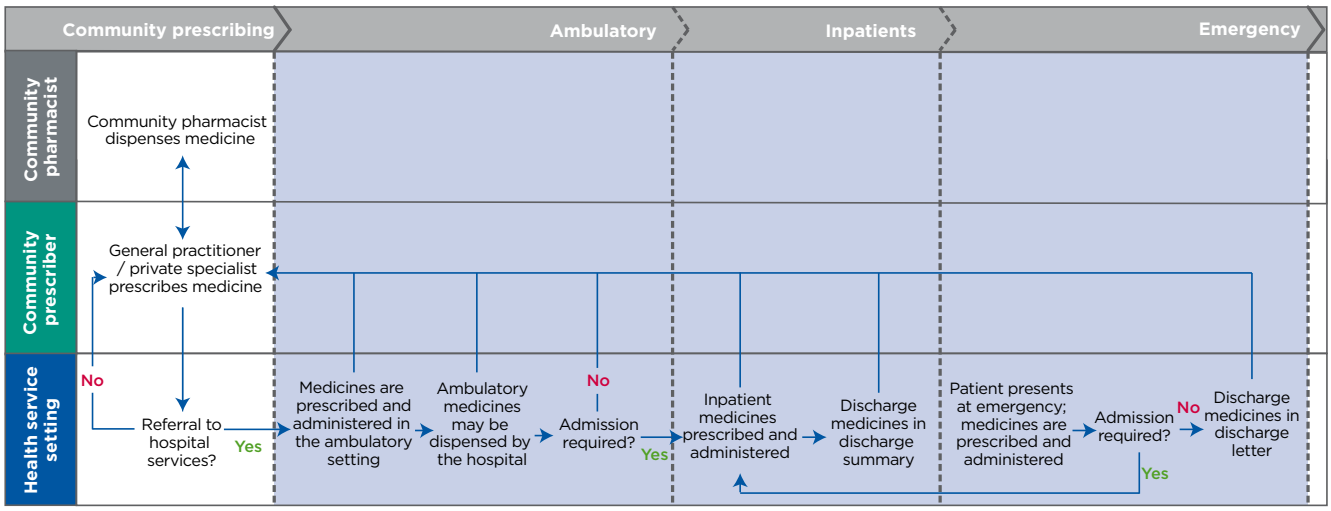
- ☐ A critical focus on all aspects of medication safety covered by the implementation scope
- ☐ Top-level engagement, leadership and commitment from the chief executive
- ☐ Sufficient funding to fully implement EMM within realistic time frames
- ☐ Robust governance structures that include strong clinical champions and EMM proponents from each clinical profession
- ☐ Commitment by senior medical staff to use EMM, and accountability for EMM use by colleagues and staff
- ☐ An experienced program manager and an appropriately resourced project team
- ☐ A carefully defined clinical scope for EMM, including how medicines will be managed at the boundaries of the EMM scope
- ☐ Clarification of the technical, operational and clinical workflow relationships between the EMM system and other clinical and administrative systems, and how these systems support medication safety; of particular importance are the relationships between the EMM system and
  - diagnostic orders and results
  - allergies and adverse drug reactions
  - other clinical information that influences medication decisions
  - other systems in use that also include medication information
  - 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
- ☐ Sufficient education and training, including refresher training and ongoing training
- ☐ Wireless point-of-care access to EMM
- ☐ Technical infrastructure that supports EMM around the clock
- ☐ Integration of EMM with pharmacy dispensing systems to avoid transcription errors and duplication of information, and to improve the efficiency of pharmacy services
- ☐ Business continuity plans to be implemented if the EMM system is unavailable, including the transition to and from paper medication charts
- ☐ Use of Australian health information and technology standards, and emerging high-value guidance, as they become available
- ☐ Ongoing governance supporting medication safety, quality use of medicines, audit, and post-implementation review and refinement of the EMM system.

5 Medication management continuum

This chapter describes the medication management continuum (Figure 5.1), which incorporates:

- Community-based medication management, including prescribing and dispensing in the out-of-hospital sector by general practitioners, specialists and community pharmacies
- Ambulatory medication management, including medication management in emergency, day procedure, outpatient and community settings
- Inpatient medication management
- The processes that support or impede the sharing of medication information across these sectors.

Figure 5.1 Medication management continuum



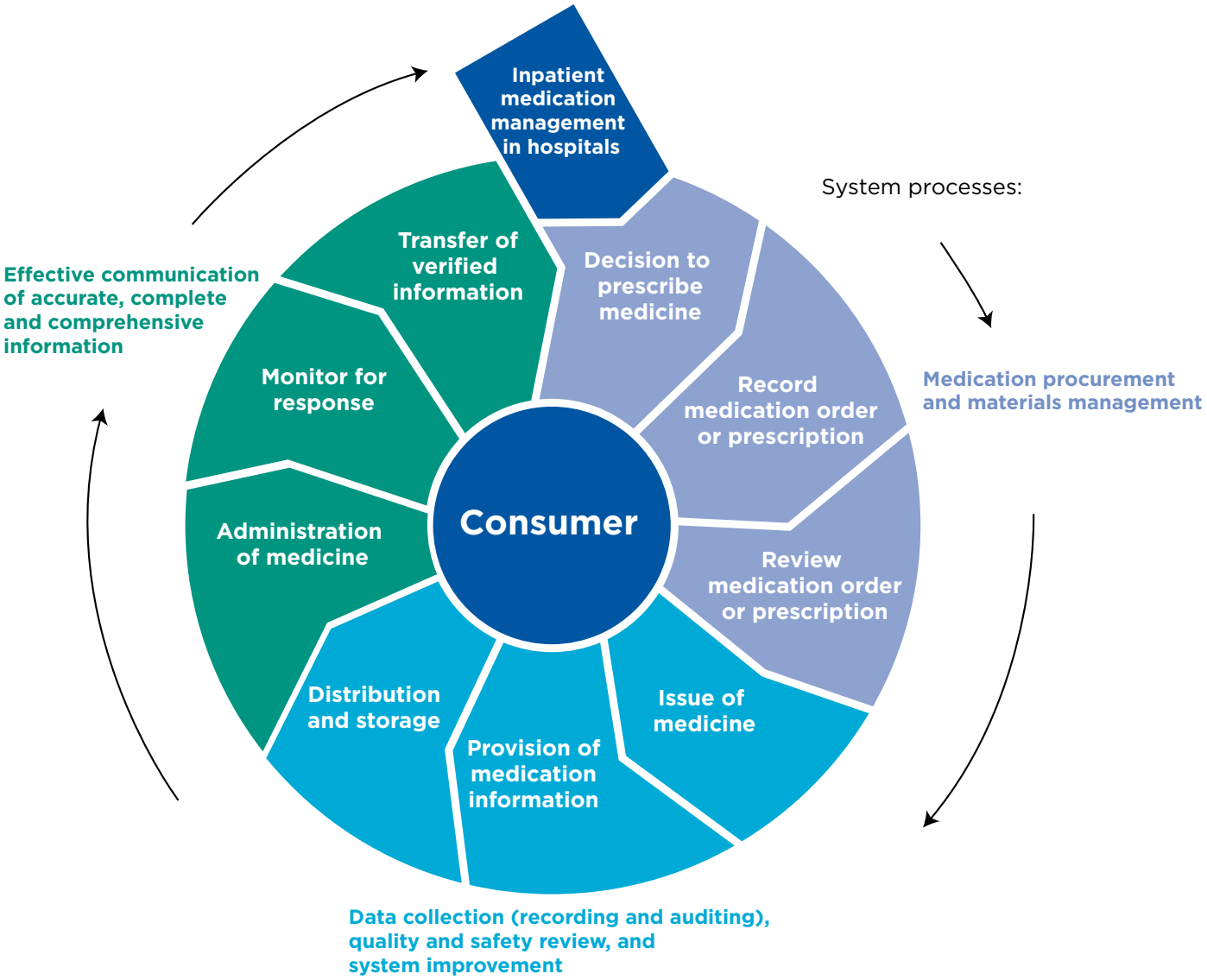
5.1 Medication management process

In this guide, medication management consists of:

- Reconciling medicines on admission to a service
- Prescribing medicines
- Reconciling medicines ordered
- Documenting the administration of medicines
- Prescribing discharge medicines
- Reconciling medicines on discharge from a service.

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

Figure 5.2 Guiding principles to achieve continuity in medication management

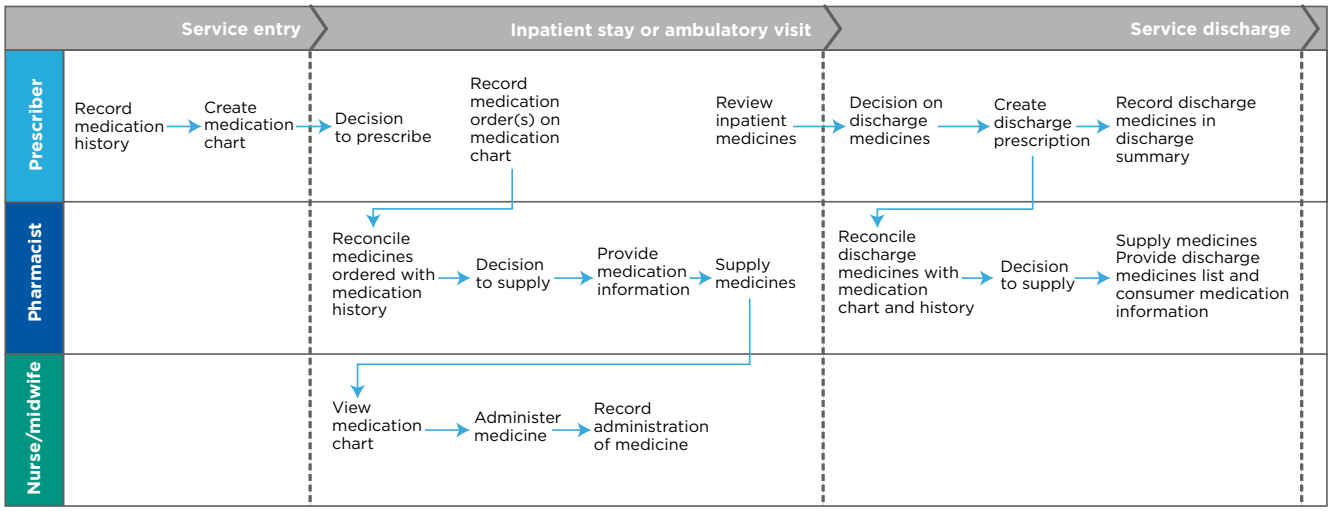


Source: Adapted from Australian Pharmaceutical Advisory Council[14]

5 Medication management continuum

Figure 5.3 provides a high-level overview of the major components of the medication management process that should be supported by an electronic medication management system. The diagram illustrates the medication continuum, and the typical relationship between the roles of the different clinicians. The responsibility for some of these roles may differ between organisations (for example, pharmacists or nurses may record the medication history in some health service organisations).

Figure 5.3 The medication management process



Medicines management components illustrated in Figure 5.3 comprise the activities listed below. In some instances, roles may overlap within activities.

On entry to a service, the appropriate clinician records a current patient medication history. This includes all the medicines taken by the patient before they entered the service (prescription, over-the-counter and complementary medicines), any previous adverse drug reactions and allergies, any recently ceased or changed medicines, and an assessment of the patient's medication-taking behaviour.[14] The medicines are verified using more than one source, which may include medication information available in My Health Record. This process is known as the best possible medication history (BPMH).

Prescribers create a medication chart that includes the medicines to continue during the stay or visit. They identify any new or changed medication orders, and document the medication plan for the patient.

Prescribers also record any medicines ceased or withheld on admission.

The appropriate clinician checks the medication orders against the BPMH. Any discrepancies are reconciled with the prescriber, and reasons for changes are documented.

During the stay or visit, prescribers:

- Create new medication orders (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
- View medication reference information, diagnostic test results and other clinical parameters that influence decisions about medicines.

Also during a patient's stay, 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 clinical settings)
- Record the dispensing and supply of medicines
- View medication reference information, diagnostic test results and other clinical parameters that influence decisions about medicines.

Finally, nurses and midwives:

- Record details of administration of medication orders
- Review and edit medication administration records
- Record clinical notes regarding administration of medicines or other clinical information (for example, physiological monitoring data)
- Review the patient's medication history and current medication chart
- Create nurse-initiated medication orders
- View medication reference information, diagnostic test results and other clinical parameters that influence decisions about medicines.

On discharge, prescribers:

- Review the current medication chart, and decide to continue, cease or restart medication orders
- Create the discharge medication prescription from the patient's medication chart and BPMH, consisting of
  - medication orders prescribed during the stay or visit that are to continue on discharge
  - new medicines prescribed
  - any medicines withheld on entry to the service that are to be resumed on discharge
- Provide patient medication information for the discharge summary reflecting
  - medicines on entry to the service
  - medicines prescribed during the stay or visit
  - medicines on discharge
- List reasons for any changes to medicines between entry to the service and discharge.

Also on discharge, pharmacists:

- Review the discharge medicine prescription(s) against the BPMH and the current medication chart before dispensing any medicines
- If necessary, contact the prescriber and suggest changes to the discharge medicines – if the prescriber agrees, they will amend the medication order and update the medication information for the discharge summary
- Prepare a complete list of discharge medicines prescribed for the patient, including changes made to the medicines during the stay or visit.

On re-entry to the service, prescribers recall and review a patient's previous medication records, including medicines recorded at previous stays or visits and discharges. Prescribers can then use the most recent discharge medication list (when appropriate) to populate the medication chart for the new stay or visit.

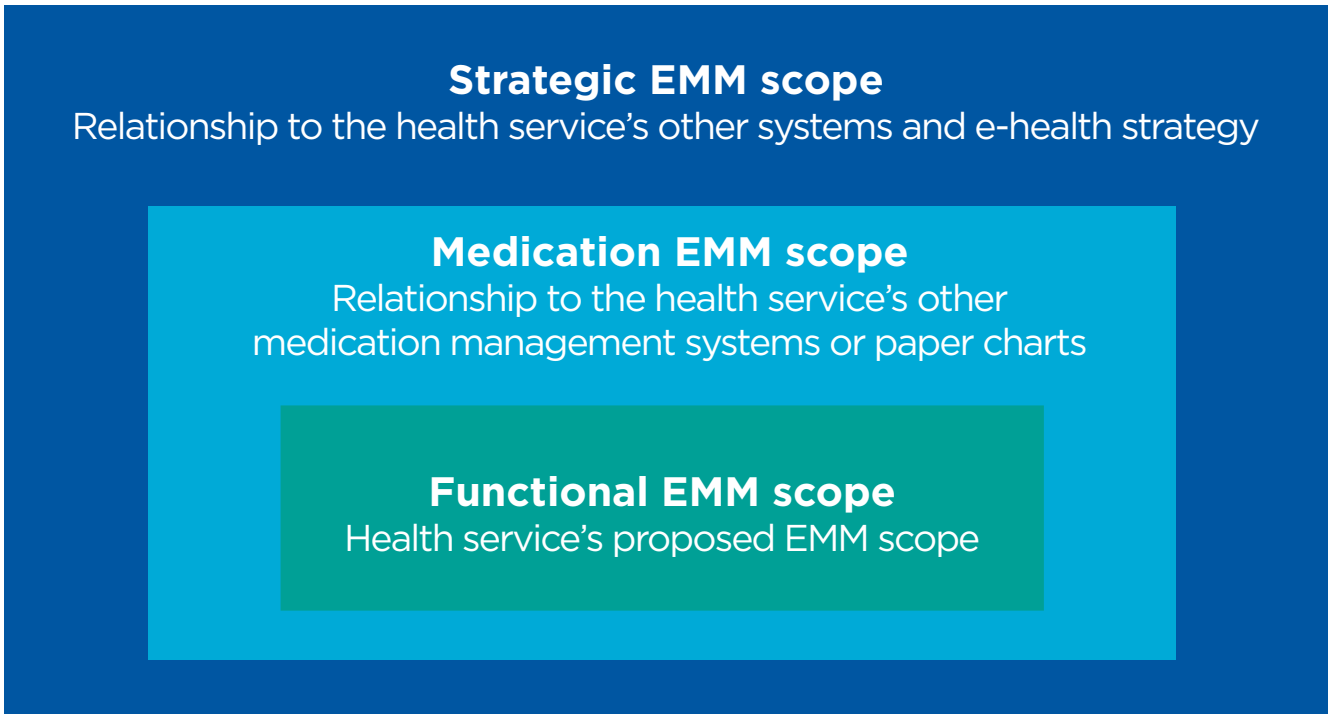
6 EMM strategic, medication and functional scope

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

- The strategic scope within which the proposed EMM will operate; this includes how the medication components or systems relate to other clinical components or systems in the health service organisation (existing or planned)
- The medicines scope for the proposed EMM system and how the boundaries of the EMM system will be managed; this will ensure medication safety across the medicines continuum in the organisation, including where multiple EMM systems operate
- The functional scope of the proposed EMM system, including
  - prescribing, review and administration of medicines
  - medicines workflow
  - inbound and outbound medicines information sharing
  - dispensing robotics and other automation
  - the supply chain
  - the extent to which closed-loop medicines administration will be provided.

The relationship between the strategic, medication and functional scope of an EMM system can be seen in Figure 6.1.

Figure 6.1 Relationship between the strategic, medication and functional scope of EMM systems



EMM = electronic medication management

Sections 6.1–6.3 consider these elements in more detail, and include worked examples that illustrate some issues that need to be considered when scoping implementation strategies for EMM.

6.1 Strategic context

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

The approach most commonly used is where EMM is part of a broader clinical information system that may include other functions. These other functions include diagnostic orders and results reporting, clinical pathways, and clinical documentation that are part of an electronic health record (EHR).

The other approach is where the EMM system is a dedicated system that is interoperable with other systems, such as diagnostic results or patient administration systems.

The approach taken will be influenced by several factors, including the organisation's:

- Information management and technology strategy
- Software application solution architecture
- Existing software application solutions
- Staged implementation plans
- Technology refresh plans
- Timing, technical or funding constraints.

The decision to implement an EMM system is a critical one for a health service organisation. It is essential that organisation executives thoroughly understand and own the decision. Box 6.1 presents a series of questions to help an organisation decide whether it should use a dedicated EMM system, or incorporate the EMM system within an EHR.

To help clarify the approach an organisation should take, a strategic assessment and cost–benefit analysis of the proposed EMM scope should be done. The relationship of the EMM system to the broader range of e-health record capabilities that may exist or be required by an organisation should also be assessed.

Where more than one EMM system is in use in a health service organisation, careful consideration should be given to medication safety as patients move between areas of the organisation. For example, a health service organisation may have one EMM system for general inpatient areas and a different system that includes medication management for intensive care or high-dependency units.

6 EMM strategic, medication and functional scope

Box 6.1 Questions to ask if the EMM system is not incorporated into the broad clinical information system

- How will clinicians access the EMM system – directly, or through a third-party clinical system? How will this approach support clinical workflow?
- How will clinicians access the EMM system on ward rounds where medicines may be changed or discharge medicines ordered, while simultaneously accessing other clinical information systems, such as diagnostic results?
- Will diagnostic results be available for review in the EMM system at the point of prescribing, or will clinicians access the results in another system before ordering and administering medicines?
- Will diagnostic results be available to EMM decision-support capabilities when ordering or administering medicines?
- Will diagnostic tests be available for order, as part of the medicines order set? This would mean that appropriate diagnostic tests can be ordered at the same time as the medicine. For example, ordering a potassium serum level test at the same time as prescribing potassium-depleting medicines.
- Where will allergy and adverse drug event information be held? How will this information be made available to, and be maintained by, the EMM system?
- How will medicines be prescribed and administered, and medication safety be managed, if the emergency department has a different system from the EMM system used by the rest of the health service organisation?
- How will medication safety be managed where intensive care units and high-dependency areas have a different EMM system from the rest of the health service organisation?
- How will medication safety be managed where oncology, renal or other specialist services have a different EMM system from the rest of the health service organisation?
- How will discharge medicines be incorporated into discharge summaries where EMM and discharge summaries are in different systems?
- How will changes to medicines before discharge be reflected in the discharge summary?
- How will discharge medicines be available for post-discharge ambulatory visits?

Ensuring medication safety is paramount in determining the scope and boundaries of an EMM system. Some of the elements listed in Box 6.1 will not be included in the EMM scope. In this case, the rationale for their exclusion and how the medication safety risks will be mitigated should be documented.

Risk mitigation should be considered and agreed as part of goal-state workflow. Risk mitigation requirements must be considered during EMM procurement, evaluation and selection.

An example of a strategic scope analysis is provided in Table 6.1.

Health service organisations might consider the following material in clarifying their strategic context:

- The Healthcare Information Management Systems Society (HIMSS) EMR Adoption Model (EMRAM)[15]
- The United Kingdom National Health Service digital maturity assessment[16], to help identify gaps in local strategies to deliver EMM in the broader context of digital health in the organisation.

Table 6.1 Example of a strategic scope analysis

Strategic scope component	Is the strategic scope component included in the EMM project scope?	What will the health service organisation do to ensure a focus on medication safety?
Existing clinical information system	No	The existing clinical information system will continue to be used, with the following elements implemented to ensure a focus on medication safety: • Synchronisation of client records will occur automatically in both the EMM system and the clinical information system • Diagnostic test results will be available for display in the EMM system wherever medicines are prescribed, reviewed or administered • EMM system alerts and reminders will prompt clinicians to update the relevant parts of the clinical information system, as appropriate
Existing ICU or HDU system	No	Manual medication reconciliation will occur on transfer into and out of the ICU or the HDU, using a system-generated and printed medication chart that incorporates the safety features of the NSMC (by both the EMM system for transfers into the ICU or the HDU, and by the ICU or HDU system on transfer out of these units to the general inpatient areas) The risks associated with this approach have been recognised and will be proactively managed
Existing chemotherapy system	No	Diagnostic test results will be available for display to the prescribing and administration screens of the chemotherapy system
ED	No	The EMM system will not be used to prescribe and administer medicines for ED presentations. ED medicines will remain on paper until a decision is made about the future replacement of the existing ED system
Ambulatory and community departments	Yes	The EMM system will be used in all ambulatory clinics and community services
Diagnostic results	Yes	Diagnostic results will be displayed wherever medicines are prescribed, reviewed or administered in the EMM system
Allergies and ADRs	Yes	The EMM system will interface with the clinical information system to retrieve existing medicine allergies and ADRs, and send any new medicine allergies and ADRs to the clinical information system to ensure a single source for allergy and ADR information

6 EMM strategic, medication and functional scope

Table 6.1 Example of a strategic scope analysis (continued)

Strategic scope component	Is the strategic scope component included in the EMM project scope?	What will the health service organisation do to ensure a focus on medication safety?
Discharge summaries	Yes	Discharge medicines, and any subsequent changes to discharge medicines, will be available electronically to the discharge summary system All changes to discharge medicines will be made in the EMM system and not in the discharge summary system Where the discharge summary has already been sent to recipients, a revised discharge summary will be provided, containing the correct discharge medicines information
Pharmacy system	Yes	An interface with the EMM system will electronically transfer non-imprest medication orders to the pharmacy system for dispensing

ADR = adverse drug reaction; ED = emergency department; EMM = electronic medication management; HDU = high-dependency unit; ICU = intensive care unit; NSMC = national standard medication charts

6.2 Medication scope

The medication scope of the EMM system needs to be clearly defined. Each care location or setting in the health service organisation where medicines are prescribed should be considered, including:

- General wards
- Intensive care units and high-dependency units
- Specialist areas such as chemotherapy and renal dialysis
- Emergency departments
- Ambulatory, rehabilitation and mental health wards
- Operating theatres and day procedure units
- Diagnostic imaging services
- Community services.

The emphasis when implementing EMM should be on safe medication management. Before implementing an EMM system, the EMM governance and project teams should consider each aspect of medication management in the proposed EMM scope. The teams should also consider how to maintain the medication management continuum and ensure patient safety as patients move between different areas of the health service organisation. This should include an end-to-end medication management 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 organisation.

Where medicines are to be prescribed and administered without an EMM system, the rationale for this decision should be documented. Any gaps in the medication management continuum should be addressed and documented to ensure medication safety. For example, if complex infusions, anaesthetics, or operating theatre and procedure room medicines are not in the proposed scope of EMM, their management needs to be documented.

An example of a medication scope analysis is provided in Table 6.2.

6 EMM strategic, medication and functional scope

Table 6.2 Example of a medication scope analysis

Medication scope component	Is the medication scope component included in the EMM project scope?	What will the health service organisation do to ensure a focus on medication safety?
Inpatient units	Yes	The scope will include all units and Hospital in the Home but exclude ICU, HDU and chemotherapy day procedure unit
ICU and HDU	No	ICU or HDU staff will update the EMM patient chart at the start and end of the ICU or HDU stay, to alert EMM users of the existence and status of the ICU or HDU chart On transfer from the ICU or the HDU to a receiving ward, medicines applicable on transfer will be printed as part of the ICU or HDU handover process and re-entered onto the EMM chart by a prescriber on the receiving ward, until the interface between the two systems has been thoroughly tested and implemented The risks associated with this approach have been recognised and will be proactively managed
Chemotherapy day procedure unit	No	Chemotherapy unit staff will update the EMM patient chart at the beginning and the end of chemotherapy treatment to alert EMM users of the existence and status of the chemotherapy chart The chemotherapy system will query the EMM system and retrieve other medication information: • Whenever the chemotherapy medicine is changed • Before each batch of chemotherapy medicine is manufactured
ED	No	Whenever an ED patient is to be admitted, the inpatient team with responsibility for the admission will update the EMM system with the prescribed medicines from the ED paper chart and sign the paper chart to confirm this has been done Clear clinical processes and training will ensure that paper charts used in the ED are adequately transcribed in a timely fashion, and are not inappropriately used for ongoing care The risks associated with this approach have been recognised and will be proactively managed If there are delays to the patient transferring to the inpatient unit, the ED nurses who have been trained in EMM administration will update the EMM system with the medicines that were administered in the ED

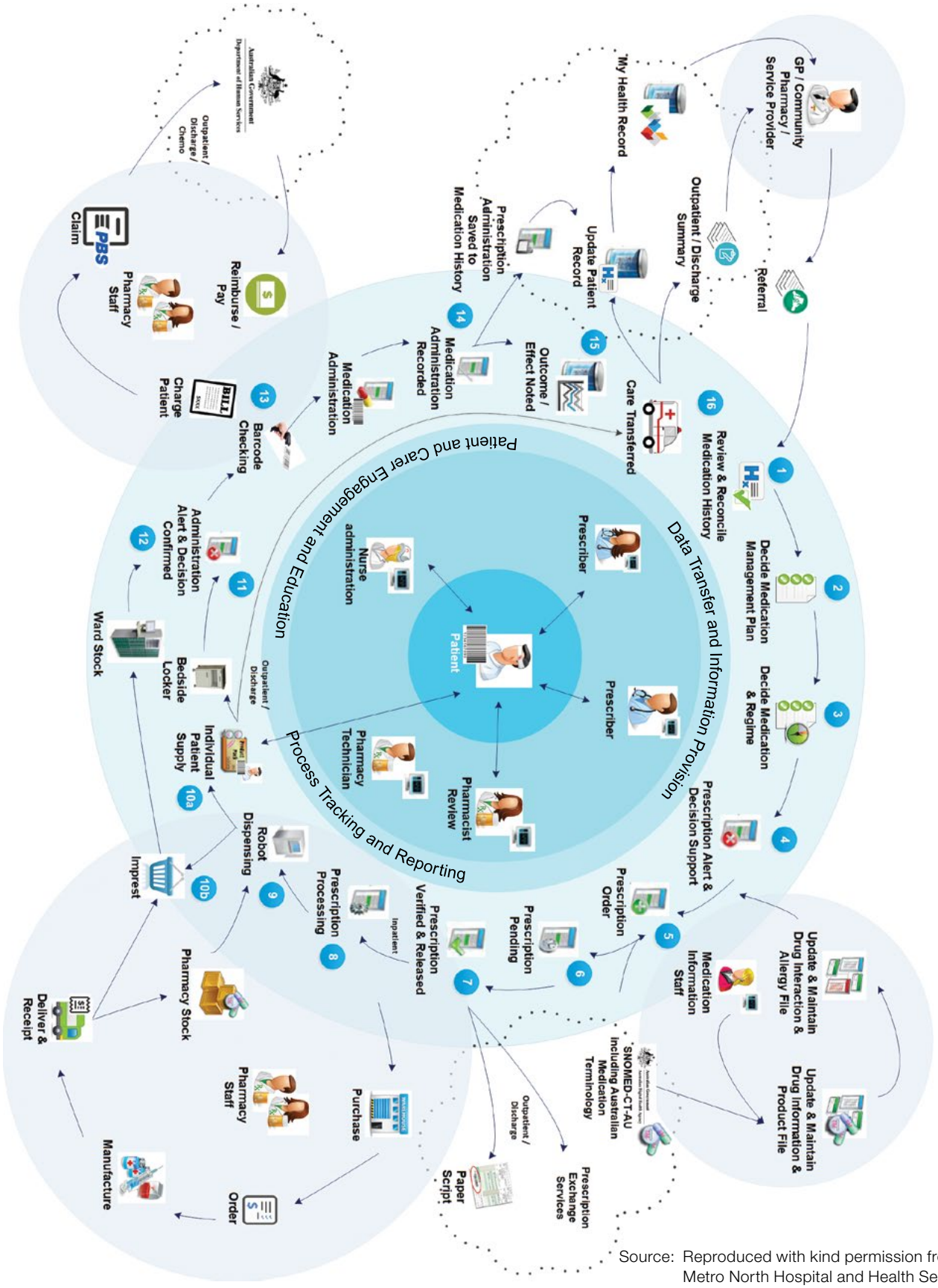
Table 6.2 Example of a medication scope analysis (continued)

Medication scope component	Is the medication scope component included in the EMM project scope?	What will the health service organisation do to ensure a focus on medication safety?
Ambulatory clinics	Yes	The EMM system supports the medication management continuum, with discharge medicines available for review and re-use in ambulatory clinics
Community services, including mental health, chronic disease clinics and remote outreach services	Yes	The EMM system supports the medication management continuum, with discharge medicines available for review and re-use in community services
Discharge medicines	No	Discharge medicines will be sent electronically to the discharge summary system to be incorporated into the discharge summary as soon as the EMM system generates the discharge prescription If the discharge medicines require subsequent amendment, the prescriber will make the changes in the EMM system and the updated discharge prescription will be re-sent to the discharge summary system The pharmacist will ensure that all changes to discharge medicines discussed with the prescriber are updated by the prescriber in the EMM system before they are dispensed

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

6 EMM strategic, medication and functional scope

Figure 6.2 Medication management continuum in a health service system



Source: Reproduced with kind permission from the Metro North Hospital and Health Service

6.3 Functional scope

Figure 6.2 illustrates the complexity and scope of the medication management continuum in a health service system.

Health service organisations should critically consider the functional scope of medication management in their EMM system, including:

- Sharing of inbound and outbound information with primary care
- Access and use of the My Health Record system
- Inpatient EMM, including medication reconciliation, prescribing, pharmacy review, medication administration and medication management workflow
- Medication supply chain and dispensing
- Discharge and ambulatory prescribing and dispensing, including medication reconciliation and the transmission of unfilled discharge prescriptions to a prescription exchange service
- Dispensing robotics, automated dispensing cabinets and medication safes, including interoperability with the dispensing system
- Closed-loop medication management.

An example of a functional scope analysis is provided in Table 6.3.

Table 6.3 Example of a functional scope analysis

Functional scope component	Is the functional scope component included in the EMM project scope?	Basis for including/excluding the functional component in the EMM project scope
Inbound medicines information	Partially	Only for patients with a My Health Record, since the health service organisation currently has no system in place for receiving and managing electronic referrals delivered by secure messaging. The EMM system will display My Health Record medication information during medication reconciliation for assisted data import
Access to the My Health Record system	Yes	Only for patients with a My Health Record during medication reconciliation inbound, submission of discharge summaries, onward referrals and specialist letters outbound
Medication reconciliation, prescribing, review and administration, including medication management workflow	Yes	Medication management workflow requirements are included in the EMM tender requirements in assessing EMM solution capabilities. Medication reconciliation will include My Health Record access and assisted data import
Outbound medication information	Yes	In structured discharge summaries sent via secure messaging to primary care and other recipients, and to the My Health Record system

Table 6.3 Example of a functional scope analysis (continued)

Functional scope component	Is the functional scope component included in the EMM project scope?	Basis for including/excluding the functional component in the EMM project scope
Prescription exchange services	Yes	In providing consumer choice of dispensing pharmacy. Particularly important for patients managed under shared-care arrangements
Medication stock and dispensing robots	No	Stock will continue to be managed by the pharmacy dispensing system. Dispensing robots are subject to a separate business case and are not included in the EMM implementation scope
Medication safes	No	Controlled medicines will be included in the automated dispensing cabinets and manual counts will continue to operate
Automated dispensing cabinets	Yes	In all inpatient units and anaesthetic bays, interfaced with the dispensing system
Closed-loop medication management	Yes	Scanning of the patient's wristband and scanning of each unit dose of medicine being administered

The EMM implementation plan (available on the Commission website*) includes a template to help identify and manage the strategic, medication and functional components of a health service organisation's proposed EMM scope.

* www.safetyandquality.gov.au/publications/electronic-medication-management-systems-implementation-plan

7 How EMM supports national medication safety priorities

National medication safety priorities include:

- Ensuring the quality use of medicines (QUM)
- Improving medication reconciliation, including best possible medication histories
- Optimising the safe use of high-risk medicines
- Implementing the clinical care standards
- Preventing and controlling healthcare-associated infections
- Increasing the accuracy of patient identification.

7.1 Quality use of medicines

QUM is one of the central objectives of Australia's National Medicines Policy. Electronic medication management (EMM) systems should support the national strategy for QUM by helping prescribers to:

- Select management options wisely
- Choose suitable medicines if a medicine is considered necessary
- Use medicines safely and effectively.

Australia's national strategy for QUM[17] outlines the principles, partners, building blocks and approach for achieving QUM in Australia. The goal of the national strategy for QUM is to make the best possible use of medicines to improve health outcomes for all Australians.

7.2 Medication reconciliation, including best possible medication histories

Maintaining the medication management continuum is essential so that medicines can be reconciled, ordered, reviewed and administered when patients transfer from one healthcare setting to another.[18] This includes taking a best possible medication history.

EMM systems should not constrain the medication management process because of any external requirement for episodic management. Rather, medication continuity should be supported across all of a patient's inpatient stays and ambulatory visits.

Australian EMM experience suggests that EMM systems should help medication reconciliation by:

- Supporting clinician access to, and review of, medication information for previous inpatient stays and ambulatory visits
- Enabling the transfer of previously supplied medicines to a new inpatient stay or ambulatory visit using EMM system functionality, not by 'cutting and pasting'
- Enabling the transfer of previously supplied medicines to a new instance of prescribing through EMM system functionality – not by 'cutting and pasting', and without having to re-enter the medicine order
- Enabling the retrospective updating of the reconciled medicines list when additional medication information becomes available
- Supporting medication safety by linking any medicines that may have been prescribed before a medication reconciliation process, so that the medicine appears only once on the medication chart, and only once on any of the discharge documentation, including the discharge summary, discharge prescription and patient take-home medication list
- Enabling previously ordered and administered medicines to continue to be administered when a patient is transferred between wards or settings
- Supporting the printing of a medication chart in line with the safety features of the national standard medication chart, whenever care is transferred to where paper charts operate, where there is no interface between different EMM systems operating in the organisation, or on discharge when appropriate
- Removing artificial constraints associated with admission episodes and ambulatory encounters – which are often determined for classification, not clinical, purposes – so that medication information can flow across occasions of service.

Health service organisations seeking to include medication reconciliation in their EMM should:

- Visit organisations that have implemented EMM to understand the extent to which they have achieved medication reconciliation, including any local workarounds
- Encourage EMM solution providers to improve their EMM systems to fully support medication reconciliation
- Encourage EMM solution providers to adopt developments in national standards, de facto standards and national infrastructure that have a positive bearing on medication reconciliation.

Efficient medication reconciliation in EMM systems has many benefits for health service organisations, including:

- Improved medication safety
- Improved productivity of clinicians reconciling medications
- Greater numbers of patients with reconciled medicines
- Smarter prescribing workflow.

Additional details about the business requirements supporting medication reconciliation are in Chapter 9.

7.3 High-risk medicines

High-risk medicines include insulin and the APINCH medicines (anti-infectives, potassium and other electrolytes, narcotics and other sedatives, chemotherapeutic agents, and heparin and other anticoagulants). For each category of high-risk medicine, the EMM system should support the safe prescribing and administration of high-risk medicines, and appropriate corrective action. The appropriate action for each medicine class is as follows:

- Insulin, support recording or reviewing of blood glucose levels
- Potassium – support cardiac electrolyte monitoring
- Narcotics, support
  - reviewing duplication of scheduled administration and PRN (taken as needed) doses
  - considering therapeutic duplications
  - configuring administration lock-outs
  - using sedation scores and pain scores
- Other sedatives, support using sedation scores
- Chemotherapy medicines, support limiting them to appropriate clinical settings and basing them on standard protocols that consider cumulative lifetime doses
- Heparin and anticoagulants, support reviewing biochemistry results.

7.4 Preventing and controlling healthcare-associated infections

When developing an antimicrobial stewardship (AMS) program, many organisations implement standalone AMS capabilities. These capabilities guide the prescriber through prescribing protocols or pathways, including generating automated approvals for restricted antibiotics and advising the prescriber to seek specialist telephone approvals for highly restricted antibiotics.

Where electronic AMS capabilities have been implemented, there are five implementation models:

1. A dedicated AMS capability with no EMM system in place
2. A dedicated AMS capability operating independently of an EMM system
3. A dedicated AMS capability synchronised with an EMM system
4. AMS functions incorporated in an EMM system
5. Reporting capabilities that bring together AMS data from an EMM system and possibly other systems, such as diagnostic results.

Model 1 is the predominant model in Australian health service organisations, where there is no EMM system in place. The opportunity for noncompliance with antimicrobial policy is greater in this model than in other models, because only antimicrobial medicines require the prescriber to use a computer system. This can be regarded as disruptive to prescriber workflow, requiring constant vigilance by the AMS team.

7 How EMM supports national medication safety priorities

In model 2, the AMS capability operates independently of the EMM system. When prescribing restricted antibiotics, the EMM system requires the prescriber to access the standalone AMS capability, then complete the prescribing protocol or pathway, and obtain a prescribing approval number. The approval number may be an automated approval by the AMS capability, or a telephone approval number following consultation with an infectious diseases specialist or microbiologist. The prescriber returns to the EMM system and enters the approval number, although usually no validation of the approval number is entered into the EMM system. Model 2 encourages greater compliance with antimicrobial policy because the prescriber is using the computer more frequently to prescribe a broader range of medicines, and is thought to be less disruptive to prescriber workflow. However, the lack of approval number validation can result in contrived approval numbers, and requires ongoing vigilance by the AMS team. Nevertheless, one Australian EMM site has reported that compliance increased from approximately 30% to 75% after moving from model 1 to model 2.

Model 3 synchronises patient demographic information and prescriber details, and embeds the use of the AMS capability in the EMM system (no separate login, no duplicate data entry). This approach streamlines prescriber workflow, reduces the time required to prescribe antibiotics and encourages prescriber compliance with AMS policy. One health service organisation in Australia is using model 3, although no data were available at the time of publishing this guide.

Model 4 provides AMS capabilities natively in the EMM system, negating the need for a separate AMS capability. However, where native AMS capabilities are available in EMM systems, AMS decision support can sometimes be more passive, necessitating greater levels of compliance follow-up. An Australian study[19] of a site that adopted model 4 demonstrated substantial improvements in compliance compared with model 1. However, the authors were unable to assess the appropriateness of antimicrobial prescribing because the medicine indication was recorded as free text.

Model 5 supports AMS through near real-time reporting of antibiotic prescribing and diagnostic test results to the AMS team for proactive review and intervention.

Currently, all AMS implementation models have limitations, necessitating ongoing compliance reporting, education and training.

Health service organisations seeking to implement AMS in their EMM system should:

- Carefully consider whether to retain or replace their separate AMS capability
- Visit organisations that have implemented EMM, and that have either retained or replaced their AMS capability
- Encourage EMM solution providers to deliver more sophisticated native AMS functionality, including
  - embedded antimicrobial protocols or pathways in prescribing workflow
  - recording of structured indications, which guide the prescribing protocols or pathways
  - validation of automated approval numbers
  - workflow support for highly restricted antimicrobials requiring infectious diseases or microbiology specialist approvals
  - real-time dashboard reporting where prescribing contradicts antimicrobial policy
- Encourage EMM solution providers to integrate EMM systems with separate AMS capabilities to better support prescriber workflow and ensure compliance with AMS policy.

Additional information about AMS can be found on the website of the Australian Commission on Safety and Quality in Health Care[20], and Chapter 10 of *Antimicrobial Stewardship in Australian Hospitals*.[21]

7.5 Patient identification

The EMM system should support the unique identification of patients and the safe prescribing of medicines.[22] This includes:

- Supporting multiple medical record numbers for a patient where multisite EMM systems operate
- Enabling the scanning of patient wristbands and the medicines being administered
- Incorporating the Individual Health Identifier in inbound and outbound clinical information that uniquely identifies the patient
- Ensuring patient privacy in line with the National Privacy Principles[23]
- Maintaining a continuous medication record for patients moving within the health service organisation.

Technical specifications for patient identification are detailed in the business requirements that accompany these guidelines.

7.6 Opportunities to support other safety and quality standards

EMM systems can support other safety and quality standards by:

- Producing an up-to-date and accurate medication list (see Action 4.6.1 in the *National Safety and Quality Health Service Standards: Standard 4*[18])
- Including new, suspended or changed medicines within medication information, supporting clinical handover communication
- Using a workflow that prompts a medication review whenever a patient is identified as a falls risk
- Autopopulating medication information in falls risk assessment tools
- Alerting prescribers when prescribing look-alike, sound-alike and high-risk medicines such as sedatives, antidepressants, antipsychotics and centrally acting pain relief to patients identified as at risk of a fall
- Adjusting abnormality thresholds for medicines known to affect specific physiological parameters or combinations of parameters, so that functions that recognise clinical deterioration and escalating care continue to operate when these medicines are prescribed.

8 EMM national infrastructure and standards

This section examines how nationally available infrastructure services, specifications and guidelines contribute to electronic medication management (EMM) systems. These include:

- The My Health Record system
- The Healthcare Identifiers (HI) Service
- The National Clinical Terminology Service (NCTS), including SNOMED CT-AU and the Australian Medicines Terminology (AMT)
- Digital supply chain solutions
- Specifications supporting secure messaging and the exchange of clinical information such as discharge summaries, prescriptions and dispensing records.

The Australian Digital Health Agency (the Agency) is responsible for these services. The aim is to achieve semantic interoperability of medication information.

Several other medication-related initiatives will also affect the design and connectivity of EMM systems, including:

- *National Guidelines for On-Screen Display of Clinical Medicines Information*[6]
- *National Guidelines for On-Screen Presentation of Discharge Summaries*[24]
- Prescription exchange services.

The implications of these initiatives for EMM systems are described in this section.

8.1 My Health Record system

The Australian Government has developed a consumer-controlled e-health record – the My Health Record system. At the time of publishing this guide, more than 4.5 million consumers were registered with the system.[25]

The My Health Record system presents clinical documents created by general practice, public and private health service organisations, private specialists, and allied health providers. It also presents content provided by Australian Government–funded programs, including the Pharmaceutical Benefits Scheme (PBS), the Medicare Benefits Scheme, the Australian Immunisation Register and the Australian Organ Donor Register.

Clinical documents held in the My Health Record system include structured and coded medication information, including:

- Shared health summaries
- Event summaries
- Discharge summaries
- Specialist letters
- Referrals
- Prescription records
- Dispensing records.

The Agency is working to improve the use of medication information in the My Health Record system. The Agency is committed to developing semantic interoperability and granular medication information.[26]

8.1.1 Medication reconciliation on entry to the health service organisation

On entry of a patient to the health service organisation, medication reconciliation should include, where available, medication information held in:

- My Health Record system clinical documents, and use My Health Record views, such as the Prescription and Dispense View, and the Planned Medicines View
- Other organisation systems (see Section 8.5).

The complete exchange of structured and coded medication information between the My Health Record system and EMM systems is not yet fully functional. However, an EMM system can use the existing information in the My Health Record system to streamline and improve medication reconciliation. Examples of this streamlining include:

- Electronically exchanging and importing structured and coded medication information (if available) in the EMM system for electronic re-use when clinicians reconcile medicines
- If the dose instruction remains free text, electronically exchanging and displaying this text so clinicians can interpret it.

During 2017, a new Medicines View in the My Health Record system will be implemented. This will improve the usability of medication information and help to streamline medication reconciliation where EMM systems can access the My Health Record system.

8.1.2 Medication information in documents sent to the My Health Record system

Examples of medication information in documents sent to the My Health Record system include:

- Discharge summaries on discharge from the health service organisation
- Event summaries
- Specialist letters following ambulatory consultations
- Prescription records for discharge prescriptions and ambulatory prescriptions
- Dispensed records for prescriptions dispensed by the health service organisation
- Postdischarge referrals to other organisations.

Other systems such as the organisation's broader clinical system, discharge summary system or dispensing system may send these documents to the My Health Record system. This can be done by using medication information from the EMM system.

Health service organisations should encourage:

- EMM solution providers to use the My Health Record system to support better medication reconciliation
- Other solution providers to send structured and coded medication information in the relevant clinical documents to the My Health Record system.

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed safe use guides for the My Health Record system, including one for providers.[27] For the latest My Health Record implementation guidance refer to *Resources for Implementers and Developers*.[28]

8.2 Healthcare Identifiers Service

The Australian Government HI Service uniquely identifies Australian consumers and healthcare providers, and consists of:

- Individual Health Identifiers for consumers
- Health Provider Identifiers – Individual for individual health professionals
- Health Provider Identifiers – Organisation (HPI-O)[29] for healthcare organisations.

EMM systems should incorporate health identifiers to:

- Import patient medication information from clinical documents held in external systems, including the My Health Record system, to support medication reconciliation
- Export patient medication information via clinical documents to external systems – including the My Health Record system, discharge summaries and specialist letters – to general practitioners, and unfilled prescriptions to prescription exchange services.

For more information on the HI Service, refer to *My Health Record system and Healthcare Identifiers* (HI).[30]

8 EMM national infrastructure and standards

8.3 National Clinical Terminology Service

The NCTS is responsible for managing, developing and distributing national clinical terminologies, and related tools and services, to support the digital health requirements of the Australian healthcare community. SNOMED CT-AU and the Australian Medicines Terminology (AMT) are national clinical terminologies developed and maintained by the NCTS.

8.3.1 SNOMED CT-AU

SNOMED CT* is a clinical terminology with global scope covering a wide range of clinical specialties, disciplines and requirements.

One benefit of SNOMED CT's broad scope is reducing the specialty boundary effects that arise from different clinicians or departments using different terminologies or coding systems. This benefit allows structured clinical information to be widely shared and re-used.

Another benefit of SNOMED CT is that the same data can be processed and presented in ways that serve different purposes. For example, clinical records presented using SNOMED CT can be processed and presented to support direct patient care, clinical audit, research, epidemiology, management or service planning.

Additionally, the global scope of SNOMED CT reduces geographical boundary effects arising from the use of different terminologies or coding systems in different organisations and countries.

SNOMED CT Australian release (SNOMED CT-AU) is the Australian extension to SNOMED CT. It includes core content from the international release, local variations and customisations of terms, and additional content developed to meet requirements for use in Australian clinical systems. Locally created content (for example, new concepts and terms, reference sets) may be requested by external and internal stakeholders, or developed to support EMM implementations (for example, guidance documents). Content is often created collaboratively as small projects with external stakeholders, including states and territories, vendors and clinicians.

Examples of SNOMED CT-AU-encoded concepts include allergies and adverse drug events, diagnoses, presenting problems, procedures, medical histories, substances, dosages and routes of administration.

8.3.2 Australian Medicines Terminology

The AMT is the national terminology that delivers unique codes to unambiguously identify originator and generic brands of medicines commonly used in Australia. It also provides standard naming conventions and terminology to describe medicines accurately.

The AMT covers all commonly used medicines in Australia, and is developed to be implemented in clinical information systems to support EMM, including:

- Prescribing
- Recording
- Reviewing
- Issuing, including dispensing
- Administering
- Transferring information.

The AMT (a formal subset of SNOMED CT-AU), is updated every month to include changes and additions to the PBS, the Repatriation Pharmaceutical Benefits Scheme and the Australian Register of Therapeutic Goods.

Prescription (scheduled) items are included as higher priority items than are non-scheduled items. Non-approved therapeutics such as Special Access Scheme products can be requested for inclusion in the AMT, based on the request submission process.† The AMT can be downloaded for free by registered licence holders.

As part of prescribing support, the AMT's earlier focus was on commercially available medicines and their packs (that is, pack or product-based prescribing), but is now extended to support dose-based ordering or prescribing, which is often used in inpatient services.

* SNOMED Clinical Terms™ (SNOMED CT®) is used by permission of SNOMED International, formally known as the International Health Terminology Standards Development Organisation. All rights reserved. SNOMED CT® was originally created by the College of American Pathologists. SNOMED and SNOMED CT are registered trademarks of SNOMED International (www.snomed.org).

† https://www.healthterminologies.gov.au/ncts/#/request

The guidance for using SNOMED CT-AU and the AMT to support dose-based orders is described in the *SNOMED CT-AU Guide for Terminology Use in Prescribing*.[31] The current scope of this document includes the following medicines:

- Regular or routine
- Once only
- When required
- Loading dose
- Reducing dose
- Variable dose
- Simple intravenous (IV) fluids, including fluid additives.

Although it is not currently fully supported, the future scope of *SNOMED CT-AU Guide for Terminology Use in Prescribing* may include more complex medicines, including:

- Complex total parenteral nutrition
- Complex IV fluids, especially where the dose is expressed as a rate
- Chemotherapy protocols
- Clinical trials
- Extemporaneous products and their preparation
- Protocols for intensive care units and other high-dependency areas, including renal dialysis
- Medical devices and consumables
- Patient-controlled analgesia.

The development and extension of the AMT and SNOMED CT-AU are ongoing. Health service organisations seeking to increasingly share medication and other clinical information electronically with other healthcare providers, or with the My Health Record system, should incorporate the AMT and SNOMED CT-AU (where relevant) into their EMM implementation.

Organisations implementing EMM should, before embarking on EMM configuration:

- Read the Agency's *SNOMED CT-AU Guide for Terminology Use in Prescribing*[31]
- Consult with the Agency's AMT team
- Consult the NCTS website for further information – such as about licensing, use cases and implementation guidance.

8.4 Digital supply chain solutions

The Australian Government, in partnership with GS1 Australia, has delivered a series of digital supply chain enablers* that play an important part in the EMM cycle, especially in ensuring interoperability and visibility across the end-to-end cycle. These are based on GS1's Global Supply Chain System of Standards.

The National Product Catalogue (NPC) is a master product data synchronisation service that helps suppliers and manufacturers to enter, validate, store, maintain and share all their product details, including regulatory information, trade-related pricing and marketing-related information. It enables master product data to be provided once to all recipients through a single synchronisation service. The NPC currently holds more than 417,000 products and is used by more than 500 organisations. The NPC supports a link between physical products uniquely identified by a Global Trade Item Number (which can be represented as a barcode) and by terminology represented by an AMT code.

The ability to uniquely identify physical locations and their purpose (for example, a pharmacy storeroom) below the healthcare organisation level (often represented by an HPI-O) is critical to visibility in and across organisations. To ensure interoperability, it is recommended that Global Location Numbers (GLNs) be used below the HPI-O level. The exchange of GLN information is supported through a location master data synchronisation service, Locatenet.

Recalling medicines is a critical part of ensuring patient safety, and Recall Health has been developed to support digitising the Therapeutic Goods Administration's *Uniform Recall Procedure for Therapeutic Goods*.[32] Recall Health enables recalls and warnings to be electronically sent to relevant stakeholders, and provides greater visibility of action taken by all.

The electronic exchange of supply chain messages using standardised e-trading messages (purchase orders, advance shipping notices, invoices) is fundamental to accelerating the benefits of e-trading nationally. This exchange enables faster supply of medicines, reduced transaction costs and increased supply chain visibility.

* Further information on these enablers can be found at https://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/supply-chain.

8 EMM national infrastructure and standards

8.4.1 Supply chain considerations

Health service organisations implementing EMM should, before embarking on EMM configuration, consider:

- What their strategy is for managing and maintaining product data, and how receiving product data from the NPC can be enabled as part of their product data flow
- How locations are uniquely identified, and how their associated hierarchy and location information is maintained and exchanged between stakeholders to ensure the exchange of accurate location information
- How recalls or warnings are managed electronically, and the ability for the EMM system to integrate directly into Recall Health
- Whether the strategy for e-trading is nationally aligned to support accelerated uptake and receipt of benefits by all stakeholders
- Whether GS1 standards are being used for product and location information to support a globally interoperable system.

8.5 Secure messaging and clinical exchange specifications

The increased adoption of secure messaging for electronic communication between primary care and acute health service organisations provides more opportunities for medication information exchange that supports medication reconciliation.

Medication reconciliation should include, where available, medicines information held in:

- The My Health Record system
- Other systems used by organisations, including previous discharge summaries and specialist letters, and electronic referrals received from general practices through secure messaging.

Although the complete exchange of structured and coded medication information between the My Health Record system and EMM systems may not yet be fully available, the EMM system should make the most of what is available in the My Health Record system in streamlining and enhancing the medication reconciliation process.

For example, where:

- Limited or no structured and coded medication information is available, the EMM system should display clinical documents in the medication reconciliation function for review by clinicians
- Structured and coded medication information is available, this information should be available electronically in the EMM system for re-use during review by clinicians
- The dose instruction component of electronic medicines information remains free text, the dose instruction should be electronically exchanged and displayed for interpretation by clinicians.

The Agency has published a guide[33] to assisted data import. Although targeting primary care systems, the guide has direct relevance to heath service EMM systems seeking to import structured and coded medicines via secure messaging.

Several specifications are available to support the secure exchange of clinical information. For the most up-to-date list of available specifications, refer to *Resources for Implementers and Developers*.[28]

8.6 On-screen display of clinical medicines information

The Commission has published *National Guidelines for On-Screen Display of Clinical Medicines Information*[6], which include design recommendations on how to display:

- Names of medicines
- Text, abbreviations and symbols
- Numbers and units of measure
- Medication information, including where items are placed, their visual weighting, font, separators and labels
- Wrapping and truncating text and lines of text.

Health service organisations should encourage EMM solution providers to ensure that the EMM system displays medication orders in line with the guidelines.

An example of how a medication order should be displayed on-screen is provided in Figure 8.1.

Figure 8.1 Display format for medication orders

6.1.3.1 Medicines order

Dose based

Do this: 6.1.3.1a

morphine sulfate – *MS Contin* – modified release tablet – oral – DOSE **30 mg** – twice a day

Don't do this: 6.1.3.1b

morphine sulfate – modified release tablet – oral – DOSE **30 mg** – twice a day

Dose based

Do this: 6.1.3.1c

Kenacomb – ear drops – right ear DOSE **2 drops** – three times a day

Don't do this: 6.1.3.1d

triamcinolone acetonide 0.1% + **neomycin sulfate** 0.25% + **gramicidin** 0.025% + **nystatin** 90,000 units/mL – ear drops – right ear – DOSE **2 drops** – three times a day

Dose based

Do this: 6.1.3.1e

Kenacomb – ear drops – right ear DOSE

triamcinolone acetonide 0.1%
neomycin sulfate 0.25%
gramicidin 0.025%
nystatin 90,000 units/mL

Don't do this: 6.1.3.1f

Kenacomb – ear drops – right ear DOSE

triamcinolone acetonide 0.1% + **neomycin sulfate** 0.25% + **gramicidin** 0.025% + **nystatin** 90,000 units/mL

Pack based

Do this: 6.1.3.1g

warfarin sodium 5 mg – *Marevan* – tablet – oral – DOSE **5 mg** – once a day at night SUPPLY 50

Don't do this: 6.1.3.1h

warfarin sodium 5 mg – tablet – oral DOSE **5 mg** – once a day at night – SUPPLY 50

Source: Australian Commission on Safety and Quality in Health Care[6]

8 EMM national infrastructure and standards

8.7 On-screen presentation of discharge summaries

The Commission has developed *National Guidelines for On-Screen Presentation of Discharge Summaries*.[24] Figure 8.2 shows how medicines on discharge should be displayed when rendering the electronic discharge summary.

Health service organisations should encourage EMM solution providers to adopt the guidelines when:

- Sending discharge medicines information from the EMM system to discharge summaries, so the discharge summary system can use the correct information
- Discharge medicines from discharge summaries are displayed for medication reconciliation in EMM systems.

Figure 8.2 Display format for discharge medicines

Medicines on discharge

Medicine	Directions	Duration/ end date	Status	Change reason/clinical indication	Quantity supplied
amoxycillin 875mg + **clavulanic acid** 125mg – *Augmentin Duo Forte* – tablet – oral	**1 tablet** – twice a day – with or after food	10 day course	New	Appendicitis	10 tablets
metronidazole 400mg – *Flagyl* – tablet – oral	**1 tablet** – three times a day – swallow whole – with or after food	10 day course	New	Appendicitis	10 tablets
paracetamol 500mg – tablet – oral	**2 tablets** – up to four times a day – maximum 8 tablets in 24 hours	–	New	As required for pain or fever	–
sotalol 80mg – tablet – oral	**1 tablet twice a day** – on an empty stomach	–	New	Atrial fibrillation	–
tramadol 50mg – capsule – oral	**1 to 2 capsules** – up to four times a day – maximum 8 tablets in 24 hours	–	New	As required for pain	–
ramipril 2.5mg – capsule – oral	**1 capsule** – twice a day	–	Changed	Dose increased, hypertension	–
alendronate 70mg – tablet – oral	**1 tablet** – once a week on Sunday – 30 minutes before food and other medicines – remain upright for 30 minutes after taking	–	Unchanged		–
aspirin 300mg – dispersible tablet – oral	**HALF a tablet** – once a day in the morning – with food	–	Unchanged		–
frusemide 40mg – tablet – oral	**1 tablet** – once a day in the morning	–	Unchanged		–
calcium 600mg + **vitamin D** 12.5MICROg **Ostelin** – tablet – oral	**1 tablet twice a day** – with or after food	–	Unchanged		–

Source: Australian Commission on Safety and Quality in Health Care[24]

8.8 Prescription exchange services

Prescription exchange services are now often used for the electronic transfer of prescriptions between primary care providers and community pharmacies. These services have the following potential advantages:

- They support consumer choice (of dispensing pharmacy) for EMM-generated prescriptions
- They provide access to existing prescriptions for dispensing, including repeat prescriptions for private hospital admissions, and for repeat prescriptions where PBS authority has already been issued for Section 100 Highly Specialised Drugs
- They enable prescriptions to be electronically exchanged between the EMM system and the dispensing system in private hospitals in the absence of interoperability between these local systems.

9 Business requirements for EMM systems

The Australian Commission on Safety and Quality in Health Care (the Commission) has redeveloped the original high-level requirements for electronic medication management (EMM) systems in hospitals presented in earlier editions of this guide. In this edition, the requirements reflect contemporary business requirements of EMM sites and national developments that affect EMM systems. The Commission has also incorporated additional EMM business requirements from the Australian context, including medication safety priorities, technical standards and national infrastructure initiatives.

The EMM business requirements aim to:

- Provide peer-reviewed requirements for EMM systems, reducing the effort required by Australian health service organisations when developing their own requirements as part of the procurement process
- Increase the medication safety features of EMM implementations, including compliance with national safety and quality standards
- Promote adoption of national e-health standards and national technical infrastructure
- Ensure that lessons are learned from previous Australian EMM implementations.

The requirements were brought together from published and unpublished information sources, and validated by an expert panel.

Health service organisations can download the requirements from the Commission website, to use when developing their own EMM procurement requirements. Some of the business requirements may not reflect the capabilities of EMM solutions operating in the Australian health sector at the time of publication.*

9.1 Introduction to the requirements

The requirements begin with the Australian context, and address:

- State and territory legislation
- Australian Government legislation
- National Safety and Quality Health Service (NSQHS) Standards
- National terminology and infrastructure
- Prescription exchange services.

State and territory legislation is considered in relation to the specific requirements of health departments' poisons legislation. This includes the need for prescription signatures, implications for electronic signatures and the management of controlled medicines.

Australian Government legislation is considered in relation to:

- the Pharmaceutical Benefits Scheme (PBS) in better supporting PBS workflow
- the Therapeutic Goods Administration in accessing Special Access Scheme medicines
- Australian Government privacy principles.

The NSQHS Standards include specific requirements about medication safety, and preventing and controlling healthcare-associated infections.

Other national guidelines also considered include:

- *National Guidelines for On-Screen Display of Clinical Medicines Information*[6]
- *National Guidelines for On-Screen Presentation of Discharge Summaries*.[24]

The Australian Digital Health Agency and the Australian Government have developed several terminology and technology infrastructure services that have important implications for EMM system requirements, including:

- Secure messaging
- Electronic transfer of prescriptions
- The My Health Record system
- The Health Identifier Service
- SNOMED CT-AU for allergies and the Australian Medicines Terminology.

* https://www.safetyandquality.gov.au/our-work/medication-safety

Prescription exchange services should also be considered regarding non-admitted patients and discharge prescriptions.

Section 2 of the requirements covers these business requirements arising from the Australian context.

Sections 3–8 of the requirements address EMM capabilities that are applicable to all organisations, irrespective of their EMM implementation scope. These include prescribing, decision support, pharmacy review, medication supply and administration, and EMM workflow.

Section 9 of the requirements considers how different EMM systems operate and the implications that arise from this, and how medication safety can be addressed at the boundaries and interfaces of EMM systems.

Section 10 of the requirements considers speciality-specific medicines. Their use will depend on the scope of a health service organisation's EMM implementation, including:

- Chemotherapy
- Paediatrics
- Anaesthetics and intensive care units
- Emergency departments, including resuscitation
- Renal dialysis
- Ambulatory settings.

Section 11 considers how EMM systems should support continuous quality improvement, including auditing and reporting, and the technical and non-functional requirements of EMM systems, including support for business continuity in the event of an EMM system failure.

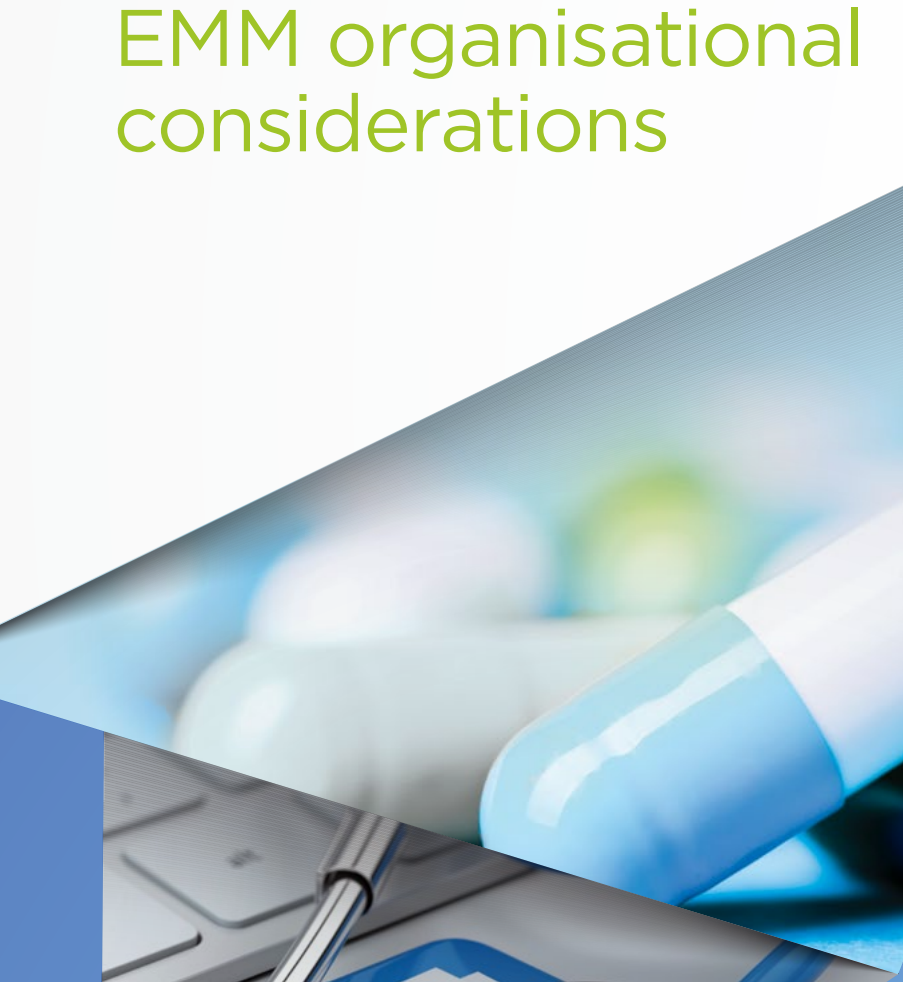
9.2 How to use the requirements

Health service organisations using the requirements should critically review them when deciding which are relevant to the organisation's proposed EMM scope, and determine any mandatory requirements. When doing this, it is important to be mindful of the capabilities and limitations of solutions operating in the Australian market. Consideration should also be given to the risks, benefits and costs of working collaboratively with EMM suppliers in enhancing the preferred EMM system capabilities to improve medication safety and quality use of medicines.

Health service organisations should also incorporate organisation-specific requirements, including:

- Technical and performance requirements that need to be applied locally
- Descriptions of any systems that will need to interoperate with the EMM system locally – for example, patient administration systems, diagnostic result systems, automated dispensing cabinets and robotics
- Details of the clinical services that are in scope for the EMM implementation
- The volume of data that the EMM system is expected to support, including the
  - expected number of users of the EMM system
  - organisation throughput (for example, separations, ambulatory services and emergency department attendances)
  - number of formulary medicines
  - number of medicines that are individually dispensed
- Implementation and training requirements
- Contractual requirements.

Part B
EMM organisational considerations



This part of the guide covers the organisational aspects of implementing an electronic medication management (EMM) system, including the interrelationship between EMM stakeholders, EMM governance and organisational change management. It includes:

- Chapter 10, Principal EMM stakeholders and users
- Chapter 11, EMM project governance
- Chapter 12, Organisational change management.

10 Principal EMM stakeholders and users

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

At the time of publication, the Australian hospital EMM experience has been (at times) characterised by:

- Insufficient involvement of chief executive officers (CEOs) and executive teams in EMM implementation; strong executive involvement is a differentiator in successful EMM implementations
- Lack of engagement by senior medical staff, with many decisions left to EMM implementation teams
- A short-term focus on the EMM implementation, with a tendency to 'set and forget' once the EMM system has been implemented; in fact, the end of the EMM implementation should be the starting point for systematic and ongoing improvements in medication safety and quality use of medicines in health service organisations
- Slow progress in linking medication and non-medication data to maximise the opportunities for smarter and more integrated EMM or e-health record support to clinicians
- Underuse of analytics for continuous quality improvement and enhanced medication safety
- Insufficient funding to operationalise EMM systems, particularly for ongoing EMM system maintenance, support, process refinement, system refinement, and ongoing education and training.

Addressing these issues in existing and new EMM implementations should be a priority for CEOs and executive teams.

This chapter summarises the main considerations for each of the organisation's senior stakeholders and decision-makers, and the clinicians who will implement and use the EMM system.

10.1 Principal stakeholders and decision-makers

The principal stakeholders and decision-makers include the:

- CEO
- Director of medical services, medical superintendent and medical champions
- Director of pharmacy
- Director of nursing and midwifery
- Chief information officer (CIO) or chief clinical information officer (CCIO)
- Clinical information officers
- Drug and therapeutics committee (DTC).

Sections 10.1.1–10.1.7 describe the specific responsibilities for these roles. However, some common roles for the CEO, the CIO or CCIO, and clinical directors include:

- Being a member of the EMM system project board (the CEO should consider chairing this board)
- Visiting other organisations that have implemented EMM systems to understand both the technical magnitude of the task and the challenges of implementation from the perspective of their clinical field
- Attending EMM information sessions and product demonstrations to provide leadership and expert advice for their staff
- Identifying strategies for training agency and locum staff
- Identifying strategies that encourage staff participation.

10.1.1 Chief executive officer

The CEO refers to the most senior executive in the organisation.

Given the size and complexity of an EMM system implementation, the CEO must be clear on the rationale for the proposed EMM system and why it is important for the organisation. The CEO must also communicate and reinforce EMM system messages – in particular, medication safety.

It is essential that the CEO is provided with costs that are realistic. Information and communications technology (ICT)–related projects can underestimate true costs, and a lack of funds will compromise both safety and efficacy when implementing an EMM system. Project costs should include sufficient funding to adequately maintain the EMM system after implementation.

CEOs should have the ICT infrastructure costs assessed separately, as this infrastructure will be shared by other organisation applications, particularly electronic medical record (EMR) systems. Access to EMM systems from mobile wireless devices or equivalent bedside access requires substantial infrastructure costs. High-availability infrastructure is also required to ensure around-the-clock availability of the system. 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.

The CEO is responsible for the proposed governance model, which should have appropriate representation and time allocated from senior medical, pharmacy, nursing, ICT, finance, and safety and quality staff. The individuals nominated should be able to ensure a high-quality and successful EMM system implementation in their areas of responsibility.

The CEO needs to ensure adequate participation of clinical service areas in EMM scoping, requirements gathering, procurement and package selection, and implementation and evaluation activities. The CEO must also ensure that, once the EMM system is implemented, arrangements are in place for a systematic and continuous approach to improving medication safety by reviewing medicines, medication data and improvements to medication workflow, and providing ongoing medication education and training.

In addition, the CEO should:

- Consider chairing the EMM system project board, given the high project costs, the technical complexities and the organisation-wide human factors associated with implementing an EMM system; the CEO may be called on to provide authority and resolve conflict
- Understand the implications of project recommendations to turn off aspects of electronic medication decision support
- Understand the significant organisational impact associated with implementing EMM
- 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
- Recognise that the implementation of EMM represents only the starting point to achieving
  - continuous quality improvement
  - ongoing improvements in medication safety
  - ongoing system and process optimisation in maximising medication safety, in line with Part D
- Adequately fund the ongoing maintenance of the EMM system.

The role of the CEO is crucial to ensure the success of the EMM system, and to achieve the expected benefits in supporting medication safety and continuous quality improvement.

10.1.2 Director of medical services, medical superintendent and medical champions

One of the biggest challenges in local EMM system implementation is gaining and maintaining the support of the health service organisation's senior medical staff. Senior medical staff are role models for junior doctors and need to encourage and support the use of the EMM system. The director of medical services or medical champions play a critical role in advocating the use of an EMM system among 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 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 that all medical staff are trained in how to use the EMM system, and identify strategies for training agency and locum medical staff; this will be particularly challenging for private health service organisations, because visiting medical officers (VMOs) are not employees of the organisation
- Appoint clinical staff super users.*

* A super user is a workforce member who trains others on clinical information systems.

10 Principal EMM stakeholders and users

In addition to the responsibilities described in Section 10.1, the director of medical services or medical champions should:

- Be an early adopter of the EMM system in the organisation
- Collaborate with senior clinical information officers
- Consider engaging a doctor to train medical staff
- Ensure that the mobile devices selected (for example, computers on wheels) enable appropriate bedside access for prescribers, and that VMOs have remote access to the EMM (because of the limited availability of on-site junior doctors in private health service organisations).

The director of medical services or medical champions should communicate several important messages to medical staff.

First, they need to emphasise 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 health service organisations, and omission or overdose of a medicine is the most frequent medication error.[34]

Second, the director needs to use local health service organisation EMM data to demonstrate the need for improvements in medication safety.

Third, the director needs to communicate the benefits of EMM systems, which:

- Help to reduce medication errors and associated clinical risks[12,35] through legible, abbreviation-free and auditable medication orders
- Align discharge summaries with patient medication 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 for patients who frequently visit the organisation, thus reducing the time required to prescribe these medicines.

Fourth, the director should manage user expectations about the implications of using an EMM system. Prescribing medicines electronically may take longer than paper-based prescribing, but this is offset by time saved in other areas, such as no longer having to rewrite medication charts or locate paper charts.

Fifth, the director needs to promote the 'whole package' of EMM, which includes easy-to-use EMM that is highly integrated with other organisation systems, supported by a robust and accessible technology infrastructure.

Finally, the director should identify opportunities to promote the EMM system to senior colleagues. For example, the system may support research, help to manage clinical trials and identify potential candidates for trials.

10.1.3 Director of pharmacy

Pharmacists are experts in the safe use of medicines. 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 an important stakeholder and decision-maker, and should take 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. They must also undertake EMM system training, and be familiar with EMM system concepts and issues as they relate to pharmacy.

The director of pharmacy must ensure that the work required of pharmacists is resourced appropriately. 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 reduce dependencies on individual pharmacists). Part-time secondment of pharmacists to EMM project roles should be avoided because of the potential conflict between a pharmacist's EMM system project duties and operational pharmacy duties.

The director of pharmacy must also ensure that the mobile devices selected (for example, computers on wheels) enable appropriate bedside pharmacy review.

The director of pharmacy should ensure that there is a clearly defined objective in the proposed scope of the EMM system project to integrate the EMM system with other systems used in the pharmacy. So far, there has been a lack of integration 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. In some cases, this has increased the workload of the organisation pharmacists and could increase the risk of medication error.

The director of pharmacy should not be the project sponsor. An EMM system represents substantial multidisciplinary organisational change, and there is a risk that the organisation may view the EMM project as a 'pharmacy project' if the director of pharmacy is a project sponsor.

In addition to the responsibilities described in Section 10.1, the director of pharmacy should:

- Delegate specific duties to nominated pharmacists
- Ensure that the EMM system addresses medication management requirements
- Free up pharmacists from other activities during the transition to the EMM system to be super users or clinical champions, and to support electronic medication reconciliation for prescribers as they make the transition to the EMM system
- Ensure that there is ongoing funding to adequately support the maintenance and upkeep of the EMM system, so that it remains relevant and up to date, and supports continuous quality improvement in medication safety
- Advocate for greater use of pharmacy robotics that free up pharmacy staff time, with the savings redeployed to support medication safety and continuous quality improvement in the use of the EMM system.

10.1.4 Director of nursing and midwifery

Nurses and midwives represent the largest staff group to use the EMM system, and several nursing and midwifery–specific issues require consideration. Strong nursing leadership is a differentiator in successful EMM implementations, so the director of nursing and midwifery is an important stakeholder and decision-maker.

The director of nursing and midwifery must:

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

In addition to the responsibilities described in Section 10.1, the director of nursing and midwifery should consider making EMM-trained nurses and midwives available to train other nurses and midwives on how to use the EMM system.

10.1.5 Chief information officer

For most health service organisations, implementing an EMM system requires substantial additional ICT investment and infrastructure. The CIO is a critical stakeholder in ensuring that the EMM system is successful.

The size and complexity of the EMM system are significant and should be incorporated into the organisation's ICT strategic plan. This includes technical infrastructure and high-end server availability options, the application architecture, and the application software solution mix used to deliver the EMM scope, interoperability and interfacing. In many health service organisations, the EMM system will be the first solution requiring high-availability and around-the-clock support arrangements.

The EMM system will need to be accessed at the point of care (including bedsides) in all clinical areas. This 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 fixed devices).

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

10 Principal EMM stakeholders and users

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

- As a separate EMM software product that is integrated with, or interfaced with, other organisation systems (such as pathology and patient administration)
- As part of a broader clinical information system that may include other functions such as orders and results reporting, and clinical documentation, typically referred to as an EMR.

The choice of EMM system will be highly influenced by the health service organisation's current or planned solution architecture. Before procurement, the organisation should make strategic decisions about the degree of integration and interoperability required between the EMM system and other clinical systems. This is so the application provides a high-quality clinician user experience, supports efficient clinical workflow and ensures medication safety.

The CIO has several roles. First, they must actively participate in the initial stages of EMM system implementation planning. This is to ensure that the ICT infrastructure is sufficient to meet the needs of an EMM system, and that the choice of EMM system (and any other system) meets the wider clinical and business requirements of the organisation.

Second, the CIO must consider preparing an ICT infrastructure business case that is separate from 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 applications. The shared infrastructure costs should not distort the EMM system business case.

Third, the CIO must consider bringing forward the implementation of ICT infrastructure dependencies so the required infrastructure does not become an obstacle to, or increase the complexity of, EMM system implementation. For example, the health service organisation should consider:

- High-availability infrastructure, including disaster recovery
- Network infrastructure, including wireless
- Remote access
- Single sign-on
- Identity management (for clinicians, contractors and students)
- Use of patient identifiers (Individual Health Identifiers, multicampus identifiers where applicable)
- Secure messaging (inbound and outbound)
- Improved analytics capacity
- Data governance to support analysis of quality use of medicines and medication safety.

The size and complexity of the required ICT infrastructure are likely to warrant several projects that are managed separately from the EMM system project, while maintaining reporting mechanisms between projects. For example, equipping the organisation with the required ICT infrastructure is sufficiently complex to be a standalone project. 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 other fixed or mobile devices.

Finally, the CIO must 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 ICT support arrangements.

The CIO should be a member of the EMM system project board, given the size and complexity of the technical requirements of an EMM system. If this is not possible, the CIO should ensure that a senior ICT services staff member is on the EMM system project board and other governance structures, and reports back to the CIO.

10.1.6 Clinical information officers

Increasingly, health service organisations are creating senior clinical informatics roles, such as:

- Chief clinical information officers
- Chief medical information officers
- Chief nursing information officers.

These staff focus on clinical outcomes. Responsibilities of these roles typically include:

- Collaboration with other senior leaders, and with the CIO and ICT staff
- Clinical stakeholder engagement
- Clinical adoption and clinical process improvement
- Clinical integration of evidence, research, analytics and best practice
- Standardisation of clinical terminology, coding and compliance
- Clinical workflow and user experience, and clinical decision-support use
- Senior clinical staff training.

10.1.7 Drug and therapeutics committee

The DTC or equivalent group in the organisation should play an integral and active role in all stages of EMM system implementation and ongoing operation, 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, health service organisation formulary items, policies and protocols, EMM system alerts or their configuration, or other system configurations that may affect the safe use of medicines
- Determine the degree to which clinical decision support is implemented, and how and when individual alerts and groups of alerts are activated in the EMM system; the extent to which clinical decision support has been implemented in Australian sites is highly variable
- Visit other EMM sites and satisfy themselves about the level of clinical decision support that will be implemented in the EMM system
- Where alerts are implemented in stages, approve the proposed alert staging, and all communication materials associated with implementing increased levels of decision support over time
- Approve the selection, and oversee the ongoing use, of third-party medication reference information sources and clinical decision-support systems used by the EMM system so they remain consistent with other information sources in the health service organisation
- Ensure that all EMM changes are supported by appropriate policies and procedures that are disseminated and made available to clinical staff using the EMM system
- Be responsible for the systematic review of how the EMM system is being used, and ongoing review of priority work programs that result in changes to the EMM system and medication workflow to improve medication safety, in line with Part D.

10.2 Clinicians using EMM

This section highlights the main issues that require consideration from the perspective of the three main groups who will use the EMM system:

- Prescribers, who prescribe medicines
- Pharmacists, who review and supply medication orders
- Nurses and midwives, who administer medicines.

These user groups include students, and agency and locum staff. Organisations should also consider other clinicians who may need to access or use the EMM, such as allied health clinicians.

10.2.1 Prescribers

Prescribers must meet their regulatory obligations, defined in Part D.

To prescribe medicines electronically, prescribers should:

- Use the EMM system consistently and in line with organisation policy
- Ensure that their training in the use of the prescribing system (including any ongoing training) is in line with their defined scope of practice
- Bring any medication safety concerns in relation to the EMM system or the way in which it is being used to the attention of the EMM system governance committee.

10 Principal EMM stakeholders and users

In addition, prescribers should ensure that any changes to electronically generated medication orders are only made electronically. Prescribers should never annotate any electronically generated medication order or pharmacy work list that has been generated for internal organisation purposes. If the medication order needs to be changed, it must be changed in the EMM system.

Prescribers should also ensure that discharge medicines in the discharge summary accurately reflect the patient's medicines on discharge. Where changes to discharge medicines occur after the discharge summary has been completed and sent to recipients, the discharge summary should be updated to reflect these changes and should be re-sent to recipients. Where electronic discharge summary arrangements prevent subsequent changes to the discharge summary, prescribers should contact recipients and advise them of the changes to the discharge medicines.

For medicines eligible under the Pharmaceutical Benefits Scheme (PBS), prescribers must prescribe in accordance with *National Health Act 1953*, including:

- Prescribing PBS medicines before they are dispensed (the only exception being urgent supply requirements, which should be managed in line with organisation policy)
- Providing all the information making up a valid PBS prescription at the time of prescribing
- Providing a streamlined authority code or authority approval number when authority items are prescribed.

Other prescriber responsibilities include supporting the national safety and quality standards, including those for antimicrobial stewardship and medication reconciliation.

The engagement and participation of prescribers are critical to the success of EMM. Based on past experiences in Australia, prescribers should:

- Be trained in how to use the EMM system
- Understand the rationale for changes to their workflow on moving from paper-based prescribing to electronic prescribing
- Be involved in determining the level of clinical decision support 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 medication management
- 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.

In addition, 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 medication reference information and dosing calculators) at the time of prescribing medicines, and use these tools in their prescribing workflow
- Review and acknowledge prescribing alerts and modify prescribing behaviour accordingly
- Be involved in developing standard order sets, and specialty or therapy-specific order sets
- Record the indication for each medicine ordered to ensure that other clinical users are aware of the intent of the medication order; the indication provides medication safety information and is particularly important when the medicine is being prescribed on behalf of another prescriber (for example, a community medical officer on behalf of a VMO in a private health service organisation)
- Record additional clinical information that may help other clinicians understand how the medicine should be managed.

Prescribers should not use paper medication charts to prescribe medicines in wards where the EMM system is fully implemented, unless required to do so in line with policy. For example, a lack of EMM system capabilities for managing certain types of medicines may require use of a paper chart. The existence of both paper and electronic medication charts for a single patient is confusing and increases the risk of medication errors.

10.2.2 Pharmacists

Pharmacists must meet their regulatory obligations, defined in Part D.

When using the EMM system, pharmacists should:

- Use the EMM system in line with organisation EMM policies
- Have a thorough understanding of how the EMM system operates and the pharmacist's role in ensuring that medicines are prescribed electronically in the EMM system in line with the organisation policy for electronic prescribing
- Use the EMM system to review and supply medicines in line with the organisation policy for review and supply of medicines
- Ensure that their training in the use of the EMM system (including any ongoing training) is in line with their responsibilities
- Bring any medication safety concerns in relation to the EMM system or dispensing systems, or the way in which these systems are being used, to the attention of the EMM governance committee
- Ensure that any changes to electronically generated medication orders, including any annotations, are only made electronically; pharmacists should never dispense electronically generated medicine orders if there is any discrepancy between the electronic prescription in the EMM system and the medicine being dispensed
- Advise prescribers that any changes to the electronically generated medication order must be changed in the EMM system before the medicine can be dispensed; this includes changes to the medication orders being dispensed on discharge so that the discharge summary accurately reflects any changes to the discharge medicines.

When dispensing PBS-eligible medicines, pharmacists must operate from an approved PBS pharmacy and dispense PBS medicines in accordance with the *National Health Act 1953*.

Pharmacist responsibilities should support the national safety and quality standards, including antimicrobial stewardship and medication reconciliation.

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 should:

- Undertake the EMM system training required to maintain the EMM system
- Understand the rationale for changes to the workflow of all professions in 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), to minimise the risk of introducing new medication errors, and maximise the efficiency and benefits of the EMM system to the pharmacy service
- Ensure that the health service organisation formulary in the EMM system and the pharmacy dispensing system is equivalent, if these two systems are not fully integrated
- Ensure that the health service organisation 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.

In addition, 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 determining the clinical decision support 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
- Support the transition to the EMM system, by becoming a super user or clinical champion, as well as supporting electronic medication reconciliation for prescribers as they make the complete transition to the EMM system
- Record clinical and supply information when reviewing medication orders to ensure that other clinical users have the information they need to manage the orders
- Be responsible for updating and maintaining the health service organisation formulary, standard order sets and decision-support rules required by the EMM system.

10 Principal EMM stakeholders and users

10.2.3 Nurses and midwives

Nurses and midwives must meet their regulatory obligations, defined in Part D.

Australian experience suggests that nurses and midwives using the EMM system should:

- Use the EMM system in line with EMM policies of the health service organisation
- Be trained in how to use the EMM system
- 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 record reasons for overdue, withheld, missed or rescheduled medicines
- Ensure that witnessing and checking specific medicines in the EMM system occurs in accordance with legislative and organisation policy requirements
- Manage medicine administration and recording as a single process, using a single device that can be accessed at the bedside, and record the administered medicine near the patient, preferably at the bedside or point of care – not, for example, in a medication storeroom
- Avoid transcribing medication orders from the bedside device onto scrap paper – for example, as a reminder to collect the medicine from a medication room; the patient's medication record should be accessed from the medication room so that transcription is not necessary.

In addition, 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
- Be involved in determining the clinical decision support to be used in the EMM system so that nursing workflow maximises medication safety
- Take advantage of the improved access to clinical decision-support tools (such as medication reference information and dosing calculators) at the time of medication administration, and incorporate these tools into nursing and midwifery workflow
- Record clinical notes about administering medicines in the EMM system to assist other clinicians in their medication management decisions (for example, 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 or actual issues or risks about 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
- Becoming familiar with the business continuity management plans and what to do if the EMM system fails
- Understanding the risks associated with multiple medication charts and abiding by the policies for the use of both electronic and paper medication charts, and understanding 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
- Reporting faulty equipment to the health service organisation department responsible for the maintenance of devices in a timely manner.

11 EMM project 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.

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. This section 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 overestimated if the required outcomes in a complex, multidisciplinary, whole-of-health service 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. There are 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 an EMM system. Project governance of an EMM system should reflect the size, complexity and cost of the project, including multidisciplinary representation from medical, nursing and pharmacy staff; consumer groups; and ICT to manage technical infrastructures.

A typical EMM system governance structure consists of four operating levels. First, 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.

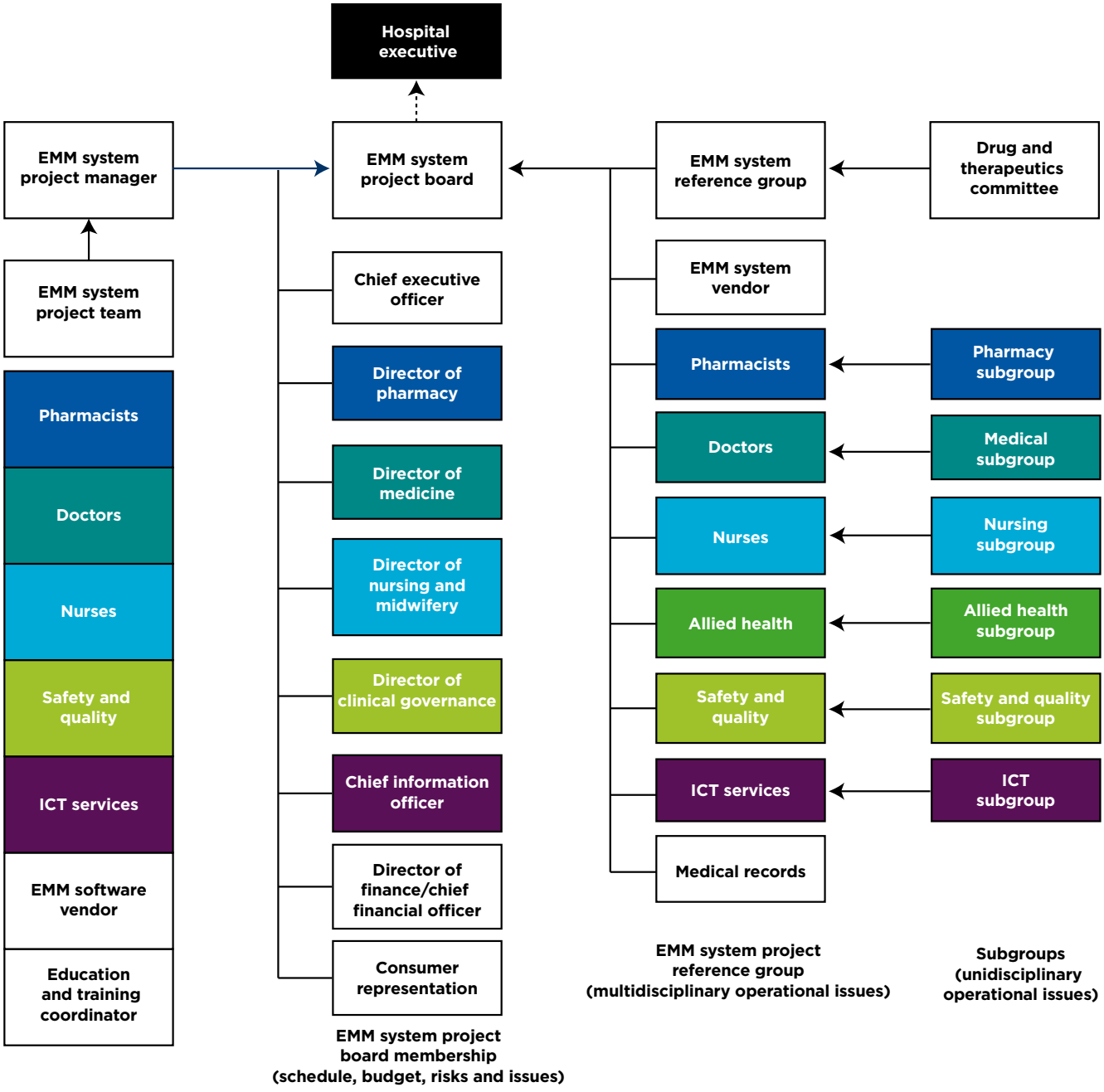
Second, the EMM system **project team** undertakes the day-to-day operations of the project and is responsible for carrying out the directions of the project manager. The project team, or members of it, should have an awareness of all aspects of the EMM system project.

Third, the EMM system **reference group** focuses on multidisciplinary aspects of the implementation. This group has responsibility for all operational aspects of the EMM system project. It 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.

Finally, **subgroups and working groups** tackle the specialty details. For example, the pharmacy subgroup focuses on establishing the health service organisation 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 medication policy and medication management processes in the EMM project.

A typical governance structure for an EMM system is shown in Figure 11.1. Smaller organisations might collapse this structure by combining the work of the reference group and the subgroups or working groups.

Figure 11.1 Typical governance structure for an EMM system



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

11 EMM project governance

11.1 Project sponsor

The project sponsor is the executive 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 although the director of pharmacy may seem like a good choice for project sponsor, this is not recommended. It is important that the EMM project is clearly communicated as a whole-of-health service project and not perceived as a pharmacy or ICT-driven project. Other candidates that should be considered are:

- The chief executive officer (CEO) – given the breadth, complexity and costs associated with EMM system implementation, the CEO would send a strong message to the organisation of the importance of EMM, and demonstrate top-level commitment to achieving a successful implementation
- The medical director, medical superintendent or director of medical services – a large resource and time cost in implementing an EMM system rests with junior medical staff in public health service organisations, so choosing a senior member of the medical staff as project sponsor should help engage and maintain medical staff support
- The director of safety and quality or director of clinical governance – EMM is a safety and quality initiative that could be led by the organisation's safety and quality unit, which provides 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 chief information officer, the senior medical staff, the director of pharmacy and the director of nursing and midwifery.

11.2 Project board

The project board should focus on overseeing the schedule for the EMM project, and, project tracking against the schedule to identify and manage: prescribers, pharmacists, nurses, finance, ICT services and consumers. The project board should focus on overseeing the EMM system project schedule, and project tracking against the schedule, to identify and manage:

- Critical milestones and time frames
- Project risks and related risk mitigation strategies
- 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. It should report through the health service organisation'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 the reference group.

11.3 Project manager

A strong emphasis on project management is required to implement the EMM system in an organisation to an agreed time frame and budget. Because of the project complexity, an experienced and appropriately resourced project manager role that reflects the EMM scope and complexity is essential. The project manager should be full time and should avoid any operational duties.

Selecting the right project manager is critical to perceptions of project ownership in the multidisciplinary stakeholder community. The project manager should be a specialist project manager, and an experienced and interested clinician such as a doctor, pharmacist, nurse or health informatics professional. It is necessary to consider 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 that all stakeholders in the multidisciplinary team

are engaged, and that their specific concerns and issues are addressed. The project manager should also ensure that the required ICT infrastructure is adequately considered, including the time needed for the associated infrastructure in EMM project plans.

11.4 Project team

The size and composition of the project team should reflect the size and scope of the organisation's services (see Box 11.1). The project team for a small independent health service organisation will be different from one implementing EMM in a chain of health service organisations, or across a state or territory. The project team needs to be multidisciplinary, and should include members from some or all 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
- EMM system software vendor.

Box 11.1 Project team resources

EMM project team members should commit full time to the project. However, in many implementations, EMM team members are part time and need to balance the EMM project work with the competing interests of their usual 'day jobs'. A successful EMM implementation is one where team members work full time on the project.

It is critical that the project team has multidisciplinary representation. As an incentive for staff to become involved, the health service organisation should provide quarantined time for work on EMM project activities. The organisation should consider full-time remunerated positions and include these in the project scoping and business case costing.

Where a junior medical staff representative is unable to participate as a project team member because of 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, most of the EMM project team members should be full time, be fully funded and have previous implementation experience. The use of part-time project team members should be discouraged, because their 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 done in the EMM project schedule. Individual discussions between project team members should also occur outside the project team meeting.

The focus of the project team meetings should be exception reporting (for project items that are not on track), critical path activities, and risks and issues.

Each member of the project team should provide 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 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 EMM project governance

11.5 Reference group and specialty subgroups

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

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

- The clinical users of the EMM system, such as medical staff, pharmacists, nurses and midwives, and allied health
- The health service organisation's safety and quality unit, to recognise the importance of monitoring and maintaining safe medication practice
- Health information teams, to ensure that patient administration system processes support the EMM system, and that EMM system outputs comply with organisation clinical documentation policies, and state and territory records management legislation
- ICT services, to establish appropriate mobile and desktop infrastructure, the central EMM system infrastructure and the required EMM system environments (for example, 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 organisation 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 health service organisation 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 health service organisation formulary developed by the pharmacy subgroup affects the medical staff's ability to prescribe
- Incorrect prescribing by medical staff will affect the pharmacy review process
- Discharge medicines identified by the pharmacists as requiring medical staff review are brought to the attention of the medical staff
- 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 should be given to the project management methodology, the project schedule, risk management and project reporting.

11.6.1 Role of the project management office

Some larger health service organisations may have a well-established project management office (PMO) that provides support and compliance monitoring for all projects. Where a PMO 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 provide 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; these include fixed and mobile devices, computers on wheels, wireless networks, and 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 (for example, results reporting, clinical information systems, electronic medical records).

The PMO has an independent and ongoing quality assurance role in the EMM system project. 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 organisation's preferred or mandated project management methodology
- The organisation'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 (for example, 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. Some health service organisations may have standardised a particular methodology. For example, projects in controlled environments (PRINCE2)* and project management body of knowledge (PMBOK) are widely used project management methodologies. 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 project management controls used in PRINCE2 would include:

- Project initiation document, project brief and project approach
- Project team structure (roles and responsibilities)
- Quality plans
- Project communication plans and plans for each stage of the EMM system implementation, such as
  - business case and procurement
  - EMM system build
  - lead EMM system implementation
  - evaluation
  - EMM rollout
  - post-implementation review
- Authorisation to proceed to next stage report
- End-stage report, exception reports and project closure report
- Lessons learned.

11.6.3 EMM project schedule

When putting together the EMM project schedule, health service organisation project teams may need to consider the time frames for:

- Establishing the project governance structure and assembling the project team, and business case development and funding approval
- Procurement, product selection and acquisition of the EMM system (see Section 14.3), and contract negotiation
- Project initiation, start-up and the implementation planning study
- Any customised software development required, including interfaces with health service organisation 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 (for example, wireless networks, bedside access to the EMM system via computers on wheels or other fixed or mobile devices, infrastructure that supports business continuity planning so the EMM system is available around the clock)
- Any other activities required during implementation planning (see Chapter 15), EMM system build and configuration (see Chapter 16), implementation and go-live (see Chapter 17).

It is important to recognise that the project schedule is primarily a communication tool that shows project activities, dependencies and time frames. It is the skill of the project manager, and the effectiveness of project governance, rather than the sophistication of the project schedule, that ensures a successful EMM implementation.

* www.prince2.com (accessed 7 April 2017)

11 EMM project governance

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 time frames 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', leadership and commitment from senior clinicians
- Insufficient planning:
  - financial – trying to implement electronic medication management (EMM) 'on the cheap'
  - technical – lack of sufficient devices at the point of care (for example, 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 multidisciplinary 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 involvement or funding resulting in inadequate technology infrastructure for clinicians' operational needs
- Inadequate or non-existent interfaces between the EMM system and third-party systems such as:
  - patient administration systems (for example, for patient identification)
  - diagnostic result systems (for example, for medicine to diagnostic result checking and medication-related diagnostic test ordering)
  - pharmacy dispensing systems (for example, to avoid transcription errors)
  - discharge summary systems (for example, for information transfer on discharge medicines)
- Insufficient business context planning in managing medication information at the boundaries of the EMM system, between different EMM systems and where clinical services operate paper medication charts
- 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 that are responsive to clinician feedback
- Insufficient resources for business-as-usual activities
- Lack of continuous quality improvement in maximising medication safety and optimising clinician workflow.

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 because of the additional time needed to prescribe using an EMM system
- Poor system performance, which affects uptake and use by clinicians
- Lack of integration between the EMM system and third-party clinical information systems, requiring workarounds
- A protracted implementation that fails to achieve the required critical mass in a reasonable time.

11.6.5 Project reporting

Project reporting depends on the organisation's overarching governance and on EMM project–specific governance. The following are examples of project reporting:

- 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 organisation'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 organisation 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, and circulate these reports before the regular project team meetings.

12 Organisational change management

Implementing an electronic medication management (EMM) system involves substantial organisational and transformational change, and changes to the way in which multidisciplinary teams operate. The failure of clinical information implementations overseas because of poor change management is well documented in the literature.[36,37] The experience of Australian EMM system implementations also shows that change management is critical. It should be appropriately resourced and communicated to ensure success. Box 12.1 provides more information.

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

- Assessing and segmenting stakeholders, and developing strategies to address their issues and concerns
- Developing targeted communication strategies rather than a 'one size fits all' approach; this reminds stakeholders of the rationale for implementing EMM, which is to improve the safety and quality of patient care
- Conducting change readiness assessments to monitor the responses of stakeholders and changes in the health service organisation culture as EMM is implemented (for example, changes in the understanding, and support for, safety and quality in the use of medicines)
- Identifying champions and change agents in the organisation.

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

Box 12.1 Change management

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

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

If professional change management support is not engaged, the electronic medication management team should at least consider employing a proven change management methodology. One example is 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.

12.1 Stakeholder assessment

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

Table 12.1 Example of a 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 to prescribe Active encouragement and support for EMM system use by junior medical staff and CMOs	Risk of EMM system not being used by senior medical staff which negatively influences junior medical staff and CMOs 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	Identify clinical champions to make the case with their peers	Director of medicine CEO EMM system vendor Project team

CEO = chief executive officer; CMO = career medical officer; EMM = electronic medication management

12 Organisational change 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 in the project. Questions that can help the project team understand their stakeholders are provided in Box 12.2.

Box 12.2 Questions for the project team to ask stakeholders

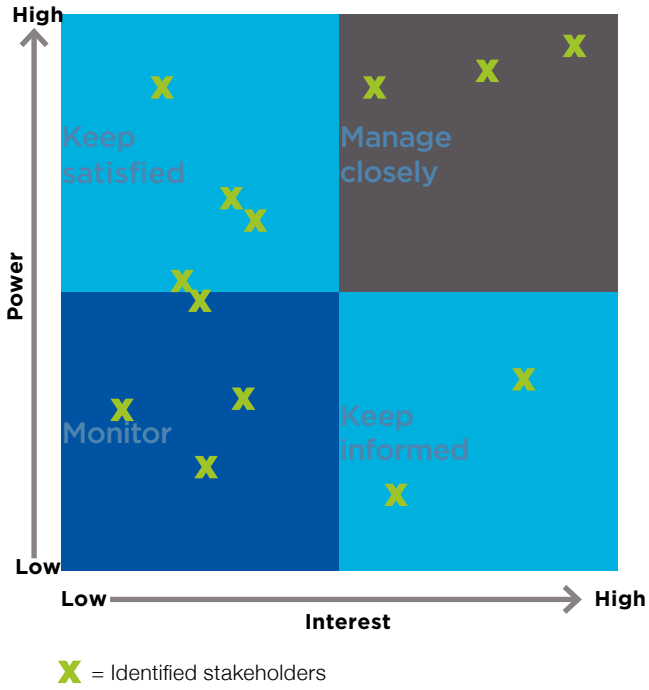
- What interest do stakeholders have in the outcome of the electronic medication management (EMM) system? Is it positive or negative?
- What do users expect from the EMM system?
- What motivates users and why?
- What information do users require from the project team?
- How do users want to receive information? What is the best way of communicating EMM project messages to them?
- What is the 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?

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

To answer the questions in Box 12.2, the project team should talk to EMM stakeholders directly. Asking stakeholders about 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 should be fully engaged, and the project team needs to make the greatest efforts to satisfy 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 that 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 an organisation's ability and willingness to change. This can be assessed in a variety of ways, but should focus on the questions in Box 12.3.

Box 12.3 Questions to assess change readiness

- Have stakeholders accepted the vision for electronic medication management (EMM)?
- How will it change the way in which the health service organisation generally, and medication management specifically, operate?
- Do stakeholders understand the need to change if EMM is to be successful? Do stakeholders feel compelled to support the implementation of an EMM system?
- Will stakeholders openly sponsor EMM?
- Are the organisation'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 for 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?

Change readiness assessments include assessment of organisational culture. For example, staff should be surveyed periodically as part of 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 better communication about EMM. This can take the form of 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 Organisational change management

12.4 Addressing stakeholder concerns

It is essential that stakeholder issues or concerns are addressed quickly. Concerns should be 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 moved up the EMM governance structures, as appropriate.

12.5 Identifying champions and change agents

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

Clinical champions should be able to 'sell' the benefits of EMM to their peers. There are two types of champion:

- Senior stakeholders that take up the leadership challenges associated with the implementation of the EMM system (for example, senior medical staff in early adopter clinical units or lead implementations) – these champions are role models for the EMM system implementation
- Ward-based champions who have undergone additional education and training, and are the first point of contact for ward staff during education, training and implementation of the EMM system.

A successful approach in some Australian EMM implementations has been the use of nurse educators as clinical champions, building on their continuing educational role. Some recent Australian EMM implementations have employed medical staff on their implementation teams, and regard this approach as critical to the success of their EMM implementations. Having pharmacist, nurse or midwife clinical champions who have an organisation-wide role is unlikely to provide sufficient leadership across the organisation. Medical staff champions are recommended for each clinical unit. This is because the Australian sites that have implemented EMM systems have 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

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 other medical staff to adopt the EMM system.

This buy-in was achieved by the senior medical champions communicating the benefits of the EMM system to other medical staff. This helped them understand the challenges associated with medical staff rostering and workload in scheduling medical staff training.

Part C
EMM implementation project

This part of the guide describes the implementation process, identifies five stages for electronic medication management (EMM) system implementation and details business continuity planning. It includes:

- Chapter 13, EMM system implementation process
- Chapter 14, Stage 1 – project initiation (including business case and EMM solution selection)
- Chapter 15, Stage 2 – implementation planning
- Chapter 16, Stage 3 – EMM system build and configuration
- Chapter 17, Stage 4 – implementation and go-live activities
- Chapter 18, Stage 5 – post-implementation review
- Chapter 19, Business continuity planning.

13 EMM system implementation process

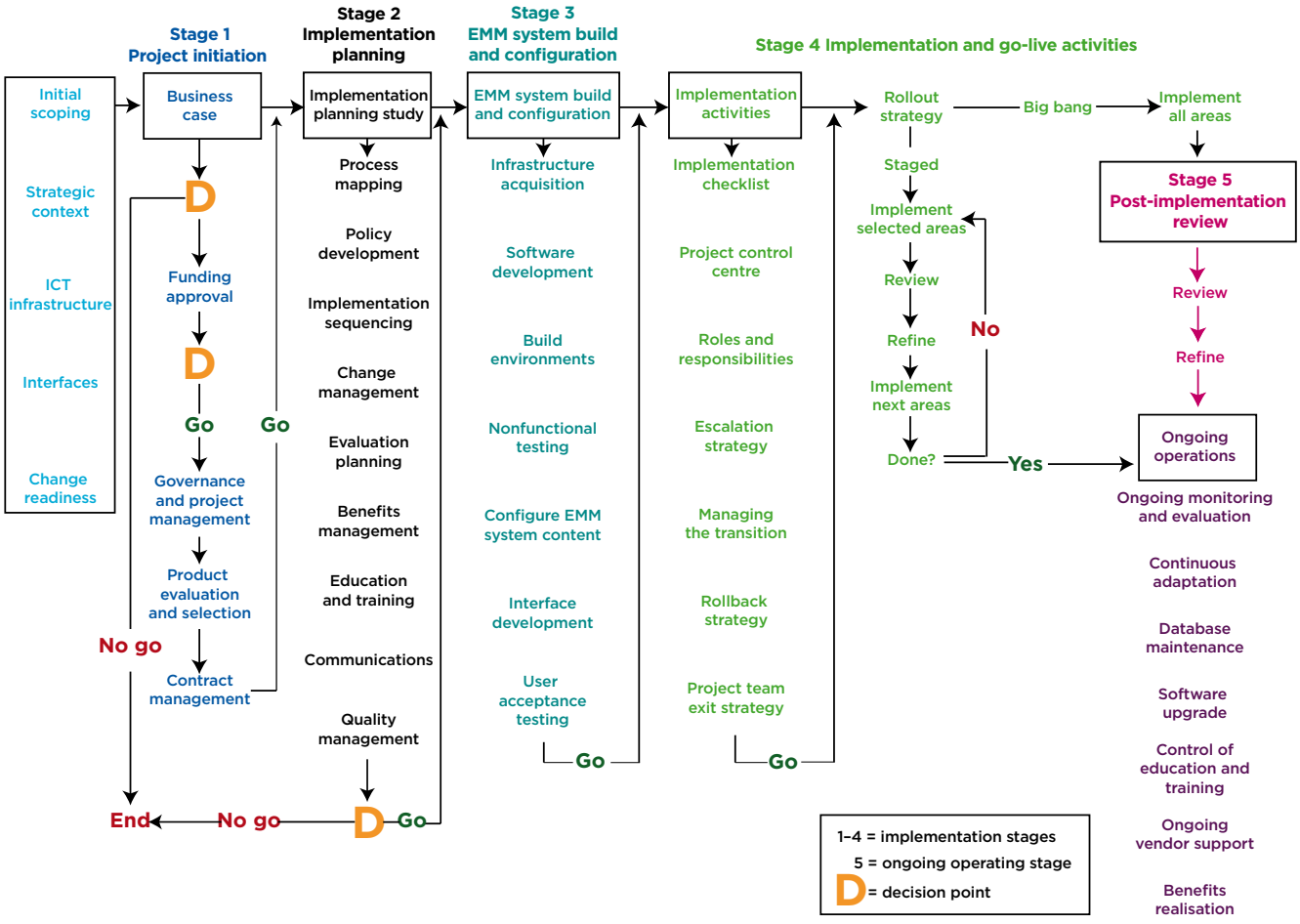
The electronic medication management (EMM) system implementation process consists of five stages:

- 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 13.1. Detailed guidance on each stage is provided in this section.

Although health service organisation 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.

Figure 13.1 Process flow for EMM system implementation



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

14 Stage 1 – project initiation

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

This chapter provides guidance on:

- The two-stage development of an EMM business case
- Funding approval
- Governance and project management
- Product evaluation and selection
- Contract management.

14.1 Developing the EMM business case

The chief executive officer (CEO) should 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 outlining project management requirements. The types of issues to be considered in the business case, a needs analysis and EMM system options are provided in Table 14.1.

Health service organisation project teams should consider adopting a two-stage approach to developing the EMM system business case[38]:

- 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
- 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. Because this infrastructure will also be used for other health service organisation applications, separate business cases for the EMM system and the ICT infrastructure should be considered. This means that the shared infrastructure costs will not distort the EMM system business case.

At the end of the first and second stages, a formal business case for EMM system implementation should be developed and submitted for approval. Some organisation project teams will use a standard business case template that contains guidance on the required content. Alternatively, templates are available online from government agencies.[39]

It is useful to request in-confidence access to EMM business cases developed by other health service organisations, and states and territories 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 who negotiated the EMM business case approval to understand the challenges they faced and use their experiences to inform your own business case content.

Table 14.1 Developing an EMM business case

Issue	Intent	First stage	Second stage
Needs analysis			
1. Prepare	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 first-stage 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 15.9) 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 gaps that need to 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 for improvements to ICT infrastructure, that could deliver an EMM system Make initial enquiries to industry for broad cost information (request for information) and prepare a shortlist of options	Focus on options selected in the first stage and draw on tender quality information from industry
7. Identify practical EMM system options	Articulate options in broad terms only (if at all)	Prepare a 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 the first stage 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

Table 14.1 Developing an EMM business case (continued)

Issue	Intent	First stage	Second stage
EMM system options			
9. Identify risks and mitigations	Discuss risks generally and subjectively, based on experience and site visits to other EMM sites	Conduct a brief, formal assessment of initial scope and technical design Prepare a risk management plan	Develop a detailed risk assessment and risk 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 an 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 communications technology; KPI = key performance indicator

14.1.1 First-stage business case

Because of the magnitude of the change required to safely implement an EMM system, the EMM team should first do an overview to ensure a thorough understanding of the requirements for EMM, including costs, time frames 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 in-house or commissioned from an external organisation. If an external organisation is used, senior stakeholders in the health service organisation should have strong ownership of the scope and content of the business case.

Specific elements to be considered in the first-stage business case include the:

- Case for change (that is, the rationale for implementing EMM), and the expected benefits from implementing an EMM system
- Medication components that are within the scope of the EMM implementation, including inpatient wards, general wards only, intensive care or high-dependency units, ambulatory and emergency
- Medication components that are not in scope and how they will be addressed
- Strategic context for the EMM system
- EMM information technology infrastructure needs of the health service organisation
- Functionality expected in 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 organisation executives) and the staff resources required to implement the EMM system (including clinicians, ICT services, project management and change management specialists)
- Requirements for education and training, ongoing EMM support (including maintaining and upgrading the EMM system), and legislative and policy requirements.

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

14.1.2 Second-stage business case

After executive approval or in-principle approval of the first-stage business case, the second-stage business case considers several elements:

1. State the case for medication safety strongly at the start of the business case, and substantiate the case for change with national and international evidence (be succinct and avoid repetition). If necessary, include a more detailed case for change as an appendix, so the audience is not overwhelmed with too much detail

2. Apply medication safety evidence to the health service organisation activity statistics to estimate adverse drug events (ADEs), readmission rates and likely deaths associated with medication errors. In other words, make medication safety directly relevant to the organisation. Also consider other benefits from implementing an EMM system, such as higher compliance with organisation medication protocols and downstream benefits based on expected workflows. For example, any additional time required to prescribe medicines on admission in intake wards can be offset by the time saved by not rewriting medication charts in receiving wards

3. Be sure to outline financial benefits in the business case. The case for change will focus on patient safety, and this correlates with efficiency gains that support greater throughput by avoiding ADEs and decreasing length of stay. Other financial benefits include improved prescribing practice and increased Pharmaceutical Benefits Scheme compliance and reimbursement. Refer to international literature and estimate potential cost reductions using the organisation's medication expenditure. Estimates and costs should be for the proposed life of the EMM system, which is typically seven years, or five years in some states and territories

4. Ensure ICT infrastructure costs are identified, costed and funded, including point-of-care and wireless devices, around-the-clock service, and business continuity planning. These elements can be included in 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.

Also include the following in the second-stage business case:

- A sensitivity analysis to understand the tipping points in the business case
- An explanation of how EMM can support new models of care, such as prescribing by other health professions
- Appropriate costings for all staffing resources 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.

14.2 Obtaining funding approval

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

A preliminary procurement strategy should be developed that sets out:

- Exactly what is being procured
- A procurement time line
- An analysis of the market's capability to meet the procurement objectives
- Options for engaging the market – these include consideration of the tendering approach or type of contract that may be offered, where a market approach has been identified
- The ability and capacity of 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.

14.3 Procurement and product evaluation and selection

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

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 health service organisation may be substantially influenced by the organisation's strategic business or ICT plans.

Understanding the range of functions in the available EMM options before commencing procurement will ensure that:

- Health service organisation project teams will 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
- The organisation's EMM specifications do not unintentionally preclude potential EMM solutions – consider the allocation of mandatory categories in EMM requirements to ensure that the procurement process is viable.

14.3.1 Project procurement plan

Before developing a detailed procurement plan, an appropriate governance structure should be in place to ensure that someone is accountable for any procurement decision. Appropriate steps should be taken to allow scrutiny of the process. Some organisations 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.

14.3.2 Procurement considerations

Before developing a request for tender (RFT), the health service organisation should clearly define the type of EMM system required. This includes the functional, technical and usability specifications, and the tender evaluation criteria.

Type of system

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

- A dedicated EMM system that is integrated or interfaced with other health service organisation systems (such as pathology and patient administration)
- A part of a broader clinical system that includes other functions such as orders and results reporting, and clinical documentation (these are usually called hospital electronic medical records, or EMRs).

The approach taken will be influenced by the organisation's ICT strategy and solution architecture. This is a critical decision for the organisation and a priority for the chief information officer (CIO) (see Section 10.1.5). Project teams embarking on an EMM system procurement process should first seek the advice of the CIO, and be very clear as to their preferred approach.

EMM business requirements

The time and resources required to develop detailed business requirements for the EMM system should not be underestimated. It should be informed by a multidisciplinary group of clinicians, ICT professionals, the drug and therapeutics committee, and the health service organisation executive. The EMM business requirements should be approved by the project team and project sponsor before being incorporated into the tender documentation (see Section 14.3.3). The requirements will then be used to evaluate tender responses for the EMM system.

The business requirements for the EMM system should include EMM software and the supporting hardware requirements, such as wireless networks, data servers and hardware devices. A set of business requirements for EMM systems is outlined in Chapter 9 and are available as an annex to the guide. The requirements are also available on the website of the Australian Commission on Safety and Quality in Health Care (the Commission).*

Specifying the acceptable usability (for example, minimum response times, visibility of medicines information, ease of access to common functions) of the EMM system is critical for a successful implementation. The usability specifications should not be restricted to the EMM software and required hardware that may be the subject of the tender. They should also consider the usability implications of dependent infrastructure, including the organisation's telecommunications network. This is a critical issue that the CIO and the CEO must ensure is addressed.

EMM software should be designed with inherent usability. Project teams evaluating EMM systems should consider good design principles and evaluate known usability issues.[2] The Commission has published *National Guidelines for On-Screen Display of Clinical Medicines Information*[6], and organisations should assess EMM systems against these standards. Mitigation strategies for usability issues are addressed in Section 15.1.

Tender evaluation plan

An evaluation plan should 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, which should include 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 and benefits management planning (see Chapter 15) can be used to support the tender evaluation plan for the EMM system.

Evaluation panel

The EMM system tender evaluation panel should be multidisciplinary and include the EMM project manager, an independent probity advisor and representatives of the following groups:

- EMM project team
- Pharmacists, such as the chair of the pharmacy subgroup
- Medical staff, such as the chair of the medical subgroup
- Nurses and midwives, such as the chair of the nursing and midwifery subgroup
- ICT services
- Safety and quality
- Finance and purchasing.

* www.safetyandquality.gov.au/medicationsafety

14.3.3 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 about the content of tender documentation. In the absence of other guidance, use the checklist in Box 14.1. The project manager should ensure that the tender documentation has been produced in line with local procurement policies and approved for release.

Box 14.1 Sample documentation checklist for the content of a tender

General conditions

- ☐ Invitation
- ☐ Enquiries by respondents
- ☐ Language and currency
- ☐ Affirmative action
- ☐ Inconsistencies
- ☐ Time frames
- ☐ Reporting
- ☐ Communications

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 participation
- ☐ Essential requirements
- ☐ Preferred respondent
- ☐ Submission evaluation criteria
- ☐ Evaluation method

Statement of requirement

- ☐ Introduction
- ☐ Background
- ☐ Context
- ☐ Objectives
- ☐ Requirements
- ☐ Essential requirements
- ☐ Optional requirements

14.3.4 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 for a potential vendor response 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. Carefully consider the allocation of mandatory categories in EMM requirements to ensure that the procurement process is viable.

Qualitative criteria

Compliant tenders should be evaluated against a set of weighted, qualitative 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 14.2 provides an example of a tender evaluation scoring approach.

Table 14.2 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 provided in Table 14.3. These example criteria reflect the view of attendees of the workshop held 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 14.3 Example weightings for tender evaluation criteria

Evaluation criteria	Weighting (%)	Range in weightings (%)
Demonstrated experience of implementing an EMM system in large and complex health service organisations	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, including pathology and diagnostic results, pharmacy, and 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 Australian Digital Health Agency standards	5	5–15
Other value-added elements in the tender proposal	2	0–2.5
Total score (out of 100%)	**100**	**n/a**

EMM = electronic medication management; n/a = not applicable

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
- 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. This will provide, as a minimum:

- Details of the tender and tender evaluation approach
- Details of the tenders received
- Relative ranking of the tenders
- Any outstanding issues
- Purchase recommendations for the preferred tender or tenders
- Rationale used to select the preferred EMM system supplier.

14.3.5 Product evaluation and selection

The health service organisation 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 15.5 on business process mapping and redesign, and Section 16.7.1 on developing test scripts and scenarios. The test scenarios should include:

- Processes that consider the entire medication management cycle, 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 multidisciplinary requirements of the EMM system and assess the overall usability of the EMM system
- Processes that demonstrate interoperability between the EMM system and other third-party systems.

A sample scenario is provided in Table 14.4.

Table 14.4 Examples of test script scenarios

Scenario	Action	Requirement identification no.*	Linked requirement
Jane Doe, date of birth 09/10/1956, female, presents to the ED 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	Not applicable	Not applicable
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 medicines on admission to the health service organisation, and demonstrate how some medicines are ceased and how some 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 name once selected	19	Only accepted Australian generic names of all medicines are to be used, as well as Australian units of measurement to indicate dosage Physicians and nurse practitioners should still be able to select a medicine 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 the 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 name of the medicine

Table 14.4 Examples of test script scenarios (continued)

Scenario	Action	Requirement identification no.*	Linked requirement
Jane indicates that she is allergic to penicillin. She had urticaria and wheezing after taking oral penicillin 20 years ago She is on a gluten-free diet because of concerns 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 details for allergies and ADRs: • Known • Medicine class or family • Reaction • Date • Recorded by • Nil known • Unknown Other requirements: • Perform reverse allergy checking • Code the allergy to belong to a whole family Medication record cannot be closed if allergy status is not completed, unless it is impossible to complete it (for example, unconscious, psychotic – this information should be collected as soon as practicable) The system should be able to receive information about the patient's known allergy status
	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: • Allergies, or none known • ADRs • Other relevant medication history, such as if the patient is on a medication clinical trial
	Point out where Jane's name, date of birth and gender appear on the screen	9	Display patient name, date of birth and gender on every screen view

Table 14.4 Examples of test script scenarios (continued)

Scenario	Action	Requirement identification no.*	Linked requirement
Jane is sent for an ultrasound, which confirms 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) Dr Edward Goode searches the medication reference database to check the half-life of heparin	Search an Australian medication reference database and locate information on the half-life of heparin	25	Australian medicine reference databases, searchable by generic and trade name, should be accessible from 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 medicines	20	Clinical decision support, such as alerts, should be available
		39	At the time of entry of a medication order, the system should alert the clinician to the following potential patient safety issues: • Known allergies and cross-allergies (additional alert if attempts are made to prescribe a medicine that the patient is allergic to) • Medication interactions – vendor to outline what medication interactions would be included as part of the proposed system, the evidence base for the alerts and the customisation available to reduce 'alert fatigue' At a minimum, drug-drug, drug-allergy and dose-range alerts are required

Table 14.4 Examples of test script scenarios (continued)

Scenario	Action	Requirement identification no.*	Linked requirement
		34	Allergies and ADR records for patient should be displayed with medication data. This should be 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 if they are prescribed a medication in the same or similar family/class as that medicine Current allergy details for a patient should be displayed on all patient-centric views
	Display an infusion chart	12	Create infusion or 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)	Demonstrate how a verbal order is recorded in 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 an electronic signature. Verbal orders to a pharmacist do not require a second witness

Table 14.4 Examples of test script scenarios (continued)

Scenario	Action	Requirement identification no.*	Linked requirement
	Display a medication list that includes the following medicines and includes as many of the dosage details as possible and indicates the current status of the order: • Atenolol 50 mg PO daily • Atorvastatin 80 mg PO nocte • Gentamicin 5 mg/kg IV daily – for example, 480 mg IV daily (dose amount and interval may change depending on levels and renal function) • Metoclopramide 10–20 mg PO/IV/IM tds • Warfarin 5 mg PO daily. Dose dependent on INR results	27	• Assist clinicians by providing easy access to basic medication lists
The opportunity arises for Jane to participate in a clinical trial for a medicine to treat deep vein thrombosis. She is switched from heparin and warfarin to the new drug, SR1234A; however, the new medicine is not in the EMM system's medication list	Show how the system accommodates medicines that are not listed in the database, and how new medicines are added. Prescribe SR1234A	52	The system should accommodate medicines that are not listed in the database, such as trial medicines
New drug SR1234A	Show how the system alerts nurses to the need to protect the new medicine (SR1234A) from light before and during administration	63	Nursing administration prompts or alerts, such as the need to protect from light, or where a non-PVC giving set is required Administrator should be able to control the level of administration and prescribing alerts to avoid excessive alerts and alert fatigue
	View and show print preview of Jane's medication chart	11	Create medication chart or medication view that can be printed. Should be compatible with a legal prescription format, such as PBS prescriptions

Table 14.4 Examples of test script scenarios (continued)

Scenario	Action	Requirement identification no.*	Linked requirement
Jane responds well to the new treatment and is ready to go home	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	18	Create a discharge prescription view for each patient that contains the following as an example: • Subset of patient demographic details • Admitting doctor • 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 and time of completion The discharge prescription should 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; EMM = electronic medication management; IM = intramuscular; IV = intravenous; kg = kilogram; mane = in the morning; mg = milligram; nocte = at night; PBS = Pharmaceutical Benefits Scheme; PO = oral; PVC = polyvinyl chloride; tds = three times daily

* Relates to the tender specifications

Source: Adapted with kind permission from ACT Health

14 Stage 1 – project initiation

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 organisation formulary
  - configure workflow in relation to pharmacy review
  - create to-do lists and reminders
  - understand interactions of the EMM system with any third-party dispensing and stock-control systems
  - understand the utility and constraints of mobile and small screen devices
- 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
  - generate discharge summaries (where integrated with the EMM system)
  - understand the utility and constraints of mobile and small screen devices
- Nurses and midwives need to
  - administer medicines
  - order nurse-initiated medicines
  - countersign for controlled medicines or complex variable-dose medicines
  - undertake telephone orders
  - understand the utility and constraints of mobile and small screen devices.

Many EMM systems were developed overseas and do not contain Australian medication information. There are often significant differences between the names of medicines overseas and their Australian equivalents. Extensive EMM system customisation and quality assurance may be required to develop Australian content for medication catalogues and 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 this reason, any system should be extensively tested by users to ensure that the proposed solution supports clinician workflow before the final product is selected and the vendor is engaged. Particular attention should be given to the workflow support available for highly repetitive or frequently used EMM functions, such as prescribing and administration.

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

If deficiencies are identified in the proposed EMM solution, they should be flagged as needing improvement and incorporated in the EMM contract. It is better to identify these issues as part of the EMM product selection, rather than find that the EMM product is a poor fit later. Late detection results in clinician push back, and expensive and time-consuming software improvements and reimplementation later.

14.4 Contract management

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

14.4.1 Contract management plan

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

- A brief description of the goods or services being provided
- Contact details of personnel associated with the contract
- A list of documents associated with the contract and their location
- Transitional arrangements, communications channels, performance evaluation measures and reporting requirements
- Identification of risks associated with the contract and risk mitigation activities
- Contract operation details, including
  - conflict and dispute resolution process
  - a list of contract milestones, 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
- The contract review process.

14.4.2 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. This includes the early identification and resolution of contractual issues.

14.4.3 Monitoring vendor performance

The project manager should regularly monitor the performance of the contractor to manage risk, manage problems and ensure that agreed outcomes are delivered. Vendor performance monitoring should occur during the contract implementation and at regular intervals throughout the life of the contract. Regular contact with the vendor will help their local knowledge of the hospital, which should benefit the operation of the EMM system.

Knowledge gained during the procurement process should be used by the project manager to evaluate the process and ascertain whether stakeholder needs and expectations have been fulfilled. This should ensure that:

- Value for money has been achieved
- Procurement outcomes match or exceed the original objectives
- Vendor performance is satisfactory, as measured against contracted evaluation measures
- Significant lessons learned are captured and disseminated.

* Government procurers will also need to consider the SourceIT Model Contracts and SourceIT Plus.

15 Stage 2 – implementation planning

This chapter outlines what needs to be considered in electronic medication management (EMM) implementation planning.

15.1 Learning the lessons of Australian implementations

It is essential that health service organisations consider the lessons of Australian EMM implementations before determining the scope and detailed implementation plans for their own EMM implementation.

This guide distils experience from Australian EMM implementations, but does not replace the need to visit other similar EMM sites. Other sites may include sites with paediatrics, sites with integrated or standalone intensive care unit (ICU) systems, or sites with standalone or integrated EMM implementations. Boxes 15.1 and 15.2 provide checklists of elements to consider and learn from.

Box 15.1 Australian EMM implementation – lessons learned

Hospitals that are considering implementing electronic medication management (EMM) should take into account the following:

- ☐ The implemented medication scope, including how medicines are managed at the boundaries of the EMM implementation
- ☐ The extent to which interoperability has been achieved, and how any lack of interoperability is managed
- ☐ The hardware and infrastructure requirements needed to support the EMM system
- ☐ The rationale for the clinical decision-support configuration
- ☐ Implementation sequencing and overall project time lines
- ☐ Project governance, project and risk management, and project team composition
- ☐ Clinician engagement strategies, including what worked well and not so well
- ☐ Workflow support and the need for workarounds
- ☐ Business continuity planning
- ☐ With the benefit of hindsight, what the EMM site would do differently
- ☐ Vendor experience, including capacity, capability, resourcing and relationship
- ☐ Ongoing or unresolved EMM system or technical issues
- ☐ Resourcing for ongoing quality improvement and innovation
- ☐ Use of medication data for continuous improvement
- ☐ Next steps and future plans.

Box 15.1 Australian EMM implementation – lessons learned (continued)

In addition, Australian hospitals that have already implemented an EMM system have provided the following suggestions:

- ☐ Obtain a list of known issues from the EMM vendor in advance of starting EMM configuration
- ☐ Complete project team job descriptions well in advance, because they may take time to be approved in public hospitals
- ☐ Consider the possibility of seconding team members who have already implemented EMM
- ☐ Consider implementing other clinical components before EMM so clinicians are already using electronic systems in their work, such as
  - diagnostic orders and results, and discharge summaries
  - nursing documentation
  - emergency department capabilities
- ☐ Ensure that the project team fully understands the EMM design features and capabilities before starting; governance should fully understand the EMM system early in the implementation to transfer this knowledge to the project team
- ☐ Demonstrate the EMM system and its decision-support capabilities to clinicians to promote clinician engagement
- ☐ Perform pilot implementations, so the EMM system is more real for clinicians and organisation executives
- ☐ Use EMM 'dress rehearsals' or walk-throughs with clinicians in clinical units, to improve their and the project team's understanding of what to expect when the system goes live
- ☐ Ensure that sufficient time is taken to learn the lessons from the initial implementation before implementing at subsequent sites, if the organisation is using sequenced implementation
- ☐ Ensure that workflow decisions are multidisciplinary to reduce the need for configuration re-work, system complexity and resulting implementation delays, which can decrease clinician confidence in the EMM system
- ☐ Consider an incremental implementation approach because of prescriber concerns about potential loss of decision-making autonomy – this allows the more constraining EMM features to be implemented after clinicians become comfortable with the initial EMM functionality
- ☐ Schedule time for EMM optimisation after go-live, particularly if the initial implementation time frames were constrained
- ☐ Recognise that the change management work really begins after go-live.

15 Stage 2 – implementation planning

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 should 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 a prevention strategy, 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 15.1.

Table 15.1 Potential pitfalls and prevention strategies

Potential pitfall	Prevention strategies
Electronic prescribing takes longer	Emphasise the safety benefits and reiterate the evidence identified in the case for change Emphasise the downstream benefits to the clinical team, including time saved by not rewriting the medication chart Emphasise time saved in discharge prescribing and reconciliation with the discharge summary Note that studies and experience suggest that the time required will reduce with experience Appreciate that good design and streamlined access are required for all prescribers, but may be particularly challenging for visiting medical officers in private health service organisations who visit less frequently
Missed medication doses	Ensure the EMM system supports workflow Ensure appropriate point-of-care access at the bedside and medication stores, and actively discourage transcribing of medicines through medication policy, education and training Ensure that users of the system are readily able to identify the current status of the medicine order, irrespective of the on-screen information chosen to be displayed by the user
Wrong medicine prescribed	Ensure EMM system design includes: • Specialty or clinician pick-lists based on frequency of prescribing habits • Use of Tall Man lettering for medicines • Guidance from the *National Guidelines for On-Screen Display of Clinical Medicines Information* Consider additional validation requirements for prescribing certain medicines Consider grouping medicines to limit the possibility of mis-selection
Alert fatigue resulting in important medication interactions being overlooked	Carefully manage the introduction of alerts and ensure that they reflect the priorities of the drug and therapeutics committee 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)
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

EMM = electronic medication management

15.2 Considering the literature

To support the guide, the Australian Commission on Safety and Quality in Health Care (the Commission) engaged the Australian Institute of Health Innovation to undertake a literature scan.[2] Table 15.2 identifies the reported success factors in implementing EMM or e-health record systems. It also cites the number of research papers that referenced each success factor; where the success factors of both the empirical studies and the opinion pieces identified by the literature scan have been combined.

Table 15.2 Success factors for EMM and e-health record systems

Success factor	Number of papers cited
System usability, design and functionality	41
Planning and resources	32
Training and technical support	27
Governance	26
Leadership and support	21
Staff culture and acceptance	11
Vendor issues	9
Standardisation	7
Communications	7
Evaluation	2
Health facility size	2

These findings are consistent with the experience of Australian EMM sites.

One success factor not considered in earlier editions of the guide is system usability, design and functionality. Table 15.3 summarises these usability, design and functionality issues, and strategies to be considered by EMM sites in reducing their effects.

Table 15.3 Mitigation strategies for usability, design and functionality issues

Usability, design and functionality issue	Mitigation strategies
Reported poor utility of systems, including: • Slow response times • Constant need to log in • Time required for prescribing medicines and completing associated documentation	Adequate funding in the EMM business case to ensure infrastructure capacity to deliver appropriate response times Remote access for prescriber out-of-hours use Single login and identity management (for clinicians, locum clinicians and students) Optimised and preconfigured order sentences and clinical pathways that reflect common clinical scenarios Where possible, use vertical scrolling and do not allow any part of the prescription to scroll horizontally off-screen Enhanced support for medication reconciliation on admission, reducing any perceived prescriber time impost on admission Project communication material that demonstrates the advantages of electronic documentation (legibility, auditability, re-use of data) and the time neutrality of using EMM systems[40]
The use of workarounds to overcome limitations of system functionality or usability. Users in several studies were observed to adopt various workarounds, including: • Delaying entering patient information • Relying on other staff to update the system on their behalf • Copying and pasting information • Using other systems (e.g. Microsoft Word) to store text temporarily • Failing to complete or update information • Entering information into the wrong place in the system • Users accessing the system logged in as a different user or by leaving identity authentication cards in the computer terminal to avoid the login process	Reduce workarounds by ensuring well-designed workflows (refer to Table 15.4) Pre-empt the workarounds in EMM configuration, education and training Emphasise the importance of personal accountability and responsibility for use of systems Educate about the importance of non-repudiation and the legal status of e-health records, reinforced through policy and compliance Use education materials, quick reference cards and screen prompts where known workarounds are occurring. For example, emphasise the clinical risk of copying and pasting text to the wrong patient records. Australian EMM sites have reported the use of copying and pasting medicines on admission to progress notes where they are re-used for discharge summaries – this practice should be discouraged Identify opportunities for the EMM system to produce work lists or reports of incomplete records, and regularly review mandatory data items through information governance Minimise, wherever possible, the ways in which the same medication information can be recorded, standardising how EMM systems are used. The integrity and re-usability of medication information in the EMM system should be validated with the EMM solution provider to ensure that medication information is used consistently by the EMM system Provide ongoing education and training to raise awareness of how to use the EMM system properly, in line with policy, as part of continuous quality improvement, including the targeting of noncomplying users for one-on-one refresher training

Table 15.3 Mitigation strategies for usability, design and functionality issues (continued)

Usability, design and functionality issue	Mitigation strategies
Appropriate hardware (e.g. remote access), hardware availability for all end users and interoperability with other systems were identified as critical factors in case studies. A system that offers a high level of interoperability with existing information systems was seen to be more likely to be successful	Adequate funding is required in the EMM business case to ensure high-availability infrastructure, disaster recovery, networking redundancy, wireless capability, and sufficient mobile and fixed devices to support optimised clinician workflow; these issues are considered in Section 10.1.5 Interoperability is increasing in Australian EMM sites for EMM and dispensing systems. Currently, there are no interfaces between different EMM systems. This issue is considered in detail in Section 8
The creation of additional or different workflows for clinicians. Poor system design, including inconsistent interface design, was considered disruptive to clinical workflow	Clearly define EMM requirements, including clinical workflow capabilities, and evaluate solutions during EMM procurement – before committing to an EMM solution Understand current-state processes, and what does not work well and needs fixing before implementing electronic systems Validate goal-state electronic clinical processes with multidisciplinary clinical teams before configuring solutions, and test thoroughly to ensure fitness for purpose, including resolution of any known issues with the current-state processes Develop start–stop–continue charts for major clinical processes to support education, training and change management Work with solution providers to maximise the opportunity for genuine workflow solutions (e.g. review queues or clinical activity task lists, integrated dashboards, clinical communication tools, well-structured clinical documentation supported by drill down and filtering)
Computerised alerts were identified as a common cause of workflow disruption. The dangers of alert fatigue were mentioned in several commentaries and case studies. The solution was to provide only limited decision support, with careful introduction initially to avoid user frustration	The problem of alert fatigue – a negative emotion of clinicians using EMM systems – has led to many Australian sites limiting the decision-support rules that are triggered currently Section 22.2 identifies ways in which EMM sites can encourage their EMM providers to improve their products to better support medication safety. However, improvements in the sophistication of alerting and reduction in alert fatigue will require vendor commitment and collaboration, and are likely to remain a longer-term goal. It is important that the drug and therapeutics committee is involved in developing the EMM decision-support strategy, including managing user expectations about the availability of intelligent alerting in EMM systems (based on predisposing patient risk factors to reduce the volume of clinically insignificant alerts)
The use of order sets and templates was seen to reduce the time of ordering and errors associated with system use	Most Australian EMM sites use order sets when ordering medicines Additional order sentence capabilities could include: • Separate formularies and order sentences for adult and paediatric cohorts • Constraining medicine orders to valid and appropriate forms, routes, frequencies, strengths or doses • Linking orders for medicines and non-medicines that are aligned to clinical pathways

15 Stage 2 – implementation planning

System usability, design and functionality are major issues associated with the unintended adverse consequences of EMM or electronic medical record systems.[41] Table 15.4 summarises these unintended adverse consequences, and strategies that might be considered by EMM sites in reducing the effects of these issues.

Table 15.4 Mitigation strategies for unintended adverse consequences of implementing e-health records

Unintended adverse consequence	Mitigation strategies
E-health records often create new work for clinical and non-clinical staff, which is most prominent at the point of care (e.g. alerts, required data entry fields, details of complex orders)	Maximise the scope of the e-health records or EMM implementation to ensure 'value adding' use of IT support for clinicians Be clear about the boundaries of the implementation and what clinicians will need to do to manage medication safety at these boundaries Define expected clinician benefits and use the expected benefits to drive the implementation priorities. Computer systems will require changes to clinical workflow, including additional tasks, but overall should be time neutral Communicate what can reasonably be expected, what will take longer and what will take less time, citing other EMM sites and the Australian literature[40] Ensure sufficient clinician review and break-testing solutions by clinicians outside the project team before they are signed off for wider implementation use Encourage solution providers to re-use existing data held in systems, and bring together and contextualise data-supporting workflow. This includes bringing together relevant diagnostic results when administering certain medicines – for example, blood glucose levels for insulin, INRs for warfarin
Unfavourable workflow issues. E-health records often highlight mismatches between intended and actual work processes in the clinical setting by adding to previously defined ineffective or dysfunctional workflows	Workflow is a term frequently used, but rarely defined. Be specific in defining EMM procurement requirements, and thoroughly understand the solution provider's workflow capabilities before committing to an EMM solution Understand current-state processes and what does not work well and needs fixing, and get agreement on the new way of working before it is configured in the EMM system Validate goal-state electronic clinical processes with multidisciplinary clinical teams before configuring solutions, and test thoroughly to ensure fitness for purpose, including resolution of known issues with the current state Develop start–stop–continue charts for major clinical processes to support education, training and change management Work with solution providers to maximise the opportunity for genuine workflow solutions. This includes review queues or clinical activity lists, integrated dashboards, clinical communication tools and well-structured clinical documentation supported by drill down and filtering

Table 15.4 Mitigation strategies for unintended adverse consequences of implementing e-health records (continued)

Unintended adverse consequence	Mitigation strategies
Frequent demands for system changes. As e-health record use increases, it becomes increasingly difficult to standardise, update, test and maintain the hardware infrastructure, application software and clinical content	Recognise the cost of ongoing business-as-usual activities in the business case Ensure that ongoing operational governance and information governance are in place to manage changes after the system goes live and continuous quality improvement Focus EMM change effort on organisational priorities and communicate them well; do not get overwhelmed by the data tsunami
Paper continues to be used as a temporary, portable, disposable, data input and output medium	Try to limit the use of mixed electronic and paper processes that disrupt efficient clinical workflow Budget for interoperability between third-party systems that will limit the need for data transcription. For example, interoperability between the e-health record and EMM, between EMM and the dispensing systems, and between EMM systems and, for example, ICU or AMS
Using e-health records often replaces synchronous, interpersonal conversations about provision of care with asynchronous computer-mediated messaging, often leading to an 'illusion of communication'	Work with solution providers to maximise the opportunity for genuine workflow solutions The business requirements in Section 9 include workflow requirements such as communication between prescribers, pharmacists, nurses and midwives
Specific e-health record features, functions or series of events that result in users succeeding or failing to reach their goal(s) can trigger emotions that affect their ability to do complex physical and cognitive tasks	The problem of alert fatigue – a negative emotion of clinicians using EMM systems – has led to many Australian sites limiting the decision-support rules that are being triggered currently Section 22.2 identifies ways in which EMM sites can encourage their EMM solution providers to enhance their solutions to better support medication safety. However, improvements in alerting and reduction in alert fatigue will require vendor commitment and collaboration, and are likely to remain a longer-term goal. It is important that the drug and therapeutics committee is involved in developing the EMM decision-support strategy, including managing user expectations about the availability of intelligent alerting (based on predisposing patient risk factors to reduce the volume of clinically insignificant alerts) Section 15.2 identifies a range of usability, design and functionality issues from the literature that could be considered by sites, in conjunction with their EMM solution provider, to reduce the negative emotions of clinicians

Table 15.4 Mitigation strategies for unintended adverse consequences of implementing e-health records (continued)

Unintended adverse consequence	Mitigation strategies
New kinds of errors can result from, for example, problematic data presentations, confusing order options, reduced visibility of medicines information, inappropriate text entries, misunderstandings related to testing and training, production versions of the system, and workflow process mismatches	This adverse consequence is consistent with the findings from the Commission's literature scan.[2] Opportunities to reduce the introduction of new kinds of errors include: • Avoiding long-hand prescribing and using preconfigured order sentences • Constraining medicine orders to valid forms, routes, frequencies, strengths or doses • Using separate paediatric and adult formularies and order sentences where children are treated in adult settings • Using comprehensive supporting medication reconciliation, including across settings and where medication reconciliation occurs after medicines have been prescribed following admission • Incorporating *National Guidelines for On-Screen Display of Clinical Medicines Information* • Displaying relevant clinical parameters when prescribing and administering medicines • Re-using existing data to avoid transcription errors • Having interoperability between EMM solutions that avoids transcription errors at the boundaries of EMM systems Encourage the EMM solution provider to collaborate with their third-party knowledge-base providers in using predisposing patient risk factors to reduce the volume of clinically insignificant alerts, potentially reducing alert fatigue
Clinicians experience a loss of power or professional autonomy when e-health records prevent them from ordering the types of tests or medicines they prefer, or force them to comply with clinical guidelines they may not embrace, or limit their narrative flexibility through structured data entry	Non-compliance with medicines management policies is commonplace in the paper environment where they are difficult to monitor and review. Visibility of medicines management policies and compliance with them are both important issues for all hospital organisations to address – irrespective of their EMM status The agreement and use of clinical guidelines before the implementation of EMM could help disassociate these feelings from use of an EMM system. For example, by embedding important medicines compliance programs such as medication reconciliation and AMS protocols and approvals in the medication management workflow before implementing the EMM system Appointing well-regarded senior clinical staff as EMM sponsors and clinical champions to help sell a positive, clinically sponsored EMM message Acknowledge up-front that these feelings are likely to be experienced, and encourage multidisciplinary clinical discussion before the implementation of EMM Use local data to demonstrate increased medication safety arising from the changes Ensure an appropriate balance between the use of structured data and free text data. Where free text data are available, they should not be constrained so as to render the clinical communication less meaningful

Table 15.4 Mitigation strategies for unintended adverse consequences of implementing e-health records (continued)

Unintended adverse consequence	Mitigation strategies
Healthcare organisations are becoming increasingly dependent on their e-health records for many aspects of clinical care delivery. When the system is unavailable, chaos may ensue	Ensure that business continuity plans are well designed, implemented and tested Following each unplanned service interruption, review and refine the BCP process Section 19 considers BCP in more detail, including the various BCP scenarios adopted by EMM sites

AMS = antimicrobial stewardship; BCP = business continuity planning; EMM = electronic medication management; ICU = intensive care unit; INR = international normalised ratio; IT = information technology

Citing Australian research has been found to strengthen the case for change in implementing EMM in Australian health service organisations. Local research is perceived as being more relevant by some stakeholders.

15.3 Implementation planning study

The implantation planning study (IPS) should be a joint effort that reflects the EMM system vendor's implementation approach and responsibility to deliver the system, as well as the organisation's implementation tasks. In developing the IPS, the vendor should demonstrate a thorough understanding of the organisation's environment. The EMM project team should become 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.

Because of the complexity of implementing EMM systems, some Australian implementation sites suggested engaging a specialist systems integrator to manage the technical and interfacing aspects of implementing the EMM system. If engaging the EMM system vendor to undertake the IPS is too costly, this work may be done in-house. An IPS checklist is provided in Box 15.2.

15 Stage 2 – implementation planning

Box 15.2 Implementation planning study checklist

Typically, an implementation planning study comprises:

- ☐ The scope of the electronic medication management (EMM) implementation, including specifying which areas of the health service organisation EMM will be implemented in
- ☐ 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 health service organisation
- ☐ 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 – this includes production, testing, training and development environments, and an environment management plan
- ☐ Capacity requirements, including number of users, user concurrency and 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 illustrates and describes the relationships between EMM systems and other systems
- ☐ The business context that 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.

Box 15.2 Implementation planning study checklist (continued)

- ☐ EMM system acceptance criteria
- ☐ A traceability framework
- ☐ EMM system education, and a user training strategy and plan
- ☐ A data migration strategy and plan, if required
- ☐ A testing strategy and plan, including
  - user acceptance testing
  - non-functional testing
  - interface testing
  - integration or 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.

15 Stage 2 – implementation planning

15.4 Implementation scope

Chapter 6 outlines the strategic and medication scope of EMM. The medication context is repeated here for convenience.

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

- General wards
- Emergency department (ED), and ICUs or high-dependency units
- Specialist areas such as chemotherapy and renal dialysis
- Ambulatory and day procedure units
- Rehabilitation
- Mental health
- Operating theatres and diagnostic imaging
- Community services.

Before implementing an EMM system, the EMM governance and project teams should consider each aspect of medication management in the health service organisation. The team should also consider how to maintain the medication continuum to ensure patient safety as patients move between different areas of the organisation. This should include an end-to-end medication 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 a streamlined and integrated workflow across the organisation.

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. It should identify how the 'gap' in the medication continuum will be addressed to ensure medication safety. Examples of how to manage the gaps are provided in Section 6.2.

The scope of medicines management implemented at Australian EMM sites varies considerably.

No EMM site has implemented all aspects of its medicines management requirements. One EMM site has implemented EMM for almost all aspects of medicines management, including complex infusions, and ICU and anaesthetic medicines. The exception was for day case chemotherapy, where paper protocol-based charts are externally generated by visiting medical officers and used to administer chemotherapy at the facility. Most EMM sites have yet to implement complex infusions, ICU and anaesthetic medicines in their EMM system, although some non-intravenous ICU medicines are included in the scope of some EMM systems.

Many EMM sites operate separate ICU systems that include medication management in addition to the EMM system. No EMM site has yet attempted interoperability between the EMM and ICU systems.

Many EMM sites operate separate chemotherapy systems in addition to the EMM system. However, no EMM site has attempted interoperability between the EMM and chemotherapy systems.

Many EMM sites operate separate antimicrobial stewardship (AMS) systems, although some are now integrating these with their EMM systems. Some EMM sites use the native AMS capabilities of their EMM systems.

Only one EMM site operates closed-loop medication management, where the patient's wristband is scanned, along with each dose of medicine administered.

Health service organisations are increasingly implementing medication automation. This can include dispensing robots (whole-pack robots and unit-dose robots), automated dispensing cabinets, anaesthetic dispensing carts and medication safes. At the time of writing, no organisation with these technologies had implemented EMM.

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

15.5 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.

EMM system vendors typically offer a methodology for process mapping. They can facilitate goal-state process mapping sessions and advise on the options available in the EMM system software. Process mapping will raise many issues that will need to be considered through multidisciplinary input using 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 multidisciplinary 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, understanding 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 project teams substantially reworked their EMM implementation approach because the original solution failed to sufficiently address workflow.

15.5.1 Current-state process maps

For current-state process maps, the project team should identify the required data sources. These include episodic datasets, medication charts, formularies, pick-lists, and current risk and incident reporting. In addition, data sources need to be standardised, especially where multiple health service organisations will be sharing a common EMM system build.

The project team should develop a complete set of process maps that document the current end-to-end processes, and the interactions between prescribing, medication review, and dispensing and administering medicines. These include:

- Recording of medicines on admission and patients' medication history, including recording allergies and adverse drug reactions
- Prescribing of new medication orders, and prescriber review of medication orders (for example, every seven days), as well as clinician processes for editing and correcting medicine orders, and for documenting clinical notes
- Requirements of complex, high-risk and variable-dose medicines (such as warfarin), and of specialised medicines (such as for patients who are in palliative care, undergoing chemotherapy or experiencing acute pain)
- Supply of imprest medicines and medicines from pharmacy, as well as pharmacy review of medicine orders
- Administration of medicines, including variations (such as patch on – patch off, fasting, future dose withholding), and of Schedule 8 medicines
- Mechanisms for reporting medication-related errors
- Processes for clinical decision support, medication reference information, and inpatient and ambulatory care medication management
- Discharge medicines prescribing, review and supply; and reconciliation and management of patient medication information recorded in the discharge summary.

The project team should validate the process maps with clinicians through multidisciplinary validation sessions. For each process map, document the issues and risks, and ensure that these are addressed in the goal-state process mapping.

15.5.2 Goal-state process maps

The development of goal-state process maps should involve the selected EMM system vendor, because the choice of EMM system software may influence the process redesign. The goal-state EMM processes should incorporate new or modified processes, arising 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.

15 Stage 2 – implementation planning

Once the preferred EMM system vendor has been selected, consider:

- Visiting other organisations that have implemented the selected EMM system to understand how it was done
- Referring to current-state process maps to identify potential improvements to current processes
- Identifying how all aspects of the current-state process maps translate to one or more goal-state process maps
- Identifying where it may not be possible to directly map current-state processes to goal-state maps, and outline potential risks, alternative processes or workarounds
- Liaising with the selected EMM system vendor to develop the goal-state process maps so that the process maps relate to how the selected EMM system will be implemented
- Testing acceptance of the goal-state process maps with clinicians, including through multidisciplinary validation sessions
- Using the process maps to inform improvements to current-process and EMM system project communications, and education and training materials.

For each goal-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. Start–stop–continue charts are widely available in the public domain, and an example is included in the EMM implementation plan on the Commission website.

The next section includes a real-life scenario from an Australian health service organisation that illustrates why process mapping should be a critical part of EMM implementation planning.

15.5.3 Supporting the Pharmaceutical Benefits Scheme

This section considers accessing the Pharmaceutical Benefits Scheme (PBS) from within EMM systems in both public and private health service organisations.

The PBS is accessible:

- To patients attending or admitted to private health service organisations
- To patients admitted to public health service organisations on discharge, or patients attending public ambulatory clinics that are part of a PBS reform scheme* (including day chemotherapy and chemotherapy ambulatory clinics)
- To all public and private health service organisations that dispense S100 medicines.

Careful consideration should be given to the management of PBS prescribing in EMM systems. At the time of publication of this guide, PBS prescriptions generated from EMM systems must be printed on approved forms and signed by the prescriber. In private health service organisations, this requirement challenges the design of efficient work practices associated with implementing EMM. In public health service organisations, the challenges are further complicated by funding arrangements that affect how prescriptions are handled for private patients being treated in areas of public health service organisations where PBS-approved prescribing paper is used to generate PBS prescriptions. In some cases, these private prescriptions are not included in the EMM system, potentially compromising medication safety.

Electronic prescribing where paper prescriptions are required for PBS purposes should be carefully managed to reduce the clinical risk of operating a dual system. This is to minimise the opportunity for introducing errors into the prescribing process.

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

The information required for an inpatient medication order is different from the information required for a medication order for discharge or for an ambulatory patient. This has implications for EMM, particularly in states or territories that have implemented the pharmaceutical reforms. Medication orders for inpatient use include (as a minimum) the medicine name, dose, form and frequency. Discharge or ambulatory medication orders for PBS items also require this information, as well as other information that complies with a PBS-listed product. This other information includes a specific strength and pack size (or quantity), and, in some cases, PBS authority codes such as streamlined 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 of 50) and warfarin (Coumadin) tablets 5 mg daily (pack of 50).

EMM solution providers are encouraged to differentiate their solutions through the development of EMM capabilities that support best-practice workflow in the prescribing of PBS medicines, including:

- Better integration of PBS prescribing in the prescriber workflow – in some cases, PBS prescribing has been insufficiently integrated and represents a time impost to prescribers
- Optimised PBS prescribing, such as using the planned online PBS Authority approval system
- Optimised mapping of generic inpatient medication orders and PBS-listed products at discharge, where applicable.

Pharmaceutical Benefits Scheme prescriptions in public ambulatory settings

In PBS reform facilities, public health service organisations can access the PBS for ambulatory patients, including day chemotherapy patients.

In this context, the EMM implementation should provide:

- Infrastructure that supports ambulatory workflows and allows prescribers to access PBS prescribing as they move between ambulatory consultation rooms – this is a requirement for electronic PBS prescribing, and can be achieved using mobile technology, portable sessions, or rapid user authentication and access to fixed computers
- Printers that support PBS prescription printing in each consultation room; shared printers can introduce confusion, with prescriptions being printed from different areas, and the risk of the wrong prescriptions being given to patients.

At the time of publishing this guide, there is little ambulatory implementation experience available from EMM sites.

Pharmaceutical Benefits Scheme prescriptions for public health service organisation discharges

In PBS reform facilities, public health service organisations can access the PBS for medicines on discharge. In this context, EMM implementation should 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)
- Adequate printing capacity for the required volume of compliant prescriptions
- A consistent approach to identifying and naming PBS prescription stationery in printer drawers or trays so that prescribers can easily select the correct printer drawer
- Integration of how to generate a PBS prescription into prescribers' workflow.

Box 15.3 presents a real-life scenario from an Australian health service organisation that accesses electronic PBS prescriptions on discharge. This illustrates the importance of considering the workflow when implementing EMM.

15 Stage 2 – implementation planning

Box 15.3 Scenario: Pharmaceutical Benefits Scheme prescriptions for public health service organisation discharges

An intern participates in the ward round, where it is decided that a patient is to be discharged.

The intern must decide whether to leave the ongoing ward round to complete the discharge prescription 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 Pharmaceutical Benefits Scheme (PBS) discharge medicines.

PBS prescription paper is kept in a secure location and should 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 prescription to the organisation's pharmacy and the intern returns to the ward round.

The pharmacist reviews the prescription and needs to clarify the prescription with the intern. The intern is paged and leaves the ward round again to discuss the prescription with the pharmacist. They agree that the prescription needs to change.

The intern then updates, prints and signs the revised PBS script, which is required by pharmacy before the prescription 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 prescription or discuss it with the pharmacist
- Transcription errors if the intern annotates some form of paper record other than the electronic chart 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.

Pharmaceutical Benefits Scheme access in private health service organisations

Inpatients at private health service organisations can access the PBS for the medicines required during their inpatient stay.

The Australian Government Department of Human Services currently requires all PBS prescriptions generated using an EMM system to be signed by the prescriber. This requirement poses substantial challenges when implementing EMM in private health service organisations, and the need for handwritten scripts negates many of the benefits of EMM systems.

Until electronic prescriptions are available, managing unsigned prescriptions is a significant impediment to using EMM in private health service organisations, and requires careful consideration of:

- EMM workflow
- EMM process mapping
- EMM solution design
- Managing prescribers' expectations
- Implementing change management.

15.6 Policy development

Implementing an EMM system will challenge existing organisation policies and provide an opportunity for the organisation 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 organisation's expectations of staff in using the system – for example, medication orders should not be transcribed on non-approved documents, such as scrap paper, even as a reminder
- The circumstances in which paper medication charts are acceptable – for example, where complex, variable-dose medicines or fluids for infusion are not yet included in the EMM scope; where the EMM implementation is staged; or on transfer of the patient to another organisation (see Box 15.4)
- How the medication management continuum is supported where EMM addresses only part of the organisation's medication management requirements, or where more than one EMM system is in place
- The process for transcribing patient medication information onto other clinical documentation such as discharge summaries, where these are not integrated.

15 Stage 2 – implementation planning

Box 15.4 EMM system policy development

The first Australian electronic medication management (EMM) system implementation sites have highlighted the need for clearly articulated policies on the use of the EMM system that are endorsed by the organisation executive.

Such policies are necessary to manage clinicians' expectations and to prevent the continued use of paper charts in areas where EMM has already been implemented.

Policy for the operation of paper versus electronic medication charts

One of the main 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 should define:

- How to ensure that discharge medicines are accurate and aligned to the discharge summary – for example, a policy could state that any changes to discharge medicines after the discharge prescription has been generated should be updated in the EMM system before the discharge summary is finalised, to ensure effective handover of care
- When the use of a paper medication chart is acceptable – for example, 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 with another – for example, where a paper medication chart should be used for specific medicines, the existence of the paper medication chart should be recorded in the EMM system; alternatively, the presence of other medicines in the EMM system should 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 people responsible, when the system is returned to normal operation following a temporary interruption to the functioning of the electronic medication management system, such as a power or network failure.

This section considers only those policies required to support the immediate period of EMM implementation. Chapter 21 considers policy development in greater detail as part of consolidating the use of the EMM system in health service organisations.

15.7 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 in a reasonable amount of time.

In Australian hospitals, there is substantial variation in EMM implementation scope, approach and time frames, and in the extent to which medication decision support has been implemented.

The scope of EMM-related implementations tends to be based on one of three scenarios:

- EMM only
- EMM as part of a broader clinical scope, where both EMM and the broader clinical scope are implemented simultaneously
- EMM as part of a broader clinical scope, where EMM has been implemented after elements of the broader clinical scope.

Implementation rollout models used by EMM sites include:

- Big-bang – that is, simultaneous go-live in all clinical units across the facility
- Big-bang for all new admissions, with existing patients remaining on paper records and medication charts throughout their admission until discharge
- Sequenced implementation based on priority cohorts (such as long-stay patients on stable medicines) or on patient flows (such as the ED going last).

Sequenced implementation may include:

- Implementing in several inpatient units at a time, with support tapering off for two weeks before starting the next group of inpatient units
- Starting with long-stay units such as rehabilitation, aged care, dementia and mental health, followed by acute medical and the ED, and the remaining inpatient units, with surgical units often last
- Deferring implementation in the ED until last to avoid returning to paper charts where ED transfers are to inpatient units that are still using paper charts.

Each approach has its merits and disadvantages. The big-bang approach requires greater surety about the EMM system planning and a more substantial EMM system build before go-live. However, it could deliver the benefits of the EMM system much earlier, with less opportunity for procrastination.

The big-bang for all new admissions approach is gentle on both the clinicians and the project team, but requires mechanisms to ensure that the correct medication chart is used for the correct patient. Mechanisms to help achieve this include alert stickers on the health record, alerts on the patient banner and configuring a parameter set for patients on paper-based charts that prevents electronic prescribing.

Sequenced implementation allows for communicating information about the EMM system, and testing the system build and concepts in a measured way before a full-scale implementation. This means that hardware purchases can be staged and implementation time frames may be more flexible. This is the most common approach used; however, it can lead to procrastination in finalising the rollout.

The preferred approach will be influenced by the:

- Skills and experience of the EMM system vendor
- Capacity of the health service organisation and the project team to deliver results
- Extent of organisational commitment, particularly the chief executive officer and the senior medical staff.

Regardless of the preferred approach, rapid EMM system deployment should always be considered because of the:

- Risks to patient safety as a result of maintaining both electronic and paper medication charts
- Need to achieve a critical mass with EMM, so that clinicians do not have to work in different ways in different parts of the health service organisation (where some wards use EMM and others use paper medication charts)
- Desire to capitalise quickly on the successes of lead implementations and minimise the opportunity for procrastination
- Need to prevent project fatigue.

15 Stage 2 – implementation planning

Where sequenced implementation is preferred, consideration should be given to which ward(s) to implement the system in first and the factors involved in selecting the lead wards. Australian organisations that were among the first to implement an EMM system selected their lead wards based on:

- Low levels of patient transfers, to minimise reconciliation between electronic and paper medication charts
- Areas of the organisation where there are strong clinical champions who are 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 (such as aged care)
- Areas of the organisation that already had wireless networks and sufficient numbers of mobile devices or fixed bedside devices in place, or where this equipment could be installed relatively easily.

An important factor is where the ED fits in the implementation rollout. All recent EMM implementations have included the ED in the EMM system. Some project teams see the ED as a significant challenge and have scheduled the ED implementation last. However, others recognise that many admissions come through the ED, and capturing patient medication 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. Although most sites have implemented EMM for all ED attendances, some sites indicated that any medicines required for the ED attendances where the patient was not going to be admitted often remain on paper. This is an important issue that will substantially affect how EMM is implemented in EDs, and how medication safety and continuity is addressed.

The view of Australian health service organisation 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 organisation in a reasonable time.

The duration of EMM implementations varied considerably and depended on:

- Whether the implementation was EMM only or part of a broader clinical scope
- Whether the implementation was sequential or big-bang
- The size of the facility
- The proportion of the health service organisation's medicines that are within the EMM scope.

The following scenarios are examples of time frames for EMM implementation:

- A >300-bed hospital big-bang implementation of EMM and all other clinical functions took place during a single weekend
- A 350-bed hospital big-bang implementation of EMM and other clinical functions took four weeks to complete, and was based on new admissions being electronic and existing admissions remaining on paper
- A 360-bed hospital sequential implementation of EMM took three months
- A 1,000-bed health service organisation sequential implementation took one year.

15.8 Evaluation planning

Evaluation planning is important to measure and communicate the successes and failures associated with implementing the EMM system. It provides an opportunity for clinical staff feedback and refinement of the EMM system, and to assess performance and utility against the proposed goal 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 health service organisations, the lessons from the first site are learned before implementation at subsequent sites.

Evaluation may be undertaken by members of the project team, people in the organisation unconnected to the EMM system implementation, 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.

EMM system evaluation formalises the refinement process and allows continuous quality improvement as the system becomes embedded in the organisation's operations.

15.8.1 Evaluation framework

The evaluation framework defines all the activities, sequences and time frames 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 will be collected, and the frequency and timing of data collection
- Evaluation activities, including
  - the type of activity, such as anecdotal evidence, surveys, EMM system–generated statistical reports or observational studies
  - the method of data capture
  - the frequency and timing of the evaluation activity, such as 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 provided in Table 15.5. Some expected outcomes and baseline indicators for evaluation may have been identified in the initial scoping study or business case, or in the product evaluation and selection stages.

Table 15.5 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 medication use	Reduced ADRs	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 Health service organisation issue and risk reporting (sentinel events) Review of medication incidents and ADRs	Audit of medication charts for a defined period Review of sentinel events	Pre-implementation Post-implementation Ongoing monitoring
		Administrative and other errors				
	Increased adherence to guidelines					

ADR = adverse drug reaction; LOS = length of stay

15 Stage 2 – implementation planning

15.8.2 Expected outcomes

Clearly defining the expected outcomes from implementing the EMM system will ensure that 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 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 medication reference information
- Increased capacity for pharmacy review
- Increased capacity to monitor appropriateness of prescribing for given conditions
- Improved routine monitoring of the timeliness of medication administration.

15.8.3 Baseline indicators

Baseline indicators should be defined and measured before implementing the EMM system. The NSW Therapeutic Advisory Group has developed indicators for quality use of medicines in Australian hospitals[42] that should also be considered when developing indicators for evaluating the success of the EMM system implementation.

The extent to which the paper medication chart complies with best practice over a defined period should be audited before implementing an EMM system. The Commission's national inpatient medication chart audit tool43 is useful for establishing baseline measures. Examples of indicators for paper-based medication charts and their expected changes under an EMM system are given in Table 15.6.

Table 15.6 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 added automatically (as a digital signature) in 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 added automatically in the EMM system
Whether the non-administering codes were used correctly	Use of non-administering codes will need to be checked against other information, such as progress notes in the health record, in a post-implementation case note audit for patients

Table 15.6 Indicators for paper-based charts and expected changes when using an EMM system (continued)

Paper-based chart indicator	Expected indicator changes in an EMM system
Whether allergies and ADRs were recorded	The EMM system can make recording allergy and ADR information mandatory at the time of prescribing, so this indicator will 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 ADR 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 health record
Whether telephone orders were validated or countersigned by the prescriber	Ideally, prescribers will be able to 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 medication 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 medication 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

ADR = adverse drug reaction; EMM = electronic medication management

The number, type and severity of medication-related errors reported through the organisation's risk or incident reporting mechanisms should also be audited. However, it is important to recognise the limitations of such an audit, because the pharmacy rectifies most prescribing errors before they become reportable issues. Incident reporting systems also under-enumerate medication incidents and errors.

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. This could include how many alerts were generated, how many alerts were ignored, or whether alert numbers varied depending on 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, the volume of pharmacist reviews before implementation of the EMM system should be analysed. This includes ensuring that 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 medication reference information sources should be measured before these resources are integrated with the EMM system. Activity data on the use of medication reference information resources should be available before implementation of the EMM system and, again, baseline data should be compared with EMM system reports.

15 Stage 2 – implementation planning

15.8.4 Evaluation activities

Evaluation activities should focus on the areas of perceived risk and the areas of expected benefit for the EMM project. These 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, locations and types of devices that were provided for the EMM system, including satisfaction with wireless network performance and identification of any blackspots
- Reviewing satisfaction with the operating performance of the EMM system
- Assessing the user experience of the EMM system implementation schedule, the communication channels and the extent to which clinicians felt involved with the implementation of the EMM system.

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 15.8.3
- Surveys of EMM system users about the utility of the system, the extent to which it improves clinical practice and on its benefits and costs – electronic survey tools could be used to deploy and report 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 at which EMM clinical decision-support alerts are accepted or overridden
  - EMM system usage durations, such as length of prescribing sessions
  - user pathways and preferences, including use of prescribing pathways such as standard order sets or order lists, or access to non-formulary items.

The EMM system should be evaluated after it is embedded in operational practice and sufficient time has elapsed to ensure stakeholders are familiar with the system. However, post-implementation review 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.

15.8.5 Checkpoint and milestone reviews

Where EMM system implementation is staggered, periodic checkpoint and milestone reviews should be instituted. This is to ensure that the implementation continues to be relevant and appropriate and continues to learn from earlier implementations, and that time lines are maintained.

15.8.6 Post-implementation review planning

After the EMM system is implemented, a formal post-implementation review (see Chapter 18) should occur. This is to assess whether the EMM deliverables defined in the business case have been achieved. The post-implementation review also provides information to inform future system implementations. The post-implementation review will address seven specific success factors and questions:

- 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, and are negative effects 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, and are there issues that should be considered more carefully in the future?

15.9 Benefits management planning

Benefits management is an important part of any project and should be appropriately resourced during implementation and throughout 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. It is important that the broader benefits of implementing an EMM system are identified and, wherever possible, measured to justify the organisation's investment in EMM.

A benefits register should be used to log all the benefits identified in the business case.

The information on each benefit should include:

- A description of the anticipated benefit
- Baseline measures and indicators to compare the benefit with
- Estimates of the most likely value of the benefits, and estimates of the best-case and worst-case scenarios
- Identification of the people responsible for measuring the benefit and the people who 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 of a benefits register is provided in Table 15.7.

Table 15.7 Example of a benefits register

Benefit	Baseline measure	Likely value	Worst case	Best case	Responsibility and beneficiary group
Reduction in prescribing errors	Baseline measure to be collected for one month before go-live*	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
Reduction in time required to rewrite medication charts	Average time required to rewrite medication chart	10 minutes per chart	No time saving for patients on few or no medicines	30 minutes for patients on complex medication regimes	R = EMM system B = Medical
Prompts provided to restart medicines at discharge that were ceased on admission	Baseline measure to be collected for one month before go-live	80% of discharges	No change	All discharges	R = EMM system B = Medical
Work flows within the EMM system that allow discharge prescriptions to be populated from the current medication list and admission medication 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

* The health service organisation's incident reporting system as an information source may be limited, because most prescribing errors are identified and prevented by pharmacy before they become reportable.

15 Stage 2 – implementation planning

Baseline measurements are required before EMM system implementation. Benefits measurement should be ongoing throughout the system implementation and for a sufficient time afterwards. It is likely that some benefits will not be realised until the EMM system is entrenched in the operational workflow of the health service organisation, 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 – an example is provided in Table 15.8.

Table 15.8 Example of a benefits table by stakeholder group

Stakeholder group	EMM functional area	Benefit
Patients	Medication reconciliation	Improved medication safety during inpatient stays by documenting general practice and community medicines in the EMM system with medicines stopped, changed or continued
		Improved medication safety postdischarge through medication reconciliation on discharge, including recommencing medicines stopped or changed on admission (where appropriate)
	Prescribing	Improved medication safety during inpatient stay through clinical decision support
		Reduced opportunity for medication errors through clearly documented and legibly prescribed medicines
	Administration	Reduced opportunity for administration errors through clearly documented and legible administration record
		Reduced opportunity for administration errors through clinical decision support
	Consumer medication information	Improved consumer understanding of medicines on discharge, the indication and the reasons for changes to medicines
		Greater opportunity for consumer compliance with their medication regime
		Reduced opportunity for overmedication because generic substitutions are identified
Prescribers	Prescribing	Reduced prescribing time, and improved medication safety and continuity by having previous medicines already available for start–stop–continue charts
		Reduced prescribing time by using 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 prescribed again
		Reduced prescribing time because discharge medicines are brought forward from the list of a patient's medicines taken on admission and the current medication chart for discharge prescribing
		Reduced prescribing time because discharge medicines automatically populate the discharge summary

EMM = electronic medication management

Table 15.9 lists some of the benefits reported by Australian sites that have implemented EMM systems. Reports of benefits from international sources include:

- *Benefits Realisation Guidance for ePrescribing Projects* from the United Kingdom National Health Service[44]
- *Managing Benefits* by Steve Jenner.[45]

Table 15.9 Benefits reported by Australian health service organisations that have implemented EMM

Type of benefit	Benefits measure	EMM site 1	EMM site 2
Medication safety	Use of telephone orders	Before EMM implementation, about 1.75% of all medication orders were by telephone. After EMM, telephone orders were reduced to almost zero because of remote access to the EMM system	–
	Allergy status recorded within 24 hours of admission	6% increase, with accuracy improving 22%	5.4% increase
	Medication reconciliation undertaken within 24 hours of admission	54% increase (while remaining a predominantly pharmacist-led activity)	–
	Use of error-prone abbreviations	2.93% reduction	35% reduction, with a 14% reduction in nursing calls to clarify medication orders
	Reduction in missed doses	Reduced by between 1.9% and 5.3% (variation across clinical units)	–
	Adherence to venous thromboembolism guidelines	38.3% increase	42% increase
	Avoidance of medication errors reaching the patient	33% reduction	–
	Reduction in pharmacist intervention in medicine omissions	62% reduction	–
	Adherence to policy for the use of restricted antimicrobials	44% increase	–
	Number of medicines verified by pharmacists	–	14% increase
Financial savings	Cost of individually dispensed inpatient medicines (with further supply based on administration volumes instead of manual checks)	–	Saved $921,000 per year

15 Stage 2 – implementation planning

Table 15.9 Benefits reported by Australian health service organisations that have implemented EMM (continued)

Type of benefit	Benefits measure	EMM site 1	EMM site 2
Efficiency (time) savings	No longer needing to rewrite medication charts every seven days	–	Junior doctor time saved equivalent to $230,000 per year
	Nursing time spent on medication administration	–	Nurse time saved equivalent to $300,000 per year

– = not reported; EMM = electronic medication management

15.10 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, whereas training is mainly concerned with how to use the EMM system.

Training provision varied greatly among Australian EMM sites – for example:

- EMM-only implementation training three weeks before go-live – junior doctors two-hour classroom training, consultants opportunistic one-on-one training, registrars and surgeons limited commitment to training, and super users four hours training
- EMM implementation training as part of a broader clinical scope (eight weeks before go-live) – medical staff six hours training, eight hours all other clinical staff groups, and super users one additional day of training
- EMM big-bang implementation training as part of a very large clinical scope – 16 hours of training for pharmacists (so pharmacists could assist medical and nursing staff), and nurses four hours in classroom plus four hours of exercises
- EMM-only implementation – no classroom training provided, only online training supplemented with go-live support; senior medical staff who did not undertake the online training were provided with 30 minutes of one-on-one training on the day of go-live.

Other training feedback included:

- Online training is very important for rural and remote sites, because junior medical staff may not have orientation and training before starting duties
- Using a training sandpit (see Section 15.10.2) required the development of clean-up scripts to remove overdue medication administration that would have made follow-up training unusable.

The following sections relate to pre-go-live education and training that is required to support a successful EMM system implementation. The requirements for ongoing training are addressed in Section 20.5.

15.10.1 Education planning and materials

Most people who 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 health service organisations 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 organisation (the vision for EMM)
- Scope of the EMM system implementation, including its staging and time frames
- Medication management cycle and the importance of ‘closing the loop’

- Processes that will change because of implementing an EMM system
- Expected benefits
- Challenges associated with implementing an EMM system
- Learner's role in an 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 are sufficiently developed to be used unchanged. However, most project teams will want to contextualise the education and training material so that it:

- Includes the vision for EMM in the organisation and an overview of the overall EMM system implementation
- Includes information on why EMM is important, citing literature on the extent and effect of medication errors, highlighting local health service organisation audit results, and (where possible) personalising the education materials with real-life case studies from clinician and client perspectives
- Clearly defines the benefits of an EMM system, including improvements in accuracy, legibility (by directly comparing the electronic and paper medication chart), transparency and auditability, ease of access, and safety and quality
- Couches any perceived disadvantages, such as 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 and 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 effect on prescribers
- Recognises the inevitability of EMM and encourages active participation in the change process.

15.10.2 Training and materials

All users of the EMM system should 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. It is also intended to build user confidence in the system, reveal and allay user concerns, and enable further development and tailoring of the system based on participant feedback.

Training requires significant resources and time. Some considerations include:

- Providing basic computer competencies training and EMM contextual training before EMM-specific training
- Ensuring training materials and facilities are available to support the training sessions, including
  - any materials that the vendor supplies, with modification if necessary to reflect local requirements
  - training facilities, particularly where the training rooms need to be booked in advance (see Section 15.10.4)
- Timing the training to occur close to the go-live date to ensure that the information remains current (see Section 15.10.5)
- Tailoring training to different roles and considering the differences in time required to train different groups (see Section 15.10.3)
- Adapting the skills and experience of the trainers, including using generic trainers alongside domain experts, such as pharmacists training pharmacists, and nurses training nurses and midwives – pharmacists may also train 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 implementation in ward areas, and providing additional training to this group
- Engaging with medical staff resourcing and medical education to determine how best to train the large number of junior medical staff in public health service organisations.

Prescheduled induction education sessions and grand rounds provide a good forum for pretraining education and awareness sessions. These sessions are often well attended, and lunch is sometimes provided.

Planning for training must also consider:

- Night duty staff, including night-time training sessions, rostering day-time training and any specific costs associated with providing this training
- Private specialists, including training in their consulting rooms
- Agency staff, including contractual arrangements where agencies train their own staff in accordance with the organisation's defined requirements
- Providing a drop-in or information room.

It is essential to provide a training 'sandpit' area. This is a separate environment in 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 should be in place to ensure EMM system learners access the sandpit.

Australian sites that have already implemented EMM systems found that it is difficult 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 health service organisation, shortened training modules are needed for this group, and access to EMM experts on the ward should be made available.

Endorsement of user EMM system competence should be a requirement before staff are allowed to practise in an EMM-equipped ward. Ideally, this endorsement would become part of staff credentials in health service organisations. User competence may be assessed using defined scenarios that the clinicians are required to step through in the EMM system with the assessor.

15.10.3 Role-based, tailored training courses

Education and training materials and their delivery should align with the goal-state EMM processes that have been identified. They should be based on clinical process flows and clinical scenarios.

Education and training delivery should be tailored specifically to each group of clinical staff who will use the EMM system, to maximise the learning experience of each staff group. This includes education and training for:

- All staff who will use the EMM system, to provide the overview about how EMM will be used in the health service organisation
- Public health service organisation prescribers
- Private health service organisation prescribers, taking into consideration the limited time that these specialists spend at the organisation
- 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 is important. Consider using pretraining awareness materials such as poster displays with annotated screenshots and EMM system use messages, fact sheets, and quick reference guides or pocket guides. These should provide an overview of EMM functions to familiarise people with basic concepts before they attend the training sessions.

In addition, consolidation training should be provided after the formal EMM system training. This includes access to a sandpit to practise using the EMM system before going live or whenever users feel that they need more practice between formal training sessions.

15.10.4 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. 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 because of the competing demands on shared training resources, and the potential for EMM training to disrupt the day-to-day education and training requirements of the health service organisation. In addition, the availability of dedicated training facilities provides the opportunity for impromptu training of new staff.

15.10.5 Timing of the training

The sequencing of education and training is important and will influence the implementation rollout schedule:

- Frequent education and awareness sessions should 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.

15.11 Project communications

Communication is an essential change management tool for EMM system implementation. The organisation's intent to implement an EMM system should be communicated clearly and early to all staff, and include details such as the expected benefits, implementation time frames and implementation sequence.

Change management messages from Australian EMM sites include:

- EMM use is time neutral[46]
- There is no need to rewrite medication orders after seven days, as is required on paper medication charts
- EMM has safety benefits to others – for example, explain this to junior medical staff when prescribing, and to junior nursing staff when administering medicines; this also avoids sensitivities around individuals making mistakes
- It is important to ensure prescribing safety for junior medical staff
- The legibility of medication charts is no longer an issue
- The EMM system is not a panacea for medication management, because EMM can create new issues.

Communications planning should include the communications plan and tools, and the delivery methods. The communications messages used during EMM system implementation should be consistent with those used in the education and training materials.

A communications plan describes the overall goals, objectives, outcomes and schedule for EMM communications, including the:

- Target audiences
- 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 15.10 for an example of a communications plan template.

Table 15.10 Example of a communications plan template

Target audience	Communication type*	Stakeholder (primary or secondary)	Responsibility	Message	Communication mode†	Timing§	Frequency#
All staff	Project announcement	Both	Project team	EMM is coming soon	Posters	Three months before go-live	Once
All clinical staff	Project announcement	Primary	Project clinicians	Medication safety	Posters, CEO newsletter	Three months before go-live	Once
Prescribers	Project update	Primary	Lead medical staff	Medication safety	Grand rounds	Two months before go-live	Monthly

CEO = chief executive officer

EMM = electronic medication management is missing from table legend

* For example, project update and project announcement

† For example, email, phone, face to face and meetings

§ Project stage or data range during which communication applies

Frequency of contact – for example, once, daily, weekly, fortnightly or monthly

The types of communication tools used should also be considered, 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. The communication tools and delivery mechanisms may need to be refined in light of these findings.

For additional information about change management, see *The Effective Change Manager's Handbook*.[47]

15.12 Quality management

Formal sign-off for project documentation is essential to ensure that the documents have received the appropriate level of quality assurance, ownership and approval. Formal sign-off is often neglected, but should be taken seriously. Adopting a project management methodology such as projects in controlled environments (PRINCE2) or project management body of knowledge (PMBOK), or even a well-developed in-house methodology will help obtain the right levels of sign-off in the EMM system project. The EMM system project documents that should be formally signed off are outlined in Box 15.5.

Box 15.5 Quality management and project delivery sign-off checklist

- ☐ Electronic medication management (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 the:

- Definition of the proposed change
- Case for change
- Time and cost impacts of the proposed change
- Approvals process.

16 Stage 3 – EMM system build and configuration

This chapter outlines electronic medication management (EMM) system 'build and configuration' activities.

16.1 Acquiring technical infrastructure

Acquiring the EMM system technical infrastructure and ensuring business continuity planning (BCP) are separate projects. These should be managed separately by information and communications technology (ICT) services. Clear reporting lines to the EMM project manager are required, as other crucial components of the EMM system depend on infrastructure and BCP.

The technical infrastructure may include central server infrastructure supporting the various EMM system environments, including development, test, training and production (live) environments. Some health service organisation ICT services may require additional environments. The technical infrastructure may also include high-availability infrastructure, such as disaster recovery – for example, duplicating 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 business continuity plan to deal with potential failure (for example, dual power supplies to air-conditioning, servers and switches).

Other components of the technical infrastructure may include:

- Desktop and point-of-care solutions such as wireless networks, fixed or mobile devices, or computers on wheels
- Robust telecommunications and wireless infrastructure
- Single sign-on and identity management
- Access and authentication requirements that support clinical workflow – these include 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 Pharmaceutical Benefits Scheme scripts are used
- Active Directory (AD) facilities for user login, single login and inactivity timeout requirements
- Remote access.

Relevant experience from one Australian EMM site includes a browser configuration that created unexpected errors. Test scripts therefore need to include tests for the unexpected. At another site,

technical issues that were not previously reported, monitored or resolved because the issues were not perceived to be business critical became problems during EMM implementation. To avoid these problems, an ICT technical readiness assessment that addresses known deficiencies should be done before implementing EMM. At another site, mobile device

trolleys were deployed before the EMM implementation so that clinical staff were already familiar with using

the devices. However, these trolleys can create traffic problems when accessing centrally located medicines cabinets or controlled medication cabinets. Another site identified that screen resolution can affect the on-screen display of medicines information. Prior to EMM implementation, system specifications should be considered with an assessment of the current and future infrastructure requirements.

16.2 Software development

The selected EMM software should be able to support the goal-state environment and processes identified during business process mapping. However, additional EMM software may be required to ensure that the system performs all the functions identified by the organisation.

Where additional software is required, EMM solution providers need to be engaged before and during business process mapping to advise on what is currently possible with the EMM software. They should also advise on what can be readily developed, and where the time and financial costs of developing additional functionality exceed the likely benefits. Where software development is required, it is essential that project teams select an EMM solution provider who is responsive to tailoring the EMM software to their local specifications.

Software development introduces additional risk for the EMM system implementation, and organisations should satisfy themselves that the additional risk and cost are justified. This is particularly important where the organisation is very inexperienced with EMM systems at this early stage of the procurement process. The additional demands on the EMM project team also need to be considered if the team is to:

- Contribute to specification development, review and sign-off
- Undertake user acceptance testing, including developing test scripts for the new software
- Provide ongoing maintenance.

Where in-house solution components are developed, the health service organisation should ensure that adequate resources are available to maintain the solution in line with releases of the EMM software.

16.3 Building the technical environments

The ICT services section of the health service organisation will be responsible for building the EMM technical environments, in conjunction with the EMM system vendor. However, some of the business owners of the EMM environments should be EMM project team members for configuration and testing.

The organisation's ICT services will determine how many EMM environments are required. Typically, there will be four types of environment:

- Configuration and development
- Testing, for user acceptance testing and interface testing
- Training, with training datasets
- Production – the live, operational environment.

Additional staging environments may also be required.

The management and synchronisation of these environments require substantial resourcing that should be factored into the EMM project budget and time frames. The environments should be managed in line with the software releases, configuration changes and training 'refresh' needs.

16.4 Non-functional testing

Non-functional tests of the EMM technology infrastructure ensure that the infrastructure meets the technical business requirements. The specific non-functional testing required will be determined by the technology infrastructure mix.

Health service organisations that are implementing EMM systems will need to undertake:

- EMM system capacity testing, to ensure that there is capacity for the proposed number of users
- EMM system performance testing, to ensure that 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 testing of 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 system.

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:

1. Developing test scripts in line with the technical requirements identified in the business case and technical requirements procurement
2. Running the test cases
3. Recording the outcome of the test cases
4. Undertaking remedial action to address test case failures
5. Repeating steps 2–4 until successful.

The traceability matrix (see Section 16.7.6) should indicate that either 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. This should occur for each of the technical requirements identified in the business case.

16.5 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.

Configuration will need to include:

- EMM system reference tables
- Health service organisation formulary(ies)

- Standard order sentences and order sets
- Clinical decision-support tools and alerts
- Access to medication reference information
- User roles and access privileges
- Interfaces between the EMM system and other systems.

Australian sites that have implemented an EMM system have noted that it is important to have access to the medication catalogue and order sentences of other EMM sites that are using the same EMM system, to reduce configuration time. These sites have also highlighted the need to refine the EMM configuration based on user experience – for example, free text medication orders being replaced by order sentences based on prescriber usage patterns, and tightening up alert override reasons.

The level of clinical decision support deployed by Australian EMM sites is highly variable:

- Most EMM sites incorporate passive decision support – for example, medication reference information
- Most EMM sites incorporate medicine to allergy checking
- Some EMM sites have implemented drug–drug interaction checking
  - some sites have limited the interaction checking to the most severe interactions (those contraindicated)
  - other sites limit drug–drug interaction checking to most of the major interactions
  - some sites have disabled drug–drug interaction checking completely
- Some EMM sites have implemented duplicate medicine checking; some sites have disabled duplicate checking completely; and some sites deploy duplicate checking for a small number of medicines, such as anticoagulants
- Some EMM sites have implemented dose-range checking, and others limit dose-range checking to high-risk medicines*
- Most EMM sites have some dose-based calculators, although some EMM implementations require some or all the data to be entered into the calculator
- Some EMM sites do not have automated patient-specific clinical decision support – for example, for variable-dose medicines that are based on diagnostic test results, clinicians need to proactively review the results and determine the dose before administering the medicine
- Some EMM sites contextually display diagnostic test results during medication administration, although the clinician still needs to manually determine the dose for variable-dose medicines.

16.6 Developing interfaces with third-party systems

Although most of the EMM system's business requirements will probably be addressed in the selected EMM system, it is most likely that some interfaces will be required between the EMM system and other organisation systems. These systems may include:

- The patient administration system
- The clinical information system or electronic medical record, if EMM is not part of a broader clinical information system
- The diagnostic results reporting system(s)
- The pharmacy dispensing system
- Other specialty-based systems such as intensive care units, chemotherapy or antimicrobial stewardship
- The discharge summary system.

Although the EMM system vendor will play a lead role in interface testing, the mix of applications in health service organisations will most likely need in-house staff to do some testing.

Interface development and testing can be a lengthy and expensive process that needs sufficient planning and resourcing to ensure that these activities are completed well in advance of implementation rollout.

* Such as APINCH medicines (anti-infectives, potassium and other electrolytes, narcotics and other sedatives, chemotherapeutic agents, and heparin and other anticoagulants)

16.7 User acceptance testing

User acceptance testing (UAT) ensures that the EMM system is fit for purpose and that 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 is 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 should be identical to the live EMM environment.

UAT involves:

- Developing a set of test scripts or cases (see Section 16.7.1) based on the original business requirements – these are written as a set of sequenced actions that align with 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
- Break-testing to identify other defects
- Managing defects to ensure that failed scripts eventually run successfully
- 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 (that is, running slightly different scripts that are modified in response to how the testing progresses), interspersed with defect resolution by the EMM system vendor. Professional testers are often employed to manage the UAT process. UAT should be done by prescribers, pharmacists, nurses and midwives who will use the EMM software. Clinicians should receive training in the use of the EMM system so they are comfortable with it before doing UAT.

It is essential to define the acceptance criteria before starting UAT to ensure that implementation time pressures do not compromise the process. UAT ensures that the EMM system is fit for purpose when it goes 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 system users needs to be carefully considered by the EMM governance, including whether the EMM implementation should be delayed until known issues are addressed.

16.7.1 Developing test scripts

Test scripts are a set of instructions or scenarios to be run on the EMM system to test that it functions as expected. These will range from basic testing such as retrieving a specific patient's current medication record, to ordering medicines and testing the associated clinical decision-support functions.

Each test script should be accompanied by:

- Test script input data
- A formal and detailed description of the operational activities to be tested, which are 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 16.1. Some larger health service organisations 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.[48] Each of the original business requirements will need 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, functions of the EMM software.

Table 16.1 Example test script template

Test script # 1							
Description: New medication order							
Script reference	**Procedure**	**Expected result**	**Actual result**	**Pass or Fail**		**Criteria and reference**	**Comments**
1.01	Select patient	Patient record displayed	Patient record displayed	☑ Pass	☐ Fail	Enter patient health service organisation no.: B99999 (for patient Mr John Dow)	
1.02	Select the 'new medication order' function	Prescribing function displayed	Prescribing function displayed	☑ Pass	☐ 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	☐ Pass	☑ Fail	Enter erythromycin	Check content of medicine entries in the database and re-run script

16.7.2 Informal user acceptance testing

It is preferable to use an informal UAT process to test the UAT scripts and EMM system configuration before starting formal UAT. This should ensure that defects identified during the formal UAT process are because of 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.

16.7.3 Break-testing

Break-testing provides an opportunity for the EMM project team to test the system in an informal and unstructured way. The objective is to 'break' the system by identifying defects that may not be found when following a formal business process scenario.

Break-testing might include:

- Entering text where numbers are expected
- Entering zeroes to ensure that division by zero calculation errors are captured
- Entering data that are 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's *Guidelines for Hazard Review of ePrescribing Systems*[49] and the Institute for Safe Medication Practices' list of high-alert medicines[50] may assist in developing tests for unsafe medication orders.

Break-testing ensures that common defects are identified and resolved before the formal UAT process.

16.7.4 Formal user acceptance testing

The formal UAT process has a defined number of test cycles and defect management cycles. In larger health service organisations, this process may be managed by ICT services, and is subject to a rigorous process that the EMM project team is unable to influence.

16.7.5 End-to-end testing

End-to-end testing is the final test process to ensure that the configured EMM system operates and interoperates with third-party 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 in the EMM system
- Diagnostic results are either accessible from the EMM system or rapidly accessed via the third-party system that manages the diagnostic results
- Patient medication information for the discharge summary
  - is correctly made available (where the discharge summary is integrated)
  - reflects medicines on admission, medicines prescribed during admission and medicines on discharge
  - lists reasons for any changes between admission and discharge
- Medication reference information is accessible through integrating the medication reference information database into the EMM system or through external links
- Changes to the health service organisation formulary at the dispensing system end are also immediately updated in the EMM system, where the dispensing system is integrated
- All external data (such as diagnostic results or demographics) that are required to trigger clinical decision-support alerts do so – this includes 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 third-party system.

End-to-end testing is complex and time-consuming, and requires appropriate resourcing.

16.7.6 Traceability matrix

The traceability matrix maps all business and technical requirements articulated in the EMM business case through to the final EMM solution. It includes 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 requirements, the traceability matrix identifies why not. It provides 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.

16.7.7 Acceptance and sign-off

Acceptance and sign-off of the UAT process should occur when all major defects have been rectified and UAT has had a clean run. The traceability matrix (Section 16.7.6) 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. It is the definitive documentation that links the original business requirement to the configured EMM system that will be implemented.

Signing off on 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.

16.8 Ensuring business continuity

BCP is the process of creating systems of prevention and recovery to deal with potential threats to the viability of the health service organisation. Any event that could negatively affect the EMM system is included in the business continuity plan.

Chapter 19 considers BCP in detail.

17 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 health service organisation. 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 before and immediately after go-live.

17.1 Implementation checklist

The checklist in Box 17.1 summarises the activities required to implement an EMM system.

Box 17.1 EMM system implementation checklist

EMM governance activities

- ☐ Governance structures are in place and operating effectively
- ☐ Electronic medication management (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 sequential) 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, and booked if necessary
- ☐ Communications plan has been developed and signed off
- ☐ Test strategy (including user acceptance testing [UAT], non-functional testing, interface testing and end-to-end testing) has been developed and signed off
- ☐ Business continuity plans have been developed and signed off
- ☐ Draft go-live plans are developed (to be finalised closer to go-live)

Box 17.1 EMM system implementation checklist (continued)

EMM technical infrastructure activities

- ☐ Central technical infrastructure requirements (including high availability, and the number and type of EMM environments) have been agreed 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
- ☐ UAT scripts have been developed and validated as representing the business requirements
- ☐ UAT has been conducted and the EMM production software release has been 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 has been configured to reflect local rules for managing medicines (that is, any restrictions or additional requirements)
- ☐ EMM system has the Pharmaceutical Benefits Scheme and/or health service organisation formulary loaded and reconciled with the pharmacy dispensing system formulary (if not integrated)
- ☐ Access to medication reference information has been tested

Final go-live activities

- ☐ EMM system has been identified as fit for purpose and signed off by governance structures, including
  - communication materials to be used during the go-live period are confirmed
  - education and training materials are confirmed
  - go-live plans are finalised

17 Stage 4 – implementation and go-live activities

17.2 Project control centre

The project control centre is established immediately before go-live and remains in place during 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 comprise 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 should 'walk the floors', be responsive and rectify issues quickly – that is, not just 'log the job'. The early implementation phase is a critical period for EMM system users to adopt and endorse the system, and they will expect any issues to be fixed quickly.

17.3 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 – frontline 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 handover at the end of shifts)
- EMM system vendor – system and user support
- Project board or executive – decision-making in the event of rollback or an implementation suspension situation.

17.4 Tasks before and after go-live

Detailed go-live planning should include the allocation of tasks to team members and a schedule 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 in 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 in to the EMM before the go-live.

Clinical staff rosters should 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 organisation staff). The roster should maximise the support cover of clinical champions and expert users, including providing extra support.

17.5 Escalation strategy

An agreed escalation strategy is essential before starting go-live, so there is clarity about 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 executive that makes the decision if rollback or project suspension is being considered.

17.6 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 clinical area that does not use EMM, 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 in the EMM system and prevent further medication orders from occurring in the EMM system after a paper medication chart is created?

An operational policy is required to underpin these decisions. It should be reinforced through EMM system education and training, and EMM communications.

17.7 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
- Duration of the failure period before a rollback or suspension decision will be considered
- Decision-makers in a potential rollback or suspension situation
- Sequence of events following a rollback or suspension decision.

17.8 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 with the help desk and third-line support with the EMM software vendor
- Arrangements for transition of the project team to an ongoing operations team (see Chapter 20)
- Mechanisms that monitor ongoing support in line with service-level agreements.

18 Stage 5 – post-implementation review

A post-implementation review (PIR) is the last step in the electronic medication management (EMM) implementation process; it closes the feedback loop. A PIR allows the health service organisation to review the success of the EMM implementation and identify areas for further improvement.

The PIR should start at an appropriate time after EMM system implementation. The timing of the PIR will vary according to individual implementations. It 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. Users should become familiar with the benefits of the EMM system but remember the medication management processes that were in place before the EMM system was implemented.

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.

A PIR can generate both short-term and long-term gains. Short-term gains include:

- Identifying ways to improve the value proposition of the EMM
- Identifying ways to help EMM users overcome implementation hurdles that require workarounds
- Increased user morale because of the PIR consultation process.

Long-term gains may include:

- Learning from the implementation experience after an EMM pilot or where there are multiple EMM implementations in a health service organisation
- Financial benefits from improved project performance
- Improved project decision-making for subsequent implementations.

A successfully completed PIR will usually result in a recommended action plan for improvements. The action plan may include:

- Changes to project or operational governance, to roles and responsibilities, or to project or ongoing resourcing
- Changes to EMM content configuration, and to medication management processes and workflow
- Recommended improvements to the EMM software, and to the interoperability of the EMM and related systems
- Recommended improvements to refresher education and training
- Identification of the need for additional or different devices
- Identification of additional benefits of using the EMM system
- Improvements to EMM system response times and performance, and tightening up of business continuity planning arrangements
- Improved reporting requirements.

Numerous PIR guidelines and templates are in the public domain.

19 Business continuity planning

Business continuity planning (BCP) creates systems of prevention and recovery to deal with potential threats to the viability of the health service organisation. Any event that could negatively affect the electronic medication management (EMM) system is included in the business continuity plan. These include:

- Inability to access the EMM system as a result of hardware or software unavailability, or database corruption
- Information and communications technology infrastructure failure that affects the availability of the EMM system, including failure of data centres, servers, telecommunication infrastructure and wireless networks
- Failure of interfaces between the EMM system and other systems, such as the patient administration system, diagnostic results or pharmacy dispensing
- Failure of medication-specific infrastructure, such as dispensing robots or automated dispensing cabinets.

Business continuity plans need to be comprehensive and consider all possible points of failure, that is, all component parts on which the EMM system depends. This includes partial failures. Partial failures might include:

- Loss of EMM service delivery, or loss of power supply, to one or more clinical service areas
- Partial failure of the wireless network or fixed device network
- Failure of the local automated dispensing cabinet
- Single EMM interface failure, for example, the dispensing system
- Stand-by chart-printing server failure
- Replication failover server failure
- Secondary data centre failure.

Business continuity plans should include a communication protocol for assessing when to invoke BCP, and the roles and responsibilities of BCP decision-makers.

In each scenario, the BCP arrangements should be specified, including:

- A description of the nature of the event that would trigger the BCP
- Any time dependencies – for example, just before or after a medication round, three hours before a medication round, two hours before a medication round, and night-time events
- Any pre-enabling activities – for example, printing paper medication charts and distributing BCP information packs
- The actions required of staff during the BCP event – for example, the process and documentation required for new medication orders, and medication order review, supply and administration
- The actions required of staff after the BCP event – for example, updating the EMM system to reflect new medication orders and administration
- Any time dependencies that change the actions required of staff – for example, if the BCP event exceeds a specified time frame, the practicalities of updating the EMM system with a large volume of data
- Any shift-based dependencies that change the actions required of staff – for example, where the clinician updating the EMM system is not the same as the one recording the paper-based documentation during the BCP event.

One Australian EMM site made the following decisions during a BCP event:

- Locally generated charts were printed for administering existing medication orders, with all new medication orders prescribed on a paper-based national inpatient medication chart (NIMC)
- All new medication orders and all medication administrations were retrospectively entered into the EMM system once service was restored, although new medication orders were discouraged during the BCP event wherever possible
- All new admissions during the BCP event used a paper-based NIMC – all new medication orders were retrospectively entered into the EMM system once service was restored, but medicines administered during the BCP event were not
- All emergency department attendances during the BCP event had their medication orders and administrations retrospectively entered into the EMM system once service was restored.

Interestingly, the site also found that new junior medical staff did not know how to complete the paper-based NIMC during the BCP event because they had only ever prescribed medicines electronically.

Another Australian EMM site does the following during BCP events:

- If the BCP event is the failure of the hospital telecommunications network, EMM users access the EMM system through the remote login facility
- A paper medication chart is printed and everyone uses the paper chart
- If the BCP event duration is short, all medication orders and administrations are retrospectively entered into the EMM system, and the printed chart is scanned in and held against the patient's record
- If the BCP event duration is long, all the medication administrations are recorded as given, with any exceptions recorded individually, and the printed chart is scanned.

EMM-related business continuity plans should be managed as part of the organisation's risk management framework, and approved by the drug and therapeutics committee.

Part D
EMM post-implementation

Consultation with electronic medication management (EMM) sites during the development of this guide highlighted the need for more content and guidance post-implementation.

This part of the guide outlines the requirements for the post-implementation continuous operation and improvement of the EMM system, including:

- Chapter 20, Operationalising the EMM system
- Chapter 21, Regulation, policy and compliance
- Chapter 22, Monitoring and evaluation
- Chapter 23, Continuous quality improvement and data analytics.

20 Operationalising the EMM system

An electroninc medication management (EMM) system is not a 'set and forget' system. Once implemented, EMM systems require substantial ongoing management, updating, refinement and improvement.

The enormous technical and cultural challenges associated with implementing an EMM system require the organisation to prioritise aspects of EMM implementation. These include project management and reporting, EMM system configuration, building and testing, and the go-live and immediate post-go-live period as the EMM system is rolled out and settles in.

Although EMM systems have reduced medication errors[40], they have also introduced unintended errors, created dissatisfied users and resulted in broken clinical workflows.[2,41] Regardless of how well an EMM system has been implemented initially, the opportunities to refine and improve how the EMM system is used over time will be numerous. The real benefits of investing in an EMM system come from the downstream opportunities to improve medication safety, improve clinician workflow, create efficiencies and engage clinicians in an ongoing cycle of continuous quality improvement.

Most EMM sites have made some post-implementation improvements in how their EMM systems are used, but little evidence exists of a systematic and longer-term approach to EMM refinement and innovation.

This could be because of a variety of factors, including:

- The perception that the EMM implementation has finished
- No clinical ownership of the EMM system
- A lack of governance oversight, leadership or interest in the EMM system
- The sense of being overwhelmed by the data tsunami generated by an EMM system
- Insufficient resources for systematic improvement activities.

Organisations should implement a yearly program of innovation and continuous quality improvement in medication management that considers Part D.

Successful implementation represents the 'tip of the iceberg' for EMM systems. It is during continuous quality improvement that all the previous hard work pays off and the EMM organisation can focus on maximising the benefits of its investment in delivering:

- Improved medication safety
- Efficient clinician workflow
- A superior clinician user experience
- Standardisation
- Greater compliance.

20.1 Governance

The operational EMM system requires ongoing governance and oversight. Overall responsibility should rest with the drug and therapeutics committee (DTC) or the clinical governance committee. However, a subgroup may be more effective in overseeing the detailed management of the EMM system, with regular reporting and approvals required from the DTC.

Where the EMM is part of a broader clinical information system, governance should reflect this, and exploit opportunities to link medication and non-medication data. However, the opportunity for EMM refinements supporting medication safety and efficient clinical workflow is substantial. Governance should ensure that systematic improvements in the use of the EMM system are not compromised by a broader clinical systems agenda.

The active involvement of the DTC in approving EMM changes legitimises the EMM system in the eyes of the clinicians who use it. This means that the EMM system will not be seen as an information and communications technology (ICT) project, or the pet project of an individual or small group of stakeholders. Responsibilities of the DTC should include:

- Ensuring that regulatory obligations are enforced (see Chapter 21)
- Approving all changes to EMM system configuration before the changes are introduced
- Approving all communication materials associated with EMM changes
- Approving the EMM audit work program
- Approving the EMM innovation work program
- Advising the executive about changes to the EMM system or the EMM workflow.

The EMM governance subgroup should comprise EMM advocates who are willing to commit the time and be prepared to promote EMM to their colleagues – that is:

- A member of the executive
- One or more members of the DTC, to ensure continuity
- Senior clinical staff representing prescribers, pharmacists and nurses
- A member from the safety and quality section
- The manager of the EMM support team
- A member of the clinical informatics team.

Responsibilities of the EMM governance subgroup should include:

- Defining the EMM reporting metrics and target measures that will be used to monitor how the EMM system is being used by the health service organisation
- Prioritising and recommending to the DTC the annual EMM system work programs for audit, innovation and data analytics
- Monitoring delivery of the approved work programs and reporting work program status to the DTC
- Reviewing EMM data quality reports, and EMM risk and issue registers
- Approving all EMM investigative work and improvements, including recommendations on their sequence during implementation
- Recommending any changes to EMM work programs and EMM workflow
- Reviewing all EMM communication materials associated with EMM changes, and all EMM training materials.

20.2 Resourcing

The number and composition of resources required to maintain an EMM system will depend on several factors, including:

- The size and geographic spread of health service organisations, and the importance of local on-the-ground EMM and technical support and training capabilities – particularly for rural and remote sites
- Whether the EMM system is a separate system requiring its own support resources, or is part of a broader clinical system where a larger resource pool can be shared
- The existing ICT support arrangements and the capacity to support the new EMM system
- The appetite of the health service organisation or EMM sponsors for continuous quality improvement.

Typically, Australian EMM sites report that between three and five full-time equivalents are required to support the EMM system. However, these numbers might not be sufficient in the early years following an EMM implementation, because of the volume of system improvements that will probably be required.

To determine the resource pool needed, organisations must avoid depending on individual support team members. It is essential to ensure that there is no single point of failure in providing EMM support, given the criticality of around-the-clock EMM use.

Operational resources for the EMM system should be adequately funded, with costs being legitimately offset against savings resulting from implementing the EMM system, including:

- The cash-releasing benefits of EMM identified in the EMM business case or subsequently (refer to Section 15.9).
- Additional savings that could be achieved by introducing medication automation, as indicated by sites that have implemented these technologies.

20.3 EMM configuration and maintenance

EMM systems require ongoing maintenance to ensure that the information remains accurate; this includes updating:

- The EMM system users
- The health service organisation formulary, such as adding new medicines
- Standard order sets and order sentences
- Changes to the Australian Medicines Terminology and the Pharmaceutical Benefits Scheme (PBS)
- Policies and procedures, education and training material, and clinical protocols (for example, antimicrobial guidelines or chemotherapy protocols)
- Alerts and clinical decision support
- Medication reference information
- The interfaces between the EMM system and other clinical systems
- 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) (also see Box 20.1).

20 Operationalising the EMM system

Box 20.1 Configuration and maintenance of the EMM system

The following examples highlight why ongoing maintenance of the electronic medication management (EMM) system and related clinical systems is needed to ensure the safe use of medicines:

- Each time a **new medicine** is added to the local health service organisation formulary, order sets or 'quick lists' may need to be created or modified, specific alerts or rules may need to be configured, and – if the new medicine is restricted – 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 medication reference information** is released, the medication reference information database in the EMM system needs to be updated
- Each time a **new organisation policy** regarding medication use is released, the policies and protocols governing its use in the EMM system should also be configured.

20.4 EMM software upgrades

The EMM software will generally require upgrading for two main reasons:

- As part of routine software improvements and known 'bug' fixing services that are periodically released by the EMM solution provider
- To introduce new EMM functionality in line with contemporary Australian clinical practice.

Upgrades to the EMM software should be fully tested in a separate test environment before being implemented in the production EMM environment. It is important for governance to approve the changes before introducing them, including any competency requirements to use the new software.

Testing is a resource-intensive activity. However, care should be given to regression testing all other Australian developments to ensure that they remain fit for purpose.

EMM system users should be made aware of any planned outages in advance, and the timing of these outages should be scheduled to minimise the impact on safe medication management (for example, at night). Depending on how long the EMM system is offline, protocols for using paper medication charts may need to be followed, in line with business continuity plans.

The production EMM system should be backed up before any upgrade, and the protocol for rolling back the EMM system should be clearly defined and rehearsed in the case of a failed upgrade that would necessitate a rollback to the previous release of the EMM system.

Health service organisations should commit to using up-to-date versions of the EMM software.

20.5 Education and training

Education and training is discussed in detail in Section 15.10.

Ongoing education and training is essential, irrespective of the quality of the initial training. Continuing training might include refresher training or targeted training. It is important that governance approves all ongoing training programs and training materials.

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 drug 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.

20.5.1 Refresher training

Refresher training should be held regularly to allow EMM users to consolidate their understanding and use of the EMM system. If possible, refresher training should be held at regular times (for example, the first Monday of every month), so that users become aware of its availability and can make time to attend. Refresher training should use a dedicated training environment that mirrors the EMM production environment. However, it is essential that each screen of the training environment is clearly marked 'For training only' to ensure that any differences between the two systems could not result in confusion for EMM system users.

It is important to provide refresher training to prevent users from adopting unsafe or inefficient work practice or workarounds, which may be perpetuated by other EMM system users.

20.5.2 Targeted training for specific issues and users

Targeted training should be held for problematic issues or for specific users.

The requirement for additional training may be identified through ongoing monitoring of EMM system data or staff feedback sessions. For example, reviewing the EMM system data will identify areas of noncompliance or poor practice. Specific training sessions can then be provided to address these issues.

Mass training – for example, in a lecture theatre – is a practical option when providing targeted training on specific issues.

20.6 EMM solution provider support

Following the implementation of any EMM system, ongoing EMM solution provider support is required to:

- Ensure that the EMM system functions as specified and remains fit for purpose
- Ensure that the EMM system continues to function in line with Australian requirements, including
  - changes to the Australian regulatory environment
  - the national safety and quality agenda
  - PBS changes and updates
  - changes to technical data standards or de facto standards
- Provide advice and guidance that optimise the medication safety capabilities of the EMM system
- Respond to organisation requests for EMM system enhancements.

Chapter 23 identifies a range of opportunities for organisations to work with their EMM solution provider to improve the effectiveness of EMM systems.

20.7 Rehearsing and refining business continuity plans

Business continuity planning (BCP) is discussed in detail in Chapter 19.

It is essential that business continuity plans are rehearsed regularly.

After a BCP event, the EMM support team should review the effectiveness of the BCP arrangements and, if required, refine the business continuity plans before submitting them for approval by EMM governance.

21 Regulation, policy and compliance

21.1 Regulation

Electronic medication management (EMM) systems must comply with the legislative requirements of the state or territory in which the EMM system operates. Additionally, to claim Pharmaceutical Benefits Scheme (PBS) entitlements, EMM systems must comply with Australian Government PBS regulation.

Chief executive officers of health service organisations should be accountable for approving and assuring the ongoing use of EMM systems to prescribe, administer and dispense medicines, and for ensuring the safe use of EMM systems. This includes:

- Implementing a protocol with procedures for assigning roles and access to EMM systems
- Appointing people with responsibility for assigning individual access credentials to EMM system users
- Assigning accountability for compliance with the protocol to the drug and therapeutics committee (DTC) or the clinical governance committee.

21.1.1 Responsibilities of health service organisations

Health service organisations should ensure that the use of the EMM system is governed by the DTC or the clinical governance committee, which should include medication safety and clinical informatics expertise.

Each EMM system user should be assigned individual access credentials, secured by at least one method of authentication that identifies the user as an authorised user of the EMM system. EMM system users need to understand the importance of keeping their access credentials confidential and secure.

Organisations need to constrain EMM user access to functions aligned to their role – as defined by legislation in the state or territory in which the EMM system operates. Only authorised roles can prescribe, review, dispense and administer medicines. All medication orders and changes to them are auditable and attributable to the person(s) who made the changes.

Organisations need to ensure that the EMM system presents medication orders in such a way that the EMM user can be confident of the validity and currency of the medication orders. For example, the EMM system should support verbal medication orders and co-signatures, as defined by legislation in the state or territory in which the EMM system operates.

The EMM system should ensure that information on the quantity of medicine prescribed is exchanged with other systems in a manner that prevents accidental or intentional dispensing above the quantity prescribed. For example, ensure end-to-end electronic transaction of medication orders between the EMM system, dispensing systems and third-party systems such as prescription exchange services.

The EMM system should ensure that controlled medicine orders are valid for prescribing, dispensing and administering only during the validity period defined by the legislation in the state or territory in which the EMM system operates. These include Schedule 8 medicines and some Schedule 4 medicines. Where these medicines are to continue beyond the duration defined in the legislation, the medication order should be renewed, and the date and time of the renewal recorded.

Records of current and recently ceased medication orders should be available during EMM system downtime, to uphold medication safety. To support EMM system downtime, business continuity plans should be documented, rehearsed, reviewed and updated regularly.

All prescribing, dispensing and administering records should be retained for a period defined by the legislation in the state or territory in which the EMM system operates, and be available in a timely manner to an inspector appointed under the legislation.

As far as possible, the EMM system should conform to the functional and non-functional requirements defined in Chapter 9.

The EMM system needs to display sufficient patient identification details to ensure that the EMM system user can verify the identity of the patient for each prescribing, dispensing and administering activity. Similarly, EMM systems must meet the mandatory prescribing data elements defined by the legislation in the state or territory in which the EMM system operates, to direct medicine administration or dispensing. For example:

- The patient's name, date of birth and unique identifiers
- The authorised prescriber's name
- The medicine's active ingredient(s) or brand name (where approved for use by the facility)
- The route of administration, and (if applicable) the strength and form
- The date and time of prescribing
- For a regular use medicine
  - the dose to be administered
  - the frequency and times for administration
  - the number of doses
  - the intended duration of treatment
  - the date and time for prescribing review (either nominated by the prescriber or as a function of the EMM system)
  - the current status of the medicine order
- For a 'when required' medicine
  - the maximum individual dose
  - the maximum daily dose
  - the hourly frequency of administration
  - the maximum number of doses, either for a 24-hour period or the minimum dosage interval
  - the duration of treatment until review (either nominated by the prescriber or as a function of the EMM system).
  - the current status of the medicine order.

Printed paper-based medication charts generated by the EMM system should be approved by the DTC and only used in the following circumstances:

- When the prescriber prints and signs the chart
- When a person authorised in line with the EMM business continuity planning procedures approved by the DTC or clinical governance committee prints the chart
- When an authorised EMM user prints the chart, to facilitate medication reconciliation where patients transfer to and from clinical areas not using the EMM system (for example, where paper medication charts operate, where a different EMM system operates and there is no interface between the EMM systems).

Printed paper-based prescriptions generated by the EMM system and used by a pharmacist for dispensing should be approved by the DTC. The prescription must be printed as defined by the legislation (and any associated technical guidance) in the state or territory in which the EMM system operates.

The prescription must be printed and signed by the prescriber where the EMM system cannot ensure that the quantity of medicine is prescribed in a way that prevents accidental or intentional dispensing above the quantity prescribed. This may occur where there is no electronic transaction of medication orders between the EMM system, dispensing systems and any third-party systems such as prescription exchange services.

To prescribe a Section 100 Highly Specialised Drugs medicine that meets PBS regulations, or to prescribe medicines for community pharmacy dispensing, the prescription must also be printed and signed by the prescriber.

21.1.2 Responsibilities of EMM users

Regulation places responsibilities on all EMM users, including obligations of privacy and record keeping. Specific responsibilities for groups of EMM users also apply.

Prescribers must:

- Be legally authorised to prescribe medicines in line with the poisons legislation of the state or territory in which they practise
- Prescribe medicines in line with the poisons legislation of the state or territory in which they practise
- Be registered with the Australian Health Practitioner Regulation Agency (AHPRA) in line with registration currency rules determined by AHPRA
- Be authorised to prescribe PBS-eligible medicines, if required to do so
- Be credentialed with a defined scope of practise at the health service organisation where they practice.

21 Regulation, policy and compliance

Pharmacists must:

- Be legally authorised to dispense medicines in line with the poisons legislation of the state or territory in which they practise
- Be registered with AHPRA in line with registration currency rules determined by AHPRA
- Practise in line with the professional practice standards of the pharmacy peak bodies
- Be credentialed with a defined scope of practice at the health service organisation where they practise.

Nurses and midwives must:

- Be registered with AHPRA in line with registration currency rules determined by AHPRA
- Practise in line with the professional practice standards of the nursing peak bodies
- Be credentialed with a defined scope of practice at the health service organisation where they practice.

21.2 Policy

The use of the EMM system must be underpinned by organisation policies that should include:

- The roles and responsibilities of those prescribing, supplying and administering medicines though the EMM system
- How the EMM system should be used in clinical workflow
- Arrangements and obligations of EMM governance
- How EMM data should be reported, prioritised and used to improve medication safety.

An EMM system is complex, and the way in which the EMM system is used will often be unique to the application software solution mix that the organisation uses. Policies that describe this complexity will mean that EMM users are clear and confident about the use of the system. For private health service organisations, it is especially important that policies are in place, because many visiting medical officers (VMOs) will use different systems, including different EMM systems at other organisations. Some VMOs visit health service organisations infrequently, making it essential that appropriate EMM policies are in place to ensure that the EMM system is used as intended.

The benefits of developing EMM policies include that they:

- Provide clarity regarding clinician responsibilities in using the EMM system
- Encourage a consistent approach to using the EMM system
- Establish a clear baseline for assessing compliance
- Promote confidence in the use of the EMM system
- Reinforce best practice and EMM training
- Act as reminders for infrequent EMM users
- Improve medication safety and quality.

Organisation policies for EMM systems should reflect:

- The legislation of the state or territory in which the EMM system operates
- Australian Government legislation in relation to PBS regulations
- The scope of EMM use within the health service organisation
- The responsibilities of clinicians using the EMM system
- The required medication management workflow
- The EMM application solution mix in place at the organisation.

21.2.1 Policies supporting legislative requirements

State or territory legislation, and PBS regulations should be clearly defined and contextualised in EMM policies so that EMM users are clear about their obligations. The legislative requirements of EMM systems, which should be supported by EMM policies, are covered in Section 21.1.

21.2.2 Policies supporting the scope of EMM use

EMM policies should clearly define the services or units that will be using EMM (the geographic scope), and the classes of medicines covered by the EMM system. Where more than one system contains medication information, policies should define which system should be used and in what circumstances.

The geographic scope of electronic prescribing should consider:

- The extent to which emergency department (ED) prescribing will occur – that is, whether for all attendances or only for those patients to be admitted
- When and where medication reconciliation will occur, and whether any prioritisation of patient cohorts is to be followed
- Pre-admission clinic prescribing for day-of-surgery admissions
- Inpatient prescribing, defining the clinical units that will prescribe electronically and any clinical units that will be exempt
- Prescribing for anaesthetic and theatre, intensive care units (ICUs), chemotherapy units, other specialist units, discharge and ambulatory settings.

EMM policies should clearly define which classes of medicines are in scope for EMM use and which should remain paper based. Medicines in scope for EMM may be all classes or specific classes, such as antimicrobials, chemotherapy medicines, intravenous fluids, patient-controlled analgesia medicines and blood products. The policy should clearly identify how prescribers will be made aware of the existence of any paper-based medication charts. It should also describe the requirements that support medication safety in transcribing medicines from electronic systems back to paper and vice versa.

21.2.3 Policies reflecting clinician responsibility

EMM policies should clearly define, for each craft group or specialty, the EMM functions that they are expected to use.

Each craft group's scope of clinical practice will determine their EMM scope. The EMM policies should consider how the EMM system will be used by:

- Public hospital senior and junior medical staff
- Private hospital VMOs and community medical officers
- Anaesthetists in relation to pre-admission clinic medication reconciliation, day-of-surgery prescribing, and in-theatre electronic prescribing and administration
- Surgeons who may be exempt from electronic prescribing, but may be required to document electronically postoperative medicines at the end of surgery for subsequent prescribing by others
- Intensivists who prescribe electronically for all patients admitted to the ICU and document electronically any post-ICU medication requirements for patients transferring elsewhere in the hospital
- Intensivists who prescribe ICU medicines in a different system from the general EMM system and need to ensure medication reconciliation on transfer into and out of the ICU
- Oncologists who might be required to use the general EMM system for general oncology patients, and prescribe electronically in a different system for day chemotherapy
- ED prescribers, whether they prescribe electronically for all ED attendances or only attendances requiring hospital admission
- Inpatient teams receiving ED admissions, including when they take responsibility for prescribing and administering medicines for patients who are still physically located in the ED.

Sufficient specificity should be provided in the policies to ensure that EMM users can meet their obligations. EMM policies should consider roles, responsibilities and workflow associated with:

- The medication reconciliation requirements on admission, transfer and discharge, and for recording medication allergies
- Requirements associated with
  - certain classes of medicines, such as antimicrobials, chemotherapy medicines, intravenous fluids, patient-controlled analgesia medicines and blood products
  - other systems in operation that include medicines, such as ICU and day chemotherapy
  - any maximum prescription duration and review times
  - ensuring a valid PBS prescription and PBS claiming
- Telephone medication orders
- Responding to prescribing alerts
- Printing, annotating and signing prescriptions, and recording changes to existing electronic prescriptions
- Discharge prescribing and discharge medication information available in discharge summaries
- Clarifying medication orders with prescribers, dispensing medicines and rejecting medication orders.

21.2.4 Policies that support medicines management workflow

EMM policies should clarify expectations regarding preferred prescribing, dispensing and administration workflow using the EMM system. Policies should consider:

- The staff member or team that has responsibility for medication reconciliation at each transfer point
- When prescribers delegate electronic prescribing to junior staff – there should be guidance about the handling of electronic prescribing alerts, so that junior doctors understand the protocol for seeking clarification from their senior colleagues or pharmacists
- Workflow that ensures PBS medication orders are valid at the point of prescribing, including defining expectations about the recording of streamlined authority codes and authority approval numbers
- How the medicine orders are relayed to the pharmacy and processed
- Interoperability between the EMM system and the dispensing system, so the medication orders are transferred electronically
  - where there is no interface between the EMM system and the dispensing systems, policies should clarify how transcription errors are to be avoided when re-entering medication orders into the dispensing system, such as by using two-person validation
- How medication orders are clarified with prescribers, and how changes made to medication orders are clarified before they are dispensed
- How telephone orders are followed up where the elapsed time for telephone orders is exceeded, according to state or territory legislation
- How to claim for PBS medicines.

21.2.5 Policies that support the EMM application software solution mix

EMM policies should consider the software solution mix in the health service organisation. The solution mix might consist of:

- One or more systems supporting medication management
- The dispensing system
- Discharge summary systems
- The clinical information system or electronic medical record, where EMM is separate from the clinical system.

Interoperability between prescribing and dispensing systems must also be considered, as well as interaction with systems external to the health service organisation, such as the My Health Record system.

Where there is more than one system in use that supports medication management, EMM policies should consider:

- A clearly defined scope of use for each system
- How medication reconciliation considers the information available in the other systems
- How the systems should be used where the patient has records in both systems, including how the existence of information in other systems is brought to the attention of the prescriber
- How medication information is transferred between systems as the patient moves between health services.

EMM policies should consider how information passes between the EMM system and dispensing systems, including how:

- Transcription errors are to be avoided when re-entering medication orders into the dispensing system (for example, using two-person validation) where there is no interoperability between the EMM system and the dispensing system
- Changes to medication orders are managed and synchronised between the EMM system and the dispensing system, where medication orders are transferred electronically
- Prescriptions are clarified and annotated, and in which system.

Where there is a separate discharge summary system, EMM policies should consider how:

- The discharge medicines are made available to the discharge summary system
- Information is made available to the discharge summary system if some of the discharge medicines are not required to be dispensed, or if some of the discharge medicines are clarified and changed
- The sequencing of transactions for prescribing, dispensing and discharge summary sign-off ensures that any changes to discharge medicines are incorporated into the discharge summary (including re-sending an updated discharge summary, if required).

21.3 Compliance

Health service organisations should regularly audit their EMM systems, to ensure that the systems are being used in line with policies to continuously improve medication safety and quality.

Audits should be in line with an agreed and published audit plan, developed by the EMM governance committee and signed off by the DTC.

The results of audits should be followed up with relevant subcommittees, clinical governance structures or individual clinicians, and agreed outcomes should be documented and reviewed.

22 Monitoring and evaluation

The electronic medication management (EMM) system should have the capacity to capture data to use for evaluation. For example, it should capture:

- 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 health service organisation medication policies
- The preferences of clinical staff in navigating the EMM system
- The timeliness of EMM activities, such as medication reconciliation on admission, pharmacy review, countersigning telephone orders and discharge medication orders.

In addition, the EMM system should be able to generate reports to:

- Monitor the usage behaviour of clinicians using the EMM system, including patterns of usage
- Identify and diagnose recurrent issues or risks, such as potential system workarounds
- Audit and evaluate the root cause of reported incidents
- Provide other data to support ongoing evaluation of the EMM system against defined baseline indicators.

Reviewing this information allows constant refinement of the EMM system and the way it supports safe medication management, and identifies the need for additional targeted training. For example, it should identify those who do not use the system as intended and frequently resort to workarounds. Review also allows communications to be tailored towards addressing EMM system issues or highlighting examples of significant improvements in medication management.

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 time lines associated with making this change should be communicated to all EMM users.

Health service organisations can use the English National Health Service *Digital Maturity Assessment*[16] to determine their priorities for continuous quality improvement and innovation.

22.1 Benefits measurement

Benefits measurement is an ongoing process that should be monitored in line with the benefits register.

Section 15.9 considers benefits measurement in detail, including benefits realised by Australian EMM sites.

22.2 Optimising EMM workflow and medication safety

It is essential that EMM systems support optimised medicines workflow in a way that encourages clinician uptake and use, and maximises medication safety.

Health service organisations should encourage EMM solution providers to differentiate their solutions for medication workflow and medication safety. Collaboration with other EMM sites using the same solutions should be considered.

Organisations should ensure that their EMM systems:

- Are implemented in as many clinical services as possible, with as few exceptions as possible
- Support national medication safety standards
- Provide optimum medication workflow
- Maximise medication safety features.

Health service organisations should encourage their EMM solution providers to maximise opportunities for medication safety, including:

- Providing improved decision support by linking data about medicines and non-medicines, making EMM systems more intelligent, streamlining clinical workflow and improving the user experience
- Avoiding the need for clinicians to re-enter clinical data that already exist in the EMM system, potentially reducing dose administration errors caused by transcribing data
- Increasing the use of predisposing patient risk factors to reduce the volume of clinically insignificant alerts, potentially reducing alert fatigue[51], which would enable EMM sites to increase their EMM clinical decision-support content
- Helping health service organisations to develop interoperable solutions where more than one EMM system is in use, minimising transcription errors as patients move between settings

- Providing longitudinal patient medication records across inpatient stays and ambulatory visits that provide better medication reconciliation between settings
- Optimising Pharmaceutical Benefits Scheme (PBS) workflow, including improved mapping of generic inpatient medication orders and PBS-listed products at discharge (where applicable)
- Ensuring optimised PBS prescribing, such as use of the planned new online PBS Authority Approval system
- Providing standard reports, integrated operational dashboards and data extraction capabilities that helps organisations to develop their data analytics capabilities.

Another way to maximise medication safety is to have the system vendors ensure interoperability between EMM and dispensing solutions that avoids transcription errors. This provides greater opportunity for transparency between what is prescribed and what is dispensed.

EMM system vendors could also ensure that interoperability is extended to bidirectional support that enables:

- The prescribed medication orders to be matched to the dispensed medication orders
- Prescribed and dispensed medicines to be included in the discharge summary
- A prescriber work queue to help resolve the medication orders that have come back because they require clarification
- Electronic communication between prescribers and pharmacists that is transparent, avoids misunderstanding and can be audited.

The Australian experience suggests that substantial work is required to optimise use of EMM systems to better support medication safety and deliver efficient clinical workflow.

23 Continuous quality improvement and data analytics

One of the most important reasons for implementing an electronic medication management (EMM) system is to use the resulting medication management data to improve medication safety through a process of continuous quality improvement and innovation.

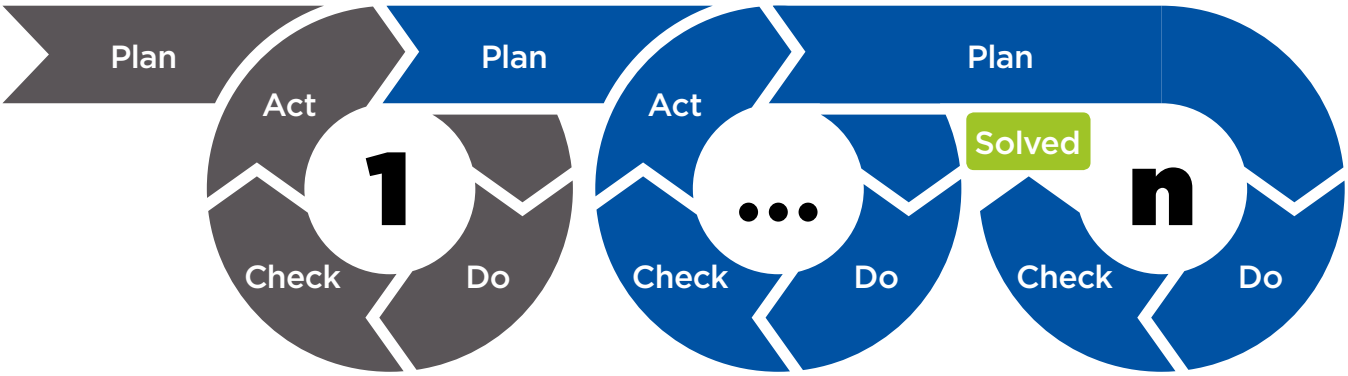
A continuous quality improvement process should be implemented and embedded in the culture of the health service organisation. Feedback loops are critical to ensure that clinician issues are fed back to the EMM support team for follow-up action.

Opportunities for improved medication safety should be identified and investigated, 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.

23.1 Continuous quality improvement

Plan–do–check–act (PDCA), also referred to as plan–do–study–act (PDSA), is an iterative four-step management method popularised by W Edwards Deming. It is used in business to control and continually improve processes and products. Multiple iterations of the PDCA cycle are repeated until the problem is solved (see Figure 23.1).

Figure 23.1 The plan–do–check–act cycle



Source: Christoph Roser (AllAboutLean.com)

Health service organisations should systematically apply PDCA-type techniques to achieve improvements in medication safety and efficient medication management workflow based on the clinical priorities of the organisation.

Once an EMM system has been implemented, Australian EMM sites report being overwhelmed by a 'data tsunami'. That is, large volumes of prescribing and medication data are easily extracted. However, a planned and systematic approach built on carefully designed queries and analyses is required to achieve the benefits first postulated in the business case.

Health service organisations should develop annual plans for the systematic improvement in medication safety and efficient clinical workflow enabled by their EMM systems. In prioritising audit and innovation work programs, organisations should consider:

- National medication safety priorities, such as medication reconciliation, antimicrobial stewardship (AMS) and venous thromboembolism (VTE) prophylaxis
- Known priority local medication safety issues
- EMM system nuisances reported by clinical users of the EMM system that, if fixed, would encourage better uptake and use of the EMM system
- State or territory medication safety priorities – for example, those set by the NSW Clinical Excellence Commission[52]
- The management of high-risk medicines.

It is important to develop a balanced annual work program that has wide organisational appeal. Ideally, the annual work program should include low-hanging fruit, strategic objectives, medication safety improvements and clinician workflow efficiencies.

The work programs should be developed through EMM governance, and be signed off and regularly monitored by the drug and therapeutics committee.

Consultation with Australian hospitals during the development of this guide identified three good examples of EMM-based continuous quality improvement processes.

One site has had three iterations of improved AMS capability. In the first iteration, a standalone AMS capability was implemented, before the implementation of EMM, with AMS policy compliance rates of approximately 30%. In the second iteration, the EMM system was implemented. The prescriber had to access the standalone AMS capability, complete the prescribing protocol or pathway, obtain a prescribing approval number and enter the approval number into the EMM system. With the implementation of the EMM system, clinicians were using the computer more frequently for their work, with less disruptive and broken workflow, resulting in AMS policy compliance rates increasing from 30% to 75%.

The most recent iteration involved the synchronisation of the standalone AMS capability with the EMM system. The AMS capability is called from within the EMM system, and there is no separate login and no duplicate data entry. This approach streamlines prescriber workflow, reduces the time required to prescribe antimicrobials and encourages prescriber compliance with AMS policy. At the time of publication of this guide, the results of this third iteration were not known.

Another site uses a glucose management tool that combines relevant diagnostic results (blood glucose levels, ketones, renal function) with prescribed medicines (such as insulin). It presents a time-based relationship across 72 hours, and displays diagnostic results and antidiabetic medication doses as graphs.

A third site uses a VTE prophylaxis tool that brings together the VTE risk assessment, review of relevant diagnostic results (including coagulation and estimated glomerular filtration rate), and commonly prescribed medicines and other orders used for VTE prophylaxis.

23 Continuous quality improvement and data analytics

23.2 Data analytics

One of the main benefits of using an EMM system is the ability to analyse data to interpret, inform, communicate and prioritise decisions on all aspects of medication management. Continuous quality improvement is underpinned by the management and analysis of data sourced from the EMM system.

Data from EMM systems will typically include:

- EMM user data, such as usage frequency, usage duration and transaction and audit logs
- Volumetric data, such as medicines ordered, doses administered, missed doses, alerts fired, alert overrides, pharmacy reviews and medicines reconciled
- Timing data, such as timeliness of medicines administered, timeliness of medicines reconciled, time to VTE prophylaxis and timeliness of discharge medicines ordered
- Usage data, such as prescriber preferences (for example, freehand prescribing), use of order sentences, off-formulary prescribing, alert override reasons, how discharge medicines are selected, how medicine orders are changed (that is, did the medicine change, or was it suspended and a new medicine ordered)
- Data on EMM system performance, such as response times, user volumes and activity peaks.

EMM data can be made available in a variety of ways:

- Ad hoc queries in response to specific issues or projects
- Standard reports
- Integrated dashboards and analytics modules
- Business intelligence (BI)
- Data extract facilities.

Standard reports are predefined in the EMM system, usually with some user-defined parameters (for example, date range and clinical unit). Although standard reports can be useful, the available information is often constrained. Some health service organisations develop their own standard reports, but many organisations lack people with the necessary skills to customise such reports.

Integrated dashboards present operational data against defined key performance indicators that support more timely intervention. This includes overdue weights for neonates, delays to the administration of priority medicines and ceased medication orders that have not been reviewed. Integrated analytics modules provide more sophisticated and flexible reporting capabilities than predefined dashboards, and support user empowerment to explore data.

BI provides reporting capabilities that are external to the EMM system. It is most effective when data from different sources are combined to create a more complete picture that cannot be derived from a single dataset. BI also supports users to undertake 'what if' scenarios from predefined datasets. BI is the vendor-neutral equivalent of the integrated analytics modules, but requires substantial organisational governance and resource commitments to develop, implement and support. BI tends to be the result of a strategic investment by health service organisations.

Using data to support continuous improvement in medication safety remains relatively underdeveloped at Australian EMM sites. EMM sites report being:

- Overwhelmed by the 'data tsunami'
- Frustrated at being unable to access EMM data to support practice improvements
- Frustrated about resistance to excessive guidance too early in the implementation – it is important to get the balance right initially, and evolve practices over time as supported by the data.

To help with data analytics, health service organisations should:

- Establish data governance arrangements
- Determine the available reporting capabilities
- Decide on the priorities for improvement
- Publish annual audit and innovation work programs
- Manage and report progress through governance.

Data governance arrangements are critical where organisations are seeking to empower users to access and use data, or where information systems (such as the EMM system) are subject to frequent change. It is essential that any changes to the EMM system are considered holistically by governance before any changes are made, to prevent unintentional downstream issues.

Given the complexity of clinical systems and the interdependencies between systems, organisations

are likely to have existing organisation-wide data governance arrangements in place. Where this occurs, mechanisms are required so that the EMM operational governance group can deliver on its EMM audit and innovation work programs.

EMM data provide enormous opportunities to refine and improve how the EMM system is used to improve medication safety, improve clinician workflow and create efficiencies. However, the audit and innovation work programs should also consider other clinical data, where they are available, in line with organisation priorities. Examples at Australian EMM sites where data from medicines and other areas have been used together include tools for glucose management and VTE prophylaxis.

The availability of data is critical for continuous quality improvement to be successful. For each element of the agreed work programs, health service organisations should:

- Review the available data
- Consult with clinical colleagues and establish consensus on a preferred way forward
- Make the case for the change
- Implement the desired changes
- Disseminate the findings
- Review and, if required, further refine the changes.

Each case for change identified by the work program could include some or all of the following:

- Awareness and education materials
- Multidisciplinary consultation and consensus
- Reconfiguration of the EMM system
- Testing
- Training
- Reporting.

Glossary

Term	Definition
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.
application mix	The mix of software and workflow solutions that are used to deliver a complete EMM system for an organisation.
around-the-clock support	Support is available 24 hours a day to fix any issues with the EMM system while users are working or using it.
assisted data import	A method to improve and better standardise the method of transferring discrete information from clinical documents to local records.
big-bang implementation	An implementation that goes live in all (or most) of the health service wards in a relatively short time.
clinician	A healthcare professional who is involved in the clinical care of a patient.
current medicine order status	The context in which a medicine order appears in the EMM system. Specific terms may vary between vendors, however generally this may include: active or current; suspended or withheld; discontinued, ceased or completed.
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 time given before implementing the EMM system for delivery of the communications strategy and other relevant planning, to ensure that stakeholders are well informed about the project objectives, planning, timing and expected benefits.
go-live	The period during which the planning for implementation is actioned (that is, the transition from planning to doing), and the EMM system that has been in development or operating in a limited test mode becomes fully active so that users can access it.
granular medication information	Data that are coded and structured to allow information to flow between systems (to support interoperability) and provide the ability to mine the information for quality improvement. Granularity is the level of depth represented by data in a fact or dimension table in a data warehouse. High granularity means a minute, sometimes atomic, grade of detail, often at the level of the transaction. Low granularity zooms out into a summary view of data and transactions.
high-availability system	A system that is always available.
rollback	A return 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.
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.

References

1. Australian Commission on Safety and Quality in Health Care. Electronic medication management systems: a guide to safe implementation, 2nd edition. Sydney: ACSQHC; 2011.
2. Baysari M, Richardson L, Zheng WY, Westbrook J. Implementation of electronic medication management systems in hospitals: a literature scan. Sydney: Australian Commission on Safety and Quality in Health Care; 2016.
3. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards – Version 2. Sydney: ACSQHC; 2016.
4. Australian Commission on Safety and Quality in Health Care. NIMC user guide. Sydney: ACSQHC; 2016.
5. Australian Government Department of Health. PBS Hospital Medication Chart [Internet]. Canberra: DoH; 2017 [cited 2017 20 April]. Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-hmc
6. Australian Commission on Safety and Quality in Health Care. National guidelines for on-screen display of clinical medicines information. Sydney: ACSQHC; 2016.
7. Australian Government Department of Health. National Medicines Policy. Canberra: DoH; 2011.
8. National Health and Hospitals Reform Commission. A healthier future for all Australians: National Health and Hospitals Reform Commission final report. Canberra: Australian Government Department of Health; 2009. http://www.cotasa.org.au/cms_resources/documents/news/nhhrc_report.pdf (accessed Jun 2017).
9. Horsky J, Kaufman DR, Oppenheim MI, Patel VL. A framework for analyzing the cognitive complexity of computer assisted clinical ordering. J Biomed Informat 2003;3(1–2):4–22.
10. Khaushal R, Shojania KG, Bates D. Effects of computerized physician order entry and clinical decision support systems on medication safety. Arch Int Med 2003;163:1409–16.
11. Schiffman R, Liaw Y, Brandt C, Corb G. Computer-based guideline implementation systems: a systematic review of functionality and effectiveness. JAMIA 1999;6(2):104–14.
12. 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, editors. 18th Annual Health Informatics Conference: Informing the Business of Healthcare; Melbourne. Informatics Society of Australia; 2010. p. 96–100.
13. Ammenworth E, Schnell-Inderst P, Mcachan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: a systematic review. JAMIA 2008;15(5):585–600.
14. Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Canberra: APAC; 2005.
15. HiMSS Europe. EMRAM: a strategic roadmap for effective EMR adoption and usage [Internet]. Berlin: HiMSS Europe; 2017 [cited 2017 Apr 20]. Available from: http://www.himss.eu/healthcare-providers/emram
16. NHS England. Digital maturity assessment [Internet]. London, UK: NHS England; 2017 [cited 2017 Apr 20]. Available from: https://www.england.nhs.uk/digitaltechnology/info-revolution/maturity-index/
17. Australian Government Department of Health. Quality use of medicines (QUM) strategy. Canberra: DoH; 2004. http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-pdf-natstrateng-cnt.htm (accessed Jun 2017).
18. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards, Standard 4: Medication safety. Sydney: ACSQHC; 2012.
19. Metcalfe J, Lam A, Lam S, de Clifford J, Schramm P. Impact of the introduction of computerised physician order entry (CPOE) on the surveillance of restricted antimicrobials and compliance with policy. J Pharm Prac Res 2016;46:1–7.

References

20. Australian Commission on Safety and Quality in Health Care. Antimicrobial stewardship resource materials [Internet]. Sydney: ACSQHC; 2017 [cited 2017 Apr 20]. Available from: https://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/antimicrobial-stewardship/resource-materials/

21. Australian Commission on Safety and Quality in Health Care. Antimicrobial stewardship in Australian hospitals. Sydney: ACSQHC; 2011.

22. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards, Standard 5: Patient identification and procedure matching. Sydney: ACSQHC; 2012.

23. Office of the Australian Information Commissioner. National privacy principles [Internet]. Sydney: Office of the Australian Information Commissioner; 2017 [cited 2017 Apr 19]. Available from: https://www.oaic.gov.au/privacy-law/privacy-archive/privacy-resources-archive/national-privacy-principles

24. Australian Commission on Safety and Quality in Health Care. National guidelines for on-screen presentation of discharge summaries. Sydney: ACSQHC; 2017.

25. Australian Digital Health Agency. My Health Record statistics [Internet]. Canberra: ADHA; 2017 [cited 2017 Apr 20]. Available from: https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/Content/news-002

26. Australian Digital Health Agency. Clinical documents [Internet]. Canberra: Australian Digital Health Agency; 2017 [cited 2017 Apr 27]. Available from: http://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/features-of-the-my-health-record-system/clinical-documents

27. Australian Commission on Safety and Quality in Health Care. My Health Record safe use guide for healthcare providers. Sydney: ACSQHC; 2016.

28. Australian Digital Health Agency. Resources for implementers and developers [Internet]. Canberra: Australian Digital Health Agency; 2017 [cited 2017 Apr 28]. Available from: https://www.digitalhealth.gov.au/implementation-resources

29. Australian Government Department of Human Services. Healthcare identifiers service for health professionals [Internet]. Canberra: DHS; 2017 [cited 2017 Apr 20]. Available from: https://www.humanservices.gov.au/health-professionals/services/medicare/healthcare-identifiers-service-health-professionals

30. Australian Digital Health Agency. My Health Record system and Healthcare Identifiers (HI) [Internet]. Canberra: Australian Digital Health Agency; 2017 [cited 2017 Apr 28]. Available from: https://www.digitalhealth.gov.au/get-started-with-digital-health/what-is-digital-health/features-of-the-my-health-record-system/my-health-record-system-healthcare-identifiers

31. Australian Digital Health Agency. SNOMED CT-AU guide for terminology use in prescribing. Canberra: Australian Digital Health Agency; 2016.

32. Therapeutic Goods Administration. Uniform recall procedure for therapeutic goods. Canberra: TGA; 2004. https://www.tga.gov.au/publication/uniform-recall-procedure-therapeutic-goods-urptg-2004-edition (accessed Jun 2017).

33. Australian Digital Health Agency. Clinical documents – My Health Record useability recommendations, v1.4. Canberra: Australian Digital Health Agency; 2016.

34. Roughead EE, Semple SJ, Rosenfeld E. Literature review: medication safety in Australia Sydney: Australian Commission on Safety and Quality in Health Care; 2013. https://www.safetyandquality.gov.au/wp-content/uploads/2013/08/Literature-Review-Medication-Safety-in-Australia-2013.pdf (accessed Apr 2017).

35. 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. Qual Safe Health Care 2007;16:279–84.

36. Littlejohns P, Wyatt JC, Garvican L. Evaluating computerised health information systems: hard lessons still to be learnt. BMJ 2003;326:860.

37. Lorenzi N, Riley RT. Managing change: an overview. JAMIA 2000;7(2):116–24.

38. Australian Government Department of Finance and Deregulation. ICT business case guide development and review. Canberra: DFD; 2008.

39. Victorian Department of Treasury and Finance. Investment lifecycle guidelines: business case. Melbourne: DTF; 2008.

40. Westbrook JI, Li L, Georgiou A, Paoloni R, Cullen J. Impact of an electronic medication management system on hospital doctors' and nurses' work: a controlled pre-post, time and motion study. JAIMA 2013;20(6):1150–8.

41. Sittig DF, Wright A, Ash J, Singh H. New unintended adverse consequences of electronic health records. IMIA Yearbook Med Inform 2016:7–12.

42. Australian Commission on Safety and Quality in Health Care and NSW Therapeutic Advisory Group Inc. National quality use of medicines indicators for Australian hospitals. Sydney: ACSQHC; 2014.

43. Australian Commission on Safety and Quality in Health Care. National inpatient medication chart audit tool. Sydney: ACSQHC; 2010.

44. NHS England. Benefits realisation guidance for e-prescribing projects. London, UK: NHS England; 2014.

45. Jenner S. Managing benefits. Second ed. London, UK: The Stationery Office; 2014.

46. Westbrook JI, Reckmann M, Li L, Runciman WB, Burke R, Lo C, et al. Effects of two commercial electronic prescribing systems on prescribing error rates in hospital in-patients: a before and after study. Pub Lib Sci Med 2012;9(1):e1001164.

47. Smith R, King D, Sidhu R, Skelsey D, APMG. The effective change manager's handbook: essential guidance to the change management body of knowledge. London, UK: Kogan Page; 2014.

48. Bates DW, Cohen M, Leape L, Overhage JM, Shabot M, Sheridan T. Reducing the frequency of errors in medicine using information technology. AJAMIA 2001;8(4):299–308.

49. National Health Service UK. Guidelines for hazard review of e-prescribing systems. London, UK: NHS; 2008.

50. Institute for Safe Medication Practices. ISMP's list of high-alert medications [Internet]. Horsham, PA: Institute for Safe Medication Practices; 2008 [cited 2011 Apr 20]. Available from: http://www.ismp.org/Tools/highalertmedications.pdf

51. Phansalkar S, Desai A, Bell D, Yoshida E, Doole J, Czochanski M, et al. High priority drug to drug interactions for use in electronic health records. JAMIA 2012;19:735–43.

52. NSW Clinical Excellence Commission. Medication safety and quality [Internet]. Sydney: NSW CEC; 2017 [cited 2017 Apr 20]. Available from: http://www.cec.health.nsw.gov.au/patient-safety-programs/medication-safety/medication-safety-and-quality

Australian Commission on Safety and Quality in Health Care

Level 5, 255 Elizabeth Street, Sydney NSW 2000
GPO Box 5480, Sydney NSW 2001

Phone: (02) 9126 3600 (international +61 2 9126 3600)
Fax: (02) 9126 3613 (international +61 2 9126 3613)

Email: accreditation@safetyandquality.gov.au
www.safetyandquality.gov.au