

NATIONAL MEDICATION SAFETY
AND QUALITY SCOPING STUDY
COMMITTEE REPORT

21 APRIL 2009



Mr Bill Beerworth
Chairman
Australian Commission on Safety and Quality in Health Care

Dear Mr Beerworth

National medication safety and quality – Scoping study report

On behalf of the members of the National Medication Safety and Quality Scoping Study Steering Committee (the Steering Committee), it is my pleasure to submit our final report for the consideration of the Commission.

The Steering Committee has met since April 2008 and considered the results of an extensive consultation process undertaken by Commission staff. Input was received from a large number of stakeholders and consultation meetings have been held in all States and the Australian Capital Territory. I would like to acknowledge the valuable contributions of stakeholders during the Study.

Australia is well respected internationally for its efforts to improve the safety and quality of health care, in large part due to the leadership of the Australian Commission on Safety and Quality in Health Care and its predecessor. There is still, however, important work to be done in national medications safety and quality to ensure that medication therapies are safe, effective and responsive to the needs of consumers.

I believe that the recommendations in this Report will, if adopted, improve current national medications safety and quality and lead to measurable improvement in the safety and quality of patient care and the efficiency of health service delivery.

I commend the Report to the Commission.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'L Sansom', with a stylized flourish at the end.

Emeritus Professor Lloyd Sansom AO

Chair

National Medicines Safety and Quality Scoping Study Steering Committee

29 November 2008

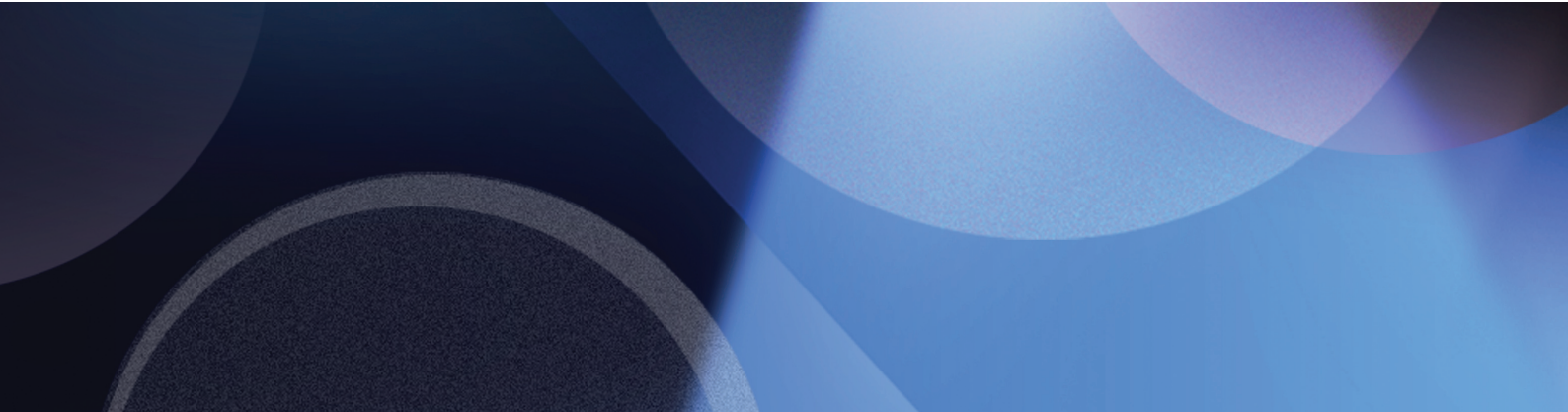
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EXECUTIVE SUMMARY



EXECUTIVE SUMMARY

Background

In 2007–2008, the Australian Commission on Safety and Quality in Health Care (the Commission) included initiatives to improve the safety and quality of medicines use in its work plan which was endorsed by Health Ministers on 13 June 2007.

Following a request from the Joint Therapeutic Advisory Groups for the Commission to assume the role of leading and coordinating medication safety nationally, the Commission proposed a scoping study to consider the whole of national medication safety and quality. The National Medication Scoping Study Steering Committee (the Committee) was set up in February 2008 to guide the work. Committee members included representatives from the key national medication safety and quality organisations as well as expert clinicians (see Section 1.1). The Committee was charged with considering the adequacy of current national medication safety and quality activity. Further, it was asked to recommend additional activity which could improve the safety and quality of medication use in Australia. This report is the result of the Committee's deliberations and its consideration of input from extensive consultation.

Medicines are one of the most common causes of harm in health care. The rate of medication related hospital admissions in Australia is estimated at around 2 to 3%, with as many as 30% of unplanned geriatric admissions being associated with an adverse medicines event.¹ Approximately 50% of these admissions are considered potentially avoidable.¹ In the community, as many as 10% of patients experience an adverse drug event within the previous six months of presentation to their general practitioner.²

Current national medication safety and quality arrangements

The policy framework for medications in Australia is the National Medicines Policy, a whole-of-government policy launched in 1999. Its aim is to improve positive health outcomes for all Australians through their access to and wise use of medicines.

New arrangements to support the future implementation of the National Medicines Policy were announced in August 2008. While the new arrangements are maturing, the Commission will need to ensure that its medication safety activities complement and are aligned to the new National Medicines Policy advisory structure.

The key national agencies responsible for safe and quality use of medicines are:

- Therapeutic Goods Administration, Department of Health and Ageing
- Pharmaceutical Benefits Division, Department of Health and Ageing
- National Prescribing Service Ltd.

Although these agencies make important contributions to the safe and quality use of medicine, none has a specific focus on improving patient safety by enhancing medication safety across all settings of care.

Much of the activity to reduce patient harm from medicines occurs in the acute care sector. State and Territory health departments have committees that advise on and coordinate medication safety initiatives. Professional organisations, registration bodies, educational institutions, standards organisations, medicines industry and research institutes also contribute to improvements in the safety and quality of medicines use.

While there is much activity to improve the safe and quality use of medicines at all levels within the Australian health system, including with consumers, the Committee concluded that much of the work is uncoordinated, there is duplication of effort and some important work is not being done.

Improved medication safety through safe systems and practice

The Committee undertook a gap analysis to assess the adequacy of current national medication safety and quality activity.

The following were identified as areas where additional activity could enhance patient safety.

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1. The patient's journey through the health system

- Consumer access to information on medicines – including an accurate record of their own medicines
- Continuity of care – the transfer of accurate information between professionals and care settings, consistent funding systems and medication management processes in the community.

2. Product Safety

- Post-marketing pharmaco-vigilance particularly by linking existing data to identify adverse events and improve the quality use of medicines
- Systems to reduce errors caused by “look alike, sound alike” names and poor labelling and packaging design.

3. Medication management systems

- National standardisation of processes in the medication management pathway to reduce potential for errors associated with human factors such as slips and lapses
- Adoption of safe medication distribution systems in acute care settings
- Use of technology in the medication management pathway including electronic systems for prescribing and recording the administration of medicines and bar code checking of medicines administration at the bedside
- A national approach to incident monitoring, data analysis and the development and implementation of strategies to prevent recurrence of serious errors.

4. Healthcare professionals

- Adoption of best practice guidelines
- Training and assessment of competency in safe medication practice.

The Committee identified a range of actions at a national level that could enhance medication safety and the quality use of medicines. Actions that could be undertaken by the Commission are listed below in Table 1.1.

Table 1.1 Recommended actions for the Commission

1. The patient's journey through the health system
1.1 Consumer access to information
1. Advocate the safety and quality benefits of the proposed e-health record for medicines.
2. Work with NEHTA and DOHA E-Health Branch on the e-health record for medicines.
3. Recommend implementation of the APAC <i>Guiding principles for medication management in the community</i> .
4. Liaise with NPS on a communication strategy for consumers and health professionals to promote available options for accessing current medicines lists.
5. Consult with consumer organisations on consumer information needs, including CMI, and communicate preferred enhancements to key information providers.
6. Advocate increased access and review of the content, and format, of CMI and the mechanisms for delivery.
1.2 Continuity of care
7. Lead advocacy for the safety and quality benefits of a national approach to an e-health record for medicines.
8. Work with NEHTA and DoHA E-Health Branch to assist development and implementation of the e-health record for medicines in all care settings.
9. Advocate interoperability of systems between healthcare providers.
10. Recommend implementation of the APAC <i>Guiding principles for continuity of medication management</i> .
11. Promote medication reconciliation at care transition points including identifying resources (tools, models) to support implementation of medication reconciliation.
12. Lead advocacy for the safety and quality benefits of a national approach to the funding of pharmaceuticals.
13. Advocate eliminating the requirement for PBS prescriptions in private hospitals and residential care facilities, using the medication chart as the primary prescription record.
14. Recommend implementation of the APAC <i>Guiding principles for continuity of medication management, Guiding principles for medication management in the community and Guidelines for medication management in residential aged care facilities</i> .
15. Promote the safety and quality benefits of: <ol style="list-style-type: none"> a. Improving access to HMR and discharge liaison services; b. Linking the HMR program with specific health populations e.g. mental health; c. Improving communication about medicines and access to HMR / discharge liaison services in rural and remote areas and communities.

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2. Product safety

2.1 Enhancing post-marketing pharmaco-vigilance

16. Advocate the safety and quality benefits of enhancing post-marketing pharmaco-vigilance through linking data from existing data repositories.

2.2 Packaging and labelling as contributors to error

17. Work with TGA to improve the safety of labelling and packaging including giving prominence to the active ingredient equal to the brand name.
18. Work with TGA to establish a process for identifying and addressing reports of errors and patient harm caused by poorly designed labelling and packaging.
19. Work with pharmacy organisations to develop standards for improving labelling on dispensed products.
20. Work with key stakeholders to establish and implement standards for user applied labels for medicines in hospitals.

3. Medication management systems

3.1 Systems improvements through standardisations

21. Develop additional standard medication charts for residential and community care and high risk drugs in acute care.
22. Facilitate the development of a National Inpatient Medication Chart that can be generated by GP e-prescribing systems.
23. Develop a guidance document on the requirements for safe e-medication management systems including safe design features, use of safety alerts, and clinical decision support systems.
24. Lead the identification and development of standardisation initiatives to improve medication safety.

3.2 Medication distribution systems

25. Recommend national adoption of *Medication Safety Self Assessment for use in Australian Hospitals* to identify risks in acute care medication management systems and drive improvement.
26. Recommend national adoption of Medication Safety Self Assessment for *Antithrombotic Therapy in Australian Hospitals* to identify risks and drive improvement in acute care management of antithrombotic therapy.
27. Inform development of safe medication practice indicators for all settings of care.
28. Report on medication distribution systems used and planned in hospitals and residential care settings, including identifying barriers and enablers to introducing safer systems.

3.3 Use of technology to improve medication safety

29. Advocate the safety and quality benefits of implementing electronic medication management systems in all care settings.

30. Work with NEHTA and DOHA E-Health Branch to improve the interoperability of systems between healthcare sectors.

31. Develop a guidance document on the requirements for safe e-medication management systems (including safe design features, use of safety alerts, clinical decision support systems) and the safe introduction of the technology into workplaces.

32. Advocate access for all professionals with prescribing responsibility to systems that support safe prescribing (including decision support tools).

33. Advocate the safety and quality benefits of bar code checking in the medicines management pathway.

34. Coordinate the development of guidelines for implementing bar code checking in the medication management pathway.

35. Advocate a mandatory requirement for bar codes on all medicines to 'unit of use' level (i.e. to the point of patient administration).

36. Promote industry awareness of the need for bar codes on products to support safe medication management systems in health care.

3.4 Incident monitoring and sharing the lessons

37. Identify a national approach to medication incident reporting, data analysis and investigation.
38. Work with stakeholders on a coordinated approach to using medication incident and adverse event data to identify and develop national safety solutions including:
 - a. Formulating and disseminating recommendations for systems changes;
 - b. Developing implementation tools and audit tools;
 - c. Liaising with key agencies on implementing change.

39. Share lessons nationally through the generation of alerts and bulletins and by working with stakeholders.

40. Network with overseas safe medication practice centres.

4. Healthcare professionals

4.1 Addressing gaps in practice

41. Set nationally agreed priorities for addressing gaps in practice in quality use of medicines and safe medication practice and monitor outcomes through the use of indicators.
42. Develop safe medication practice indicators.
43. Develop and disseminate alerts, implementation and audit tools to address important gaps in safe medication practice.

4.2 Competencies in safe medicines practice

44. Advocate inclusion of safe medication practice in curricula for health professionals.
45. Advocate competency in safe medication practice as a registration requirement for health professions with medicines management responsibilities.

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National approach to medication safety and quality

While there is a significant level of medication safety activity in Australia, the study found a number of important patient safety activities that are not occurring or being implemented inconsistently. The Commission could provide a national focus for medication safety and quality improvement activity as well as the strategic leadership and coordination required to effect medication error prevention solutions through standardisation and systemisation.

The breadth of the recommendations reflects the complexity of the task required to improve medication management practices and reduce preventable harm from medicines across all sectors of care. The Committee agreed that the actions recommended for the Commission would need to be prioritised and a work plan developed.

Recommendation 1

The Commission accept the report and prioritise the recommendations in Table 1.1.

Recommendation 2

The Commission action the priority recommendations.

Working with stakeholders

A national approach to medication safety and quality requires the Commission to work with key stakeholders. The Commission, with the support of an expert group representing key stakeholders, is the organisation best placed to set national priorities for improving medication management and addressing gaps in safe medication practice with a clear focus on reducing patient harm.

Recommendation 3

The Commission establish an expert Medication Reference Group to advise on national strategies and priorities for medication safety and quality.

The Medication Reference Group will work with the Commission's other standing committees to advise on priorities for action and implementation. The activities of the committee will contribute to the work of the National Medicines Policy Executive and its advisory committee and forum.

A national focus for medication safety and quality

A national focus for medication safety is a prerequisite for leading and coordinating systems improvements across the health sector, and for implementing the recommended activities identified in the study.

Recommendation 4

The Commission identify a National Medication Safety Unit within the Commission:

1. to effect the recommended actions;
2. as a national focus for medication safety and quality.

A National Medication Safety Unit that integrates with the Commission's broader work and the National Medicines Policy is essential for reducing adverse medicines events and effecting measurable improvements in patient safety in all Australian health settings.

The Commission is the appropriate agency for the unit as it is the only national organisation with:

- A remit to lead and coordinate activities for improving patient safety across all health settings;
- Links into all health settings through its committees (Inter-Jurisdictional, Private Hospital Sector and Primary Care Committees) to inform policy development and overcome structural barriers to change;
- The role of identifying policy direction and providing strategic advice to Health Ministers on best practice thinking and implementation strategies to drive quality improvements.

The Committee consider that the establishment of a national medication safety unit would bring Australia into line with the U.S.A., Canada, the United Kingdom and other European countries which have established national safe medication practice centres to focus national medicines safety and quality activity. It would work within the Commission's current committee structures and with existing medication safety and quality organisations (listed in Appendix 2).

Summary

The Committee agreed that the scoping study demonstrated a need for a national approach to reducing medicines related adverse events and medication error in Australia. Although there is much activity occurring in medication safety and the quality use of medicines, some important patient safety activities were not occurring or being implemented inconsistently.

The Commission was considered to be the appropriate agency to provide national leadership and strategic direction for a national approach to reducing patient harm from medicines.

In 2007–2008, the Australian Commission on Safety and Quality in Health Care (the Commission) included initiatives to improve the safety and quality of medication in its work plan which was endorsed by Health Ministers on 13 June 2007.

The Commission was asked to assume the role of leading and coordinating national medication safety and quality by the Joint Therapeutic Advisory Groups in August 2007. While not averse to this, the Commission was conscious that the Joint Therapeutic Advisory Groups represented only a part of the medicines community. Therefore the Commission proposed a scoping study to consider the whole of national medication safety and quality. The objectives of the study were to: identify leadership and coordination activities not being undertaken; any gaps in current national activities in medication safety and quality; and to recommend a national approach to improving the safety and quality of medication in Australia.

The National Medication Scoping Study Steering Committee (the Committee) was set up to guide the work (see Table 1). Committee members included representatives from the key national safety and quality organisations as well as content experts. The Committee was charged with considering the adequacy of current national medication safety and quality activity. Further, it was asked to recommend additional activity which could improve the safety and quality of medication use in Australia. This report is the result of the Committee's

deliberations and its consideration of input from extensive consultation and two literature reviews.

The rationale for the Commission's medication program is supported by the frequency with which medicines are used in the community (medicines are the most common treatment used in health care) and the incidence of adverse events associated with their use, many of which are potentially avoidable.

It is estimated that the rate of medicines related hospital admissions in Australia remains at around 2 to 3%, with as many as 30% of unplanned geriatric admissions being associated with an adverse medicines event.¹ Approximately 50% of these admissions are considered potentially avoidable (range 32–77%).¹ In 2006–7 there were 101,003 hospital separations associated with an adverse medicines event.³ In the community, as many as 10% of patients experience an adverse drug event within the previous six months of presentation to their general practitioner.²

Many solutions to medication error are found in standardisation and systemisation and often require strategic leadership and coordination. Thus, many developed countries have established national centres for safe medicines practice either as independent organisations or within national agencies for safety or within national agencies for quality use of medicines. These act as a national focus for coordinated medication safety and quality improvement activity. Australia has not done so to date.

1. INTRODUCTION

1.1 STEERING COMMITTEE

The National Medication Scoping Study Steering Committee (the Committee) was chaired by Professor Lloyd Sansom AO and its functions were to:

- Advise on perceived gaps in current national medication safety and quality arrangements and on emerging issues
- Identify leading and coordinating activities not currently undertaken nationally
- Recommend national actions to improve medication safety and quality.

Members of the Committee are listed in Table 1.

Scoping Study Steering Committee

Meetings – 16 April 2008, 18 June 2008, 2 July 2008 (by teleconference), 21 July 2008

The Committee met four times; three times in person and once by teleconference. It also considered documents and provided feedback out of session.

The first meeting agreed a structure for the report and key gaps. The second meeting considered national actions; the subsequent teleconference considered outstanding issues from the second meeting. The third meeting confirmed the actions for the Commission arising from the agreed activity gaps including the key recommendation that the Commission lead and coordinate national medicines safety and quality.

Committee members provided comment on this report and agreed it out of session.

Table 1 – Committee membership

Professor Lloyd Sansom AO Chair	Emeritus Professor, School of Pharmacy and Medical Sciences University of South Australia
Mr Kim Bessell	Principal Advisor, Pharmaceutical Benefits Division, Department of Health and Ageing
Dr Tracey Bessell (16 April Meeting)	Quality Use of Medicines Adviser, Pharmaceutical Benefits Division Department of Health and Ageing
Dr James Best (18 June Meeting)	General Practitioner, Leichhardt, NSW
Ms Naomi Burgess	Pharmacy Consultant, Medication Safety and Pharmaceutical Reform, SA Health Department
Dr Richard Hill	Senior Medical Advisor, Adverse Drug Reactions Unit, Therapeutic Goods Administration, Department of Health and Ageing
Professor Cliff Hughes AO	Chief Executive Officer, Clinical Excellence Commission, NSW
Mr John Jackson	Group Director of Pharmacy, Australian Pharmaceutical Healthcare Systems

Ms Karen Kaye	Executive Manager, Quality Use of Medicines Programs, National Prescribing Service Ltd.
Ms Anne McKenzie (16 April meeting)	Consumers' Health Forum
Prof Andrew McLachlan	Professor of Pharmacy (Aged Care), Centre for Education and Research on Ageing, Concord Hospital, NSW
Ms Alison McMillan	Director, Quality and Safety Branch, Department of Human Services, Victoria
Prof Charles Mitchell	Safe Medication Practice Unit, Queensland Health
Dr Stephen Phillips OAM	General Practitioner, Maroochydore, Queensland
Associate Professor Libby Roughead	School of Pharmacy and Medical Sciences, University of South Australia
Adjunct Professor Debra Thoms	Chief Nursing and Midwifery Officer, NSW Health, NSW
Ms Penny Thornton	Director Pharmacy Services, Westmead Children's Hospital
Ms Patti Warn	Consumers' Health Forum
Ms Margaret Williamson	Manager, Research and Development, National Prescribing Service Ltd

1.2 CONSULTATIONS

The consultation process included:

- Meetings and teleconferences with 54 organisations and key stakeholders involved in medicines safety and quality
- Forums conducted with clinicians involved in medicines safety in three states involving 40 clinicians
- A workshop on medicines safety in primary care and the community held in collaboration with the National Prescribing Service at the National Medicines Symposium, Canberra, May 2008
- Two forums (an open forum and a forum for nurses) conducted during the Improving medicines safety symposium: Sharing the lessons learned held by Change Champions, Melbourne, March 2008.

Committee members were provided with advice of outcomes from these activities. Further information on organisations involved in medicines safety and quality, many of which were consulted through this process, is provided at Appendix 2 – *Organisations with roles in improving safe and quality use of medicines*.

1.3 INTERNATIONAL PERSPECTIVE

Information on overseas models of safe medication practice agencies was obtained through site visits, telephone interviews and from the internet.

Site visits were made to the Institute of Safe Medication Practice in Philadelphia, U.S.A. and the Institute of Safe Medication Practice in Toronto, Canada. Details of the different centres, their structures and scope of activities is outlined in Appendix 3 – *Overseas models of safe medicines practice centres*.

1.4 LITERATURE REVIEWS

A literature review on medication safety in acute care was commissioned.¹ The objective was to provide an update on studies conducted in the acute health care setting in Australia since the time of publication by the former Australian Council for Safety and Quality in Health Care of the *Second National Report on Patient Safety – Improving Medication Safety*.⁴

The National Prescribing Service also provided a literature review on medication safety in the community.⁵



2. CURRENT NATIONAL MEDICATION SAFETY AND QUALITY ARRANGEMENTS

2.1 NATIONAL COORDINATION OF MEDICATION SAFETY ACTIVITIES

The environment in which medicines are regulated, prescribed, supplied, administered and monitored in Australia is complex. It involves many stakeholders, government and non-government, at national, State and Territory levels, and includes health professionals, researchers, large and small corporations, consumers and carers.

The policy framework for medication in Australia is the National Medicines Policy. The National Medicines Policy was launched in 1999 with whole-of-government support. Its aim is to improve positive health outcomes for all Australians through their access to, and wise use of, medicines.

The Policy has four central objectives:

1. Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines; and
4. Maintaining a responsible and viable medicines industry.

The remit of the Australian Commission on Safety and Quality in Health Care relates mostly to the second and third objectives of the Policy. However, the remit is not exclusive and there are major national organisations charged by government with acquitting elements of the second and third objectives as well as many State, Territory and non-government organisations operating in the space.

The original consultative arrangements which supported the National Medicines Policy have ceased. A new advisory structure was announced in August 2008 and comprises a National Medicines Policy Executive (representing the four arms of the policy), a National Medicines Policy Committee and an annual National Medicines Policy Forum.

The key national agencies responsible for safe and quality use of medicines are:

- Therapeutic Goods Administration, Department of Health and Ageing;
- Pharmaceutical Benefits Division, Department of Health and Ageing;
- National Prescribing Service Ltd.

Table 2 provides a brief description of the roles of these agencies in medication safety and quality and some of the medication safety activities delivered through their programs. It is clear from the table that although all the agencies make important contributions to the safe and quality use of medicine, none has a specific focus on improving patient safety through safe medication practice and quality use of medicines across all settings of care. (A further list forms Appendix 2)

2.1 NATIONAL COORDINATION OF MEDICATION SAFETY ACTIVITIES (continued)

Table 2 – Major national medication safety and quality organisations

Body	Roles	Medication safety activities
Therapeutic Goods Administration (TGA) A division of the Commonwealth Department of Health and Ageing responsible for administering the <i>Therapeutic Goods Act 1989</i> and the Regulations.	<p>TGA ensures therapeutic goods available in Australia are of an acceptable standard. It does this through a range of assessment and monitoring activities including:</p> <ol style="list-style-type: none"> Product registration (includes approval of product labelling, packaging, product information and assessing consumer medicines information meet criteria within the regulations); Pre-market assessment; Licensing of manufacturers; Post market vigilance; Recall of unsafe and defective medicines. <p>The Office of Medicines Safety Monitoring monitors adverse drug reactions.</p> <p>The Adverse Drug Reactions Advisory Committee (ADRAC), formed in 1970, provides advice to the TGA on the safety of medicines.</p>	<p>Conducting pre-market risk assessments and post marketing pharmaco-vigilance activities. (The TGA is currently enhancing pharmaco-vigilance activities).</p> <p>Managing the adverse drug reactions reporting system.</p> <p>Issuing medicines alerts and advice.</p> <p>Developing a repository of consumer medicines information and product information to be available on its website in 2009.</p> <p>Maintaining a data base of adverse drug reactions and contributing to identification of previously unrecognised reactions.</p> <p>Publishing the Australian Adverse Drug Reactions Bulletin bi-monthly.</p>
National Prescribing Service (NPS) An independent, non-profit organisation primarily funded by the Commonwealth Department of Health and Ageing.	<p>NPS provides medicines information and resources for consumers, health professionals, members and stakeholders involved in Quality Use of Medicines.</p> <p>The NPS supports quality prescribing and provides services and programs nationwide.</p>	<p>Many NPS programs incorporate medication safety messages and/or work towards improving medication safety. They include:</p> <ol style="list-style-type: none"> A consumer section on their website providing medicines information, access to Consumer Medicines Information; Curricula and training via on-line prescribing modules, including a training module for the National Inpatient Medication Chart; Quality prescribing indicators for general practice; Phone line services for health professionals, consumers seeking information and for consumers to report adverse medicines events.
Pharmaceutical Benefits Division A division of the Commonwealth Department of Health and Ageing responsible for achievement of Departmental outcome 2 – access to pharmaceutical services.	<p>The Pharmaceutical Benefits Division aims to provide all Australians with access to cost-effective and high quality pharmaceutical services.</p> <p>The Division is responsible for policy implementation including National Medicines Policy and the National Strategy for Quality Use of Medicines. It has various advisory and program entities including:</p> <ol style="list-style-type: none"> National Medicines Policy Committee; Paediatric Medicines Advisory Group; Consumer Medicines Information – Quality Reference Advisory Group; Drug Utilisation Subcommittee of Pharmaceutical Benefits Advisory Committee; Expert Advisory Panel on ATSI Medicines; Activities under the 4th Community Pharmacy Agreement. 	<p>Quality assurance for Consumer Medicines Information.</p> <p>Hosting website reports of QUM research and projects through Queensland University.</p> <p>Monitoring usage of Pharmaceutical Benefits Scheme (PBS) listed drugs to ensure safe and effective use of PBS drugs.</p> <p>Funding:</p> <ol style="list-style-type: none"> Pharmacy services; Dose administration aids; Patient medicines profiles; Residential medicines management program; Home medicines review program; Research projects on Quality Use of Medicines and medicines safety.

2.2 STATE AND TERRITORY MEDICATION SAFETY STRATEGIES

Much of the activity in medication safety to reduce patient harm from medicines occurs at State and Territory level. Leadership and strategic direction is provided through quality and safety branches of State and Territory health departments and, in a number of States, through a Medication Safety Committee of the State Therapeutic Advisory Group.

Table 3 – Major State and Territory medication safety and quality bodies

States and Territories	Roles	Examples of activities
<p>Safety and quality branches, councils and commissions</p>	<p>Generally a strategic role. Report directly to ministers on safety and quality issues.</p>	<p>Issue safety alerts within their jurisdictions.</p> <p>Develop strategic plans for medication safety.</p> <p>WA Office of Quality and Safety on Health Care have published a pharmaceutical review policy, audit tools.</p> <p>South Australia have a planned implementation of APAC <i>Guiding principles for continuity of medicines</i> including development of indicators to measure performance.</p>
<p>Medication safety committees and bodies</p> <p>Victorian Medicines Advisory Group</p> <p>NSW Medication Safety Strategy Committee</p> <p>ACT Health QUM reference Group</p> <p>Queensland Health Safe Medicines Practice Unit</p>	<p>Monitor incidents, root cause analyses and identify actions.</p> <p>Issue safety alerts on drugs and practices.</p> <p>Monitor QUM indicators.</p> <p>Evaluate interventions.</p>	<p>NSW Clinical Excellence Commission collaborated with NSW TAG to produce <i>Medicines Safety Self Assessment (MSSA) Tools for Australian Hospitals</i>, <i>MSSA for Antithrombotic Therapy in Australian Hospitals</i> and <i>QUM Indicators for Australian Hospitals</i>. Hosts website for sites reporting MSSA data.</p> <p>Develop strategies to manage high risk drugs.</p> <p>Issue safety alerts e.g. NSW and Oxycodone, Victoria and oral dispensers.</p> <p>Recommend indicators for monitoring.</p> <p>Develop charts, tools to support practice changes e.g. Queensland Health Safe Medicines Practice Unit's specialist medication charts, medication action plan.</p>
<p>Therapeutic advisory groups, drug and therapeutics committees</p> <p>Therapeutic advisory group medication safety committees</p> <p>NSW TAG Safer Medicines Group</p> <p>Vic TAG Safer Medicines Group</p> <p>WA Medications Safety Group</p>	<p>Support State and Territory Quality Use of Medicines programs and networks.</p> <p>Support Drug and Therapeutic Committees.</p> <p>Publish safety alerts, guidance documents.</p> <p>Develop and promote medication safety tools.</p>	<p>NSW TAG collaboration with the Clinical Excellence Commission on Medication Safety Self Assessment tools and QUM indicators for Australian Hospitals.</p> <p>Safety alerts – e.g. opioid patches (NSW, WA).</p> <p>Guidance document on terminologies, abbreviations and symbols (NSW).</p> <p>Medicines history on admission form and <i>Living with warfarin</i> booklet (WA).</p>

2.2 STATE AND TERRITORY MEDICATION SAFETY STRATEGIES

(continued)

States and Territories	Roles	Examples of activities
Pharmaceutical sections of Health Departments	Administer State/Territory Poisons and Therapeutic Goods legislation. Develop policies and guidelines to complement the legislation.	NSW policy directives: <i>Medication handling in public hospitals; Medication handling in community based health services/residential facilities; Safe use of methotrexate.</i>
Health care complaints commissions	Manage health care complaints which may involve medicines.	Queensland Health Quality Complaints Commission sets and monitors performance against standards including some relating to Quality Use of Medicines.
Registration boards for medicine, nursing and pharmacy	Set requirements for registration of health professionals. Manage complaints about professionals. Distribute information bulletins.	Medication safety messages in bulletins. Pharmacy Board requirements for mandatory barcode checking in the dispensing process in some States and Territories.

2.3 OTHER ORGANISATIONS

There are other organisations which play important roles in improving the safety and quality of medication use including professional organisations, registration bodies, educational institutions, standards organisations, medicines industry and research institutes. (Appendix 2 lists some of the organisations, particularly those that have medication safety listed as a component of their service. Many of these organisations were consulted during the study).

2.4 DISCUSSION

At a national level the Therapeutic Goods Administration of the Department of Health and Ageing has responsibility for ensuring the quality, safety and efficacy of therapeutic products. The National Prescribing Service promotes the quality use of medicines through: national initiatives and incentives that support quality prescribing of medicines; providing independent information about medicines to prescribers and consumers; and encouraging cross discipline and cross sector collaborations that promote quality use of medicines. Although many programs include messages on medication safety their main focus is to influence decisions made by health professionals and consumers on the therapeutic use of medicines. The Department of Health and Ageing directly funds services in the community that support the quality use and timely access to medicines at an affordable cost. There are no national programs with a specific focus on medication error reduction and improving patient safety through safe medication practice and systems improvement.

Much of the activity in medication safety in Australia occurs within the acute care sector. State and Territory health departments have committees that advise on and coordinate medication safety initiatives. Many of these activities are directed at improving systems for managing medicines and learning from error. However, advances in safe medication practice established in one jurisdiction or health care setting may not occur in other jurisdictions or health care settings.

2.5 CONCLUSION

While there is much activity to improve the safe and quality use of medicines at all levels within the Australian health system, including with consumers, much of the work is uncoordinated, there is duplication of effort and some important work is not being done.

The Therapeutic Goods Administration of the Department of Health and Ageing, the National Prescribing Service and the Pharmaceutical Benefits Division of the Department of Health and Ageing play important roles in the national strategy for Quality Use of Medicines, including activities that support safe and effective use of medicines. However their contribution to medication safety is limited and none of these agencies has a specific focus on improving patient safety through systems improvement and medication error prevention.

There is a role for the Commission to provide a national focus for medication safety and quality improvement activity and the strategic leadership and coordination required to effect the medication error prevention solutions based in standardisation and systemisation.



3. IMPROVING MEDICATION SAFETY THROUGH SAFE SYSTEMS AND PRACTICE – FOUR KEY AREAS

3. IMPROVING MEDICATION SAFETY THROUGH SAFE SYSTEMS AND PRACTICE – FOUR KEY AREAS

The Committee undertook a gap analysis to assess the adequacy of current medication safety and quality activity and identify areas where additional activity would enhance patient safety.

1. The patient's journey through the health system

- Consumer access to information on medicines – including an accurate record of their own medicines
- Continuity of care – the transfer of accurate information between professionals and care settings, funding systems and medication management processes in the community.

2. Product Safety

- Post-marketing pharmaco-vigilance particularly via the use of data linkage to identify adverse events and improve the quality use of medicines
- Systems to reduce errors caused by “look alike, sound alike” names and poor labelling and packaging design.

3. Medication management systems

- National standardisation of processes in the medication management pathway to reduce potential for errors associated with human factors such as slips and lapses
- Adoption of safe medication distribution systems in acute care settings
- Use of technology in the medication management pathway – including electronic systems for prescribing and recording the administration of medicines and bar code checking of medicines administration at the bedside
- National approach to incident monitoring, data analysis and the development and implementation of strategies to prevent recurrence of serious errors.

4. Healthcare professionals

- Adoption of best practice guidelines
- Training and assessment of competency in safe medication practice.

Each of the identified key areas were considered in detail by the Committee. The following chapters provide information on each key area and outcomes from the Committee's deliberations. They are structured as follows:

- Issue;
- Discussion;
- Identified gaps and needs;
- Options for national actions;
- Key organisations with a role in the actions; and
- Recommended actions for the Commission.

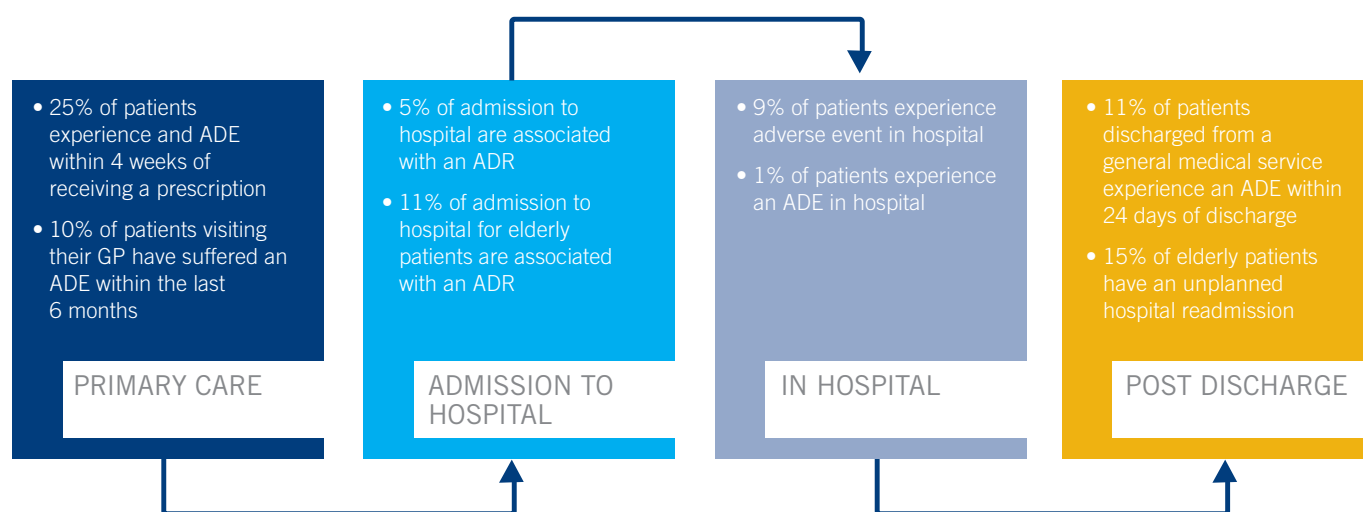


4. THE PATIENT'S JOURNEY THROUGH THE HEALTH SYSTEM

4. THE PATIENT'S JOURNEY THROUGH THE HEALTH SYSTEM

There are many opportunities for patients to experience harm from medicines as they journey through the health system. Figure 1 depicts the incidence of adverse medicines events (ADE) and adverse drug reactions (ADR) associated with the various stages of the patient journey from primary care through admission to hospital, hospital stay and discharge from hospital.⁶

Figure 1. Incidence of adverse medicines events at transitions of care.



Source: Unpublished figure by Professor G Peterson, School of Pharmacy, University of Tasmania.

4.1 CONSUMER ACCESS TO INFORMATION

The consumer is the only constant throughout their journey across the health system. To enable them to safely manage their medicines and successfully navigate the journey, they need to be literate about health issues and adequately educated and informed about medication issues, including knowledge about their own current medicines regimen.

Poor communication between health professionals and patients has been shown to contribute to medication errors in the community and at points of transfer of care.⁷⁻⁹

4.1.1 Comprehensive list of current medicines

Issue

An accurate and current list of medicines including over the counter and complementary medicines, and their indications for use, is an important tool to assist consumers manage their medicines. It also assists the transfer of information if the consumer is admitted to hospital or other care setting. Supporting consumers to maintain a current list of all their medicines is Guiding Principle 5 of the Australian Pharmaceutical Advisory Committee (APAC) *Guiding principles for medication management in the community*.¹⁰

Discussion

The Committee considered that all consumers should have ready access to a list of current medicines. On line access to medicines information held within an individual electronic health record was considered important for the future, although it would not suit all consumers. It was noted that the National E-Health Transition Authority was well advanced with the development of an individual e-health record and that this needs to be supported and inclusion of medicines information advocated. In addition, the Department of Health and Ageing recently commissioned reports on electronic health records and electronic prescribing and dispensing.

Educating consumers about systems that are currently available to them for accessing and maintaining a current and comprehensive list of their medicines was considered a useful initiative. This included the National Prescribing Service's Medilist system or the availability of patient medicines profiles, including prescription, non-prescription and complementary medicines, from community pharmacists. (Provision of patient medicines profiles by community pharmacists is currently being trailed through a program subsidised under the Fourth Community Pharmacy Agreement and is due to report by mid-2009).

Identified gaps and needs

- Consumer access to an accurate and current list of their medicines including:
 - Pharmaceutical Benefit Scheme and non-Pharmaceutical Benefit Scheme subsidised medicines;
 - Over the counter medicines;
 - Complementary medicines;
 - Indications for use.

Comprehensive list of current medicines – Options for national action

- Providing consumers with access to a current medicines list, which will ultimately link with their e-health record
- Educating patients to:
 - maintain a current list of medicines and previous adverse drug reactions;
 - obtain a current medicines profile from their community pharmacist;
 - access resources from the National Prescribing Service website to record their current medicines (Medilist) and prompt ongoing discussion about medicines with health professionals (Medimate).
- Educating GPs and pharmacists to maintain a current list of medicines for their patients
- Requiring a standard data element for medicine indications in e-prescribing systems for transferring information to pharmacists and consumers via the labels applied to dispensed medicines
- Working with NEHTA and DOHA E-Health Branch on e-health record developments for medicines.

Key organisations with a role in the actions

Department of Health and Ageing, National Electronic Health Information Principal Committee, National E-Health Transition Authority, National Prescribing Service Ltd, State and Territory health departments, Pharmacy Guild of Australia.

Recommended actions for the Commission

- Advocate the safety and quality benefits of the proposed e-health record for medicines.
- Work with NEHTA and DOHA E-Health Branch on the e-health record for medicines.
- Recommend implementation of the APAC *Guiding principles for medication management in the community*.
- Liaise with NPS on a communication strategy for consumers and health professionals to promote available options for accessing a current medicines list.

4.1 CONSUMER ACCESS TO INFORMATION

(continued)

4.1.2 Access to medicines information

Issue

Consumers require access to information about medicines, including Consumer Medicine Information, in formats that suit the individual.

Discussion

Consumers should have access to medicines information, including Consumer Medicine Information, 24 hours a day in the format that meets their needs. This may be directly from a health professional, by telephone or through the internet. Vulnerable populations, including culturally and linguistically diverse consumers, older consumers, mental health clients and those being treated for cancer, have specific needs.

Poor compliance with the supply of Consumer Medicine Information (CMI) and their use by health professionals to educate consumers about their medicines was noted.

Independent information sources

The National Prescribing Service Ltd (NPS) was viewed as the principal source of independent advice for consumers seeking information about medicines. It provides a medicines information section for consumers on their website, including access to CMI. The NPS also funds a telephone line for consumers seeking medicines information (the Medicines Line) and a separate line for reporting adverse medicines events (the Adverse Medicines Event Line). Access to these services would be improved by extending operating hours beyond the current office hours and increasing community awareness of their availability.

Consumer Medicine Information

Currently not all CMI are available on line as there is no single repository for CMI. (This will be rectified when the Therapeutic Goods Administration commence hosting a central repository of CMI on their website in 2009). The Committee also identified issues around the currency and format of CMI, its alignment with the Product Information, as well as the use of CMI by health professionals. There was a need to address the integration of CMI into the workflow of general practitioners and pharmacists.

It was noted that a project to consolidate the evidence of CMI effectiveness, and substantiate the validity of anecdotal evidence, had been funded through the Fourth Community Pharmacy Government Agreement. This will aid development and evaluation of alternative formats to improve the effectiveness and delivery of medicines information in community pharmacy practice. It is expected to report in early 2009.

Identified gaps and needs

- Access to medicines information 24 hours a day in the format that meets consumer needs and available in languages other than English
- A single repository for CMI for prescription medicines (to be available in 2009)
- Processes for:
 - Assuring currency of CMI and their alignment with Product Information
 - Evaluating content, format and delivery mechanisms
- Provision and use of CMI by health professionals to educate consumers.

Access to medicines information – Options for national action

- Reviewing consumer medicines information to make information readily available in formats that meet consumer needs
- Providing a single telephone service for medicines information and adverse medicines events reporting. This could be considered as part of development of the National Health Call Centre Network
- Reviewing content and format of CMIs and delivery mechanisms
- Investigating mechanisms for incorporating CMI into workflow of prescribers and pharmacists.

Key organisations with a role in the actions

Department of Health and Ageing, National Prescribing Service Ltd, Therapeutic Goods Administration, Consumers Health Forum and other consumer organisations/support groups, Medicines Australia, Generic Medicines Industry of Australia.

Recommended actions for the Commission

- Consult with consumer organisations on consumer information needs, including CMI, and communicate preferred enhancements to key information providers.
- Advocate increased access and review of the content, and format, of CMI and the mechanisms for delivery.

4.2 CONTINUITY OF CARE

“The interface between different care settings is particularly prone to error and a potential target for interventions to reduce medication error.”⁵

4.2.1 Information transfer between settings and health professionals

Issue

The risk of error during the transfer of information between health care settings or between health professionals is high. In the community, consumers may visit multiple practitioners which increases the risk of adverse medicines events. Assuring medicines accuracy at transitions of care is an international priority.

The World Health Alliance on Patient Safety nominated clinical handover as one of its High 5s safety and quality priorities. The Commission is leading the clinical handover initiative on behalf of Australia. The Commission's National Clinical Handover initiative includes two projects involving medicines: one on the transfer of information between residential care facilities to hospital, the other the discharge of patients from a mental health facility to the community.¹¹

Further comment is made using four headings:

1. Communication between health care settings;
2. Communication in the community sector;
3. Information technology;
4. Medication reconciliation.

Discussion

Communication between health care settings

Consumers, clinicians and medication safety experts consider the timely transfer of accurate medicines information between health care settings to be a key area for improving patient safety. Medical colleges cited inaccuracies in lists generated from general practitioner software, and the low rate of discharge summaries provided by hospitals, as major problems. This is confirmed in the literature. Variances of 30–70% between the medicines patients are taking before admission and their prescriptions on admission have been reported.¹² In one Australian study, only 36% of the medication changes made during patient admissions were recorded in patient discharge summaries from two medical wards.¹³

The Committee noted that a number of projects for improving communication and continuity of supply of medicines between residential care facilities and hospitals were occurring in South Australia.

Communication in the community sector

Communicating information on consumer's current medication regimens between health care professionals in the community (e.g. between general practitioners (GPs) and specialists, between other GPs and other prescribers (including non medical, complementary and traditional medicines practitioners), between GPs and pharmacists, and between pharmacists performing medicines reviews in residential care facilities and nursing staff) was considered problematic and a contributor to medicines error in the community.^{9, 14, 15}

Poor communication amongst residential care facilities, general practitioners and pharmacy providers was cited as a cause of errors in medicines supplied to residential care facilities in dose administration aids.¹⁶

“The system for communicating changes in doctors orders among GPs, pharmacists and RACFs [Residential Aged Care Facilities] should be streamlined.”¹⁶

Extending the range of practitioners with prescribing rights was considered to add further complexity and risk to medication safety and increased the need for accurate communication between health practitioners about consumers and their medicines. As prescribing is extended to more practitioners, systems are needed to give all prescribers access to a common record of medicines prescribed for an individual, such as a national electronic medicines record.

Information technology

The use of technology to improve the transfer of information between care settings and between health professionals was seen as an important component of any solution for improving transfer of information at care transfer points. Several medical colleges supported the development of a national standard format for discharge summaries.

“The delivery and perhaps the quality of discharge summaries can be improved substantially through health information technology.”¹⁷

It was noted that work is being undertaken at State and Territory level on electronic health records, including electronic discharge summaries (with medicines information), and that an individual e-health record is being developed at the national level. Committee members noted that the current approach to development and implementation of information systems for health records and medicines management (including electronic

4.2 CONTINUITY OF CARE

(continued)

prescribing) at State and Territory level was fragmented. There was little interoperability of applications between, and within, care settings which impeded information transfer. Advocating interoperability of information systems between health care settings was considered an important action for the Commission. The complexity of electronic information systems for medicines was further increased by the need to build systems around the various funding models currently in place for medicines. Evaluation of these information systems in Australia was limited and poorly planned implementation and e-prescribing without decision support and alerting systems has been shown to increase medication error.^{18, 19}

It was noted that there had been some success in the Northern Territory with information transfer between hospitals and residential care facilities, and in the Illawarra region of NSW between general practitioners and residential care facilities.²⁰ Medical computing in the residential aged care sector, and its use by GPs to communicate changes in medication orders reduces the risk of errors that occur with verbal orders or illegible writing.¹⁶

Medication reconciliation

Medication reconciliation is defined as “the formal process of obtaining a complete and accurate list of each patient’s current medications; comparing the clinician’s admission, transfer or discharge orders with that list; and bringing any discrepancies to the attention of the prescriber. Where appropriate, changes are made to the orders and documented.”²¹

Medication reconciliation on admission and discharge has been shown to reduce errors associated with poor quality of medication information at transfer and inaccurate documentation of medication histories on admission. Both processes are founded in the principles described in the Australian Pharmaceutical Advisory Committee (APAC) *Guiding principles to achieve continuity of medication management*.¹⁰ However, implementation of medication reconciliation nationally has been inconsistent, as has the implementation of pharmaceutical review (defined as “the systematic appraisal of all aspects of a patient’s medication management to optimise patient outcomes”).²²

The Committee noted that some significant work was occurring. For example, the Western Australian Department of Health’s Office of Safety and Quality has a policy, standards and audit tools for pharmaceutical review.²² Other states are in the process of developing policies. For example, the South Australian Department of Health is planning implementation of, and has developed indicators

for monitoring performance against, the APAC *Guiding principles for continuity of medication management*.²³ Standards have been published on medication reconciliation.²⁴ Queensland Health’s Safe Medication Practice Unit, the Western Australian Therapeutic Advisory Group and individual hospitals in other states have developed tools for medication reconciliation.

Some teaching hospitals in Victoria and South Australia have implemented models using clinical pharmacists working extended hours in emergency departments to perform medication reconciliation.

Further work

Further work to assure timely transfer of accurate medicines information and confirmation of the accuracy of the information was considered a high priority. Major solutions identified were:

- the use of information technology for information transfer, and;
- the process of medication reconciliation at care transfer points.

Both strategies have data to support their use. Although there is significant existing work in this area, a nationally coordinated approach to implementing medication reconciliation and pharmaceutical review could improve the safety and quality of medication use and reduce current duplication of effort. The lack of national coordination was a common issue raised in the consultations.

Identified gaps and needs

- E-health record with e-medicines history
- Interoperable information systems in community and acute care sectors to transfer information on admission and discharge between health professionals and from facilities and settings. Information should include:
 - A current comprehensive medicines list
 - History of medicines
 - Patient allergies
 - Adverse drug reactions.
- Consistent application of the APAC *Guiding principles for continuity of medication management* nationally including:
 - Consistent implementation of medication reconciliation for patients at risk across all care transfer points;
 - Accurate and timely discharge summaries to GPs, community pharmacies and residential care facilities.
- Provision of discharge medicines information to consumers on discharge

4.2 CONTINUITY OF CARE

(continued)

- Trained workforce and redesign of clinical processes to support medicines reconciliation processes (e.g. clinical pharmacists in emergency departments and pre-admission clinics)
- Performance standards for timely, accurate transfer of information (including reasons for changes and monitoring requirements) from acute care facilities to residential care facilities, general practitioners and community pharmacies.

Information transfer between settings and health professionals – Options for national action

- Linking hospital systems with community systems for data transfer at admission and on discharge
- Recommending implementation of the APAC *Guiding principles for continuity of medication management* nationally
- Providing tools and models for implementation of medication reconciliation.

Key organisations with a role in the actions

Department of Health and Ageing, National Electronic Health Information Principal Committee, National E-Health Transition Authority, National Prescribing Service Ltd, State and Territory health departments, Pharmacy Guild of Australia (PGA)

Recommended actions for the Commission

- Lead advocacy for the safety and quality benefits of a national approach to an e-health record for medicines
- Work with NEHTA and DOHA E-Health Branch to assist development and implementation of the e-health record for medicines across all care settings
- Advocate interoperability of systems between healthcare providers
- Recommend implementation of the APAC *Guiding principles for continuity of medication management*
- Promote medication reconciliation at care transition points including identifying resources (tools, models) to support implementation of medication reconciliation.

4.2.2 Medication supply and management in the community and residential care facilities

Issue

Four issues were identified by the Committee as contributing to the risk of adverse events relating to medicines management in the community and residential care facilities:

- Funding of pharmaceuticals and pharmacy services;
- Co-ordination of care;
- Availability of discharge medicines management services;
- Access to Home Medicines Review.

Discussion

Funding of pharmaceuticals and pharmacy services

The lack of a single funding system for medicines and pharmacy services was considered to contribute to adverse patient outcomes by producing inequitable access to medicines and discontinuities in care.

The absence of single funding basis for medicines can result in inequitable access to medicines. Local decision making on hospital formularies can vary and consumer access to therapy may depend on where they reside. Patients admitted to private hospitals have access to subsidised medicine through the Pharmaceutical Benefits Scheme (PBS) whereas in public hospitals, where medicines are funded by the State government, patients may be unable to access PBS listed medicines if the facility considers they are unaffordable. This can affect the quality of care.

There are particular problems for paediatric patients in accessing subsidised medicines, particularly where paediatric formulations are not marketed in Australia.

Discontinuities are evident when patients are discharged from hospital to their home or a residential care facility with insufficient quantities of medicines or medicines supplied in an inappropriate form. The supply may be insufficient to tide them over until the patient's next appointment with their general practitioner, or the patient may cease taking the medicines when the supply is finished – the omission of essential therapy causing adverse outcomes.

The current funding system was considered a barrier to implementing interventions with safety and quality benefits such as discharge medication liaison services using home visits in the immediate discharge period. Patients often fall through the gap between State and Commonwealth funded services with the hospital providing no medication liaison service and the GP unable to organise a Commonwealth-funded home medicine review within the necessary time period (see below).

4.2 CONTINUITY OF CARE

(continued)

There was general support amongst medical practitioners and pharmacists for reforms to the current PBS funding arrangements for private hospitals and residential care facilities that would eliminate the requirement for PBS prescriptions separate from medicines charts. This would reduce the risk of error that exists in the current system where the requirement for PBS prescriptions, in addition to orders on medication charts, has been shown to contribute to errors in residential care facilities.¹⁶ The current Department of Health and Ageing consultancy reviewing supply of PBS medicines in private hospitals and residential care facilities was noted.

The Committee considered that a single funding system for medicines and permitting script-free prescribing in private hospitals and residential aged care facilities were important reforms that could improve patient safety and provide efficiencies.

Co-ordination of care

Poor co-ordination of the supply of medicines on discharge and in the community, including supply in dose administration aids to residential care facilities, hostels and home situations and to those consumers living in remote communities, including Aboriginal and Torres Strait Islander people, was reported and noted by the Committee. Supply discontinuity can leave consumers without essential medicines. Examples were cited of medicines being supplied on hospital discharge in an inappropriate form, for example not in a required dose administration aid. This resulted in care facility residents having medicines withheld until a general practitioner was able to visit and order the medicines from the community pharmacy in the required dose administration aid.

Availability of discharge medicines management services

Limited access to liaison services and formal processes for managing medicines post-discharge from acute care for consumers at risk was considered an important systems gap. This included consumers in rural and remote areas, including Aboriginal and Torres Strait Islander people, and those with special needs such as mental health clients, older consumers and those with multiple morbidities. Discharge medicines management services provided in the home by pharmacists, or by pharmacists and nurses, have been shown to improve patient outcomes and reduce undesirable medicines events.²⁵⁻²⁸

Access to Home Medicines Review

The Committee considered uptake of Home Medicines Review (HMR) to be low. In the last quarter of 2007, claims for HMR were submitted by 2,179 general practitioners, at an average of four HMR per general practitioner.

General practitioners and pharmacists reported that current business rules impede HMR use. For example, within the current arrangements, HMR referrals may only be made by the patient's GP when it may be more appropriate for another health professional to refer. An important gap was the inability of consumers at risk of harm from medicines to access HMR in the immediate discharge period. In an implementation pilot study of a service using a pharmacist to liaise with the GP and the community pharmacy to arrange an HMR, the mean time for an HMR to take place post discharge was 18±7.4 days.²⁹

Barriers to accessing HMRs after discharge include time constraints for both general practitioners and community pharmacists, lack of patient interest, unwillingness of general practitioners to learn how to make an HMR referral and the ability to engage an accredited pharmacist within a timely manner.^{29, 30}

Changing the business rules for ordering and accessing HMR was seen to be an important step in reducing barriers to accessing HMR, particularly in the immediate discharge period. (It was noted that qualitative research on the HMR program is currently being undertaken by the Department of Health and Ageing.)

Identified gaps and needs

- Single national funding system for pharmaceuticals.
- Implementation of pharmaceutical reforms across jurisdictions
- Coordination of care around supply of medicines, including supply in dose administration aids to residential care facilities, hostels and homes (including Aboriginal and Torres Strait Islander people and other consumers living in remote communities)
- Access to liaison services and formal processes for managing medicines for consumers at risk post discharge from hospital. This includes consumers in rural and remote areas and those with special needs such as mental health clients, older consumers and those with multiple morbidities
- Timely access to home medicines reviews.

4.2 CONTINUITY OF CARE

(continued)

Medication supply and management in the community and residential care facilities – Options for national actions

- A single funding model for pharmaceuticals across all jurisdictions
- Eliminating the requirement for PBS prescriptions as well as medication charts for claiming PBS subsidised medicines for private hospitals and residential care facilities
- A nationally consistent approach to pharmaceutical supplies from hospitals on discharge
- Increasing access to discharge medication management services, HMRs in immediate discharge period
- Linking government health initiatives with HMRs e.g. facilitate medicines review for mental health clients
- Developing options for medicines review and follow up for consumers in rural and remote areas and communities.

Key organisations with a role in the actions

Department of Health and Ageing (DoHA), State and Territory Health Departments, Private hospital sector, Pharmacy Guild of Australia, Pharmaceutical Society of Australia, Society of Hospital Pharmacists of Australia, Royal Australian College of General Practitioners, Royal College of Nursing, Australia, Rural Nurses Association.

Recommended actions for the Commission

- Lead advocacy for the safety and quality benefits of a national approach to the funding of pharmaceuticals
- Advocate eliminating the requirement for PBS prescriptions in private hospitals and residential care facilities, using the medication chart as the primary prescription record
- Recommend implementation of the APAC Guiding principles for continuity of medication management, Guiding principles for medication management in the community and Guidelines for medication management in residential aged care facilities
- Promote the safety and quality benefits of:
 - a. improving access to HMR and discharge liaison services;
 - b. linking the HMR program with specific health populations e.g. mental health;
 - c. improving communication about medicines and access to HMR/discharge liaison services in rural and remote areas and communities.

The Committee found two main issues relating to product safety:

- the safety of the medicine following registration and marketing; and
- the labelling and packaging of the medicine and its contribution to medication errors.



5. PRODUCT SAFETY

5.1 ENHANCING POST-MARKETING PHARMACO-VIGILANCE

Issue

The safety of medicines post-marketing is monitored currently by the Office of Medicines Safety Monitoring (OMSM) hosted by the Therapeutic Goods Administration. Spontaneous reporting of adverse drug reactions occurs through the Adverse Medicines Events Line and the Australian Adverse Drug Reaction Reporting System.

Internationally, registration agencies have been enhancing their pharmaco-vigilance programs to meet the demand by sponsors for early entry of products onto the market and to improve early identification of medicines safety issues. This is occurring through the introduction and monitoring of post-marketing risk management plans, and the introduction of pharmaco-epidemiological surveillance studies. The latter studies provide information about the actual use of medicines in the community and insights into the risks and benefits of medicines use in both the short and long term.

Discussion

There was general agreement that current systems were not easy for professionals or consumers to report adverse drug reactions. In addition, there was a need to include reports of medication errors caused by naming, labelling and packaging within the pharmaco-vigilance program. The need for improved pharmaco-vigilance in the use of medicines for “off label” (unregistered) indications in children was also identified.

It was noted that the Therapeutic Goods Administration was enhancing its pharmaco-vigilance activities by taking an active “whole-of-life cycle” approach in a number of areas including:

- the introduction and monitoring of post-marketing risk management plans;
- improving reporting systems for adverse drug events;
- a new statutory committee to replace the Adverse Drug Reaction Advisory Committee with responsibilities for the oversight, assessment and review of sponsors’ risk management plans.

Despite this, further enhancement of pharmaco-vigilance capability nationally by linking existing data (such as linking Medicare Australia prescription data with patient outcomes data from state databases and disease registries) is required. It was suggested that a national advisory board or expert panel take responsibility for coordinating data linkage projects on a national basis. The board or panel remit should include adverse drug reaction identification and identifying events concerning potentially inappropriate use of medicines.

The Department of Veterans’ Affairs MATES (Medicines Advice and Therapeutics Education Services) program is a good example of how data linkage can be used to identify medicines with potential or actual adverse events, and inappropriate prescribing of medicines, and deliver a quality improvement program to improve patient outcomes.³¹ Some activity was noted at the jurisdictional level linking medicines use data to patient outcome data.

Identified gaps and needs

- Coordination of national developments for further enhancing pharmaco-vigilance
- Access to Medicare Australia data for more extensive use of data for:
 - Data scanning for trends;
 - Data linkage with patient outcomes, registry data.
- Current adverse drug reactions and errors spontaneous reporting systems are not conducive to reporting by professionals and consumers
- Consumer knowledge of the AME Line.

Enhancing post-marketing pharmaco-vigilance – Options for national action

- Coordinating national pharmaco-vigilance efforts. This could include
 - Forming a national expert panel to advise on use of data sets for post-marketing surveillance
 - Negotiating linkage of Medicare Australia data with morbidity and mortality data, registry data
 - Improving early identification of drug safety issues through enhanced pharmaco-vigilance.

Key organisations with a role in the actions

Therapeutic Goods Administration, Department of Health and Ageing, Medicare Australia, Health professionals, Commonwealth, State and Territory governments, Pharmaceutical industry, National Prescribing Service Ltd, Department of Veterans’ Affairs, Academia, Consumer’s Health Forum.

Recommended actions for the Commission

Advocate the safety and quality benefits of enhancing post-marketing pharmaco-vigilance through linking data from existing data repositories.

5.2 PACKAGING AND LABELLING AS CONTRIBUTORS TO ERROR

Issue

Unlike most developed countries, Australia does not have a nationally co-ordinated approach to identifying and reducing errors caused by “look alike, sound alike” names and poor labelling and packaging. It also does not require user testing of products prior to registration. The prevalence of generic products on the market, and the practice of over the counter product brand extension, risks confusing consumers and health professionals and creates additional risks of medication errors and adverse medicines events. The issue of “look alike, sound alike” medication names is a World Alliance Patient Safety Solution.³²

Discussion

There was wide support for a national approach to reducing errors caused through “look alike, sound alike” names, poorly designed labelling and packaging and the confusing range of suffixes used for sustained release products and combination products.

A national approach requires a process to identify naming, labelling and packaging errors and a forum of key stakeholders to develop solutions. Safety testing by users of drug names, and the labelling and packaging of new products, should be a requirement for registration.

Design guides on medicines packaging for oral medicines and injection labelling are published by the United Kingdom’s National Patient Safety Agency Medicines Unit and should be used to inform revision of the Therapeutic Goods Administration *Best practice guideline on prescription medicine labelling*.

Labels applied to products by health professionals (e.g. dispensing labels with unreadable font size) or not using labels (e.g. use of unlabelled syringes in hospitals) are further causes of error requiring attention. Uniform standards are required for labels applied to dispensed products including the use of larger type font for elderly patients. Guidelines and standards for the labelling of medicines in hospitals are required to reduce the risk of administration of incorrect medicines from unlabelled syringes and containers. Requiring all medicines to have machine readable or bar codes at ‘unit of use’ level will assist implementation of electronic medicines checking at the bedside to reduce administering errors.

Participating in international forums, such as the International Network of Safe Medication Practice Centres, provides the opportunity to learn about initiatives occurring in other countries and to contribute to global solutions.

Identified gaps and needs

- Requirement for safety testing by users prior to registration of trademark, product name, package label, package design
- Mandatory requirement for bar-coding of products.
- National process to identify problems with packaging and labelling causing medicines error and patient harm after marketing
- National forum for liaising with pharmaceutical industry and the TGA to resolve packaging and labelling issues identified as contributing to patient harm after marketing
- Engagement of medicines industry in medicines safety and quality
- Standards for user applied labels.

Packaging and labelling as contributors to error – Options for national actions

- Mandating testing of naming, labelling and packaging of products for safety as a requirement for registration
- Mandating equal prominence of active ingredient (generic) name and the brand name of medicines on the label
- Establishing a national process to identify problems with “look alike, sound alike” names, packaging and labelling
- Establishing a forum to liaise with industry and Therapeutic Goods Administration
- Developing and implement standards for user applied labels
- Requiring application of machine readable, bar codes to all medicines at ‘unit of use’ level
- Participating in international initiatives on “look alike, sound alike” names.

5.2 PACKAGING AND LABELLING AS CONTRIBUTORS TO ERROR

(continued)

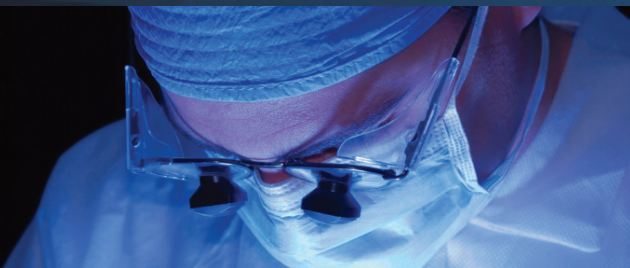
Key organisations with a role in the actions

Therapeutic Goods Administration, Pharmacy organisations, State and Territory health departments, Private hospitals, State Therapeutic Advisory Groups Medical colleges, Nursing organisations, National Prescribing Service Ltd, Consumer organisations

Recommended actions for the Commission

- Work with TGA to improve the safety of labelling and packaging including giving prominence to the active ingredient equal to the brand name
- Work with TGA to establish a process for identifying and addressing reports of errors and patient harm caused by poorly designed labelling and packaging
- Work with pharmacy organisations to develop standards for improving labelling on dispensed products
- Work with stakeholders to establish and implement standards for user applied labels for medicines in hospital.

This section addresses the processes that relate to prescribing, supplying, administering, monitoring and documenting medicines.



6. MEDICATION MANAGEMENT SYSTEMS

6.1 SYSTEMS IMPROVEMENT THROUGH STANDARDISATION

Issue

There are many opportunities for error in the medication management pathway. Standardisation of processes reduces the potential for errors associated with human factors (such as slips and lapses) and unfamiliarity with different systems as health professionals move between care settings. Examples of national standardisation in Australia include the National Inpatient Medication Chart³³ and the *National terminology, abbreviations and symbols used in prescribing and administering of medicines* in Australian hospitals.³⁴

Discussion

Clinicians and medication safety experts support standardisation of systems to reduce the potential for errors associated with human factors. Slips and lapses are the most common cause of medication error in acute care.

Maintaining and extending national medicines charts to high risk drugs and beyond the acute sector were considered key activities for the Commission. There was significant support for

- a standard medication chart for use in residential care; and
- an urgent need for rural general practitioners to generate a printed version of the National Inpatient Medication Chart from their prescribing software for use in rural hospitals.

The need to move the safety features of standardised medication charts into the electronic environment in both acute and residential care settings was agreed to be an important safety initiative.

Identified gaps and needs

- Standardised paper medication charts beyond the acute care sector
- Ability to print copies of medication orders in an National Inpatient Medication Chart format from GP e-prescribing systems for use by rural hospitals
- Process for ensuring safety gains though paper-based standardisations in prescribing, dispensing and administering are migrated into the electronic environment
- National approach to identifying and developing initiatives for improved medication safety through standardisation.

Systems improvement through standardisation – Options for national actions

- Developing further national standardised medication charts such as a residential care chart, a chart for use in community settings and charts for high risk drugs in acute care
- Enabling printing of medication orders through GP e-prescribing systems onto paper in the NIMC format for use in rural hospitals. Extending it to residential care settings following development of a national chart
- Developing guidelines for migrating safe medication management practices into electronic processes for prescribing, dispensing, administering and monitoring medicines
- Progressing further standardisations in the medication management pathway which would improve medicines safety.

Key organisations with a role in the actions

National Prescribing Service Ltd, Council of Australian Therapeutic Advisory Groups, National E-Health Transition Authority, National Electronic Health Information Principal Committee, Department of Health and Ageing, State and Territory Governments, Private hospital sector, Residential care sector, software developers.

Recommended actions for the Commission

- Develop additional standard medication charts for residential and community care and high risk drugs in acute care
- Facilitate the development of a National Inpatient Medication Chart that can be generated through GP e-prescribing systems
- Develop a guidance document on the requirements for safe e-medication management systems including safe design features, use of safety alerts and clinical decision support systems
- Lead the identification and development of standardisation initiatives to improve medication safety.

6.2 MEDICATION DISTRIBUTION SYSTEMS

Issue

The opportunity for error while administering medicines in hospitals is high. Many Australian hospitals continue to use a combination of ward stock and individual patient supply systems which is associated with high rates of error (12.7% to 16.7%). Error rates reported with individual patient supply systems are considerably lower (4.8% to 8.3%).⁴

Australian acute care institutions have been slow to adopt safe medication distribution systems such as:

- individual patient supply systems;
- use of patient's own medicines;
- automated dispensing systems; and
- barcode checking through to the patient's bedside.

Discussion

Identifying the barriers to the introduction of safer drug distribution systems in hospitals was considered an important action. Automation and the use of the patient's own medicines would provide efficiency gains as well as safety improvements.

The NSW Therapeutic Advisory Group and the NSW Clinical Excellence Commission recently released an Australian version of the Institute of Safe Medication Practice *Medication Safety Self Assessment Tool for Use by Australian Hospitals*³⁵ to assist staff by identifying weaknesses in, and improve, medicines management systems. This has not been adopted nationally. A national approach to using this and other tools was considered an important strategy for improving medicines management practices, as was developing a similar tool for the residential care sector. A set of indicators for safe medication practice, including indicators specific to the paediatric setting, was also recommended to measure performance and drive improvement.

Staff working in the residential care sector were concerned about the accuracy of the dispensing of medicines into Drug Administration Aids (DAA). This concern was supported by research in this sector where medication incidents were detected in 4.3% of DAA packs and affected 12% of residents in 42 aged care facilities.¹⁶ However, these error rates are less than those detected in hospitals where individual patient supply systems are not used.

Developing a national strategy to implement machine readable, bar-code checking in dispensing and administering medicines would reduce the risk of medicines error. (See Section 6.3 Use of technology.)

Identified gaps and needs

- Continued use of distribution systems associated with a high level of error
- Incentives for hospitals to improve their distribution systems
- Standards for medicines handling in residential care facilities
- Tools for assessing safety of medicines distribution systems in the community including in residential care facilities and hostels
- National approach to ensuring systematic implementation of safe medication distribution systems
- Australian data on cost effectiveness of different distribution systems
- Use of machine readable or bar code checking technology in the medication administration process and dispensing processes.

Medicines distribution systems – Options for national action

- Introducing the *Medication Safety Self Assessment Tool for Use in Australian Hospitals* and the *Medication Safety Self Assessment Tool for Antithrombotic Therapy in Australian Hospitals*³⁶ across all jurisdictions
- Measuring compliance with the *Medication Safety Self Assessment Tool for Use in Australian Hospitals* and *Medication Safety Self Assessment Tool for Antithrombotic Therapy in Australian Hospitals* nationally to drive improvement
- Developing and implementing medication safety self assessment tools for community and residential care sectors
- Encouraging the introduction of automation into medication supply systems in acute care
- Identifying barriers to use of safer distribution systems in hospitals
- Evaluating different distribution systems and determine where the most gains can be made through application of technology in the medication distribution cycle.

6.2 MEDICATION DISTRIBUTION SYSTEMS

(continued)

Key organisations with a role in the actions

Department of Health and Ageing, State and Territory governments, Private hospital sector, Residential care sector, Council of Australian Therapeutic Advisory Groups, NSW Therapeutic Advisory Groups and the NSW Clinical Excellence Commission, Pharmacy organisations.

Recommended actions for the Commission

- Recommend national adoption of *Medication Safety Self Assessment for Use in Australian Hospitals* to identify risks in acute care medication management systems and drive improvement
- Recommend national adoption of *Medication Safety Self Assessment for Antithrombotic Therapy in Australian Hospitals* to identify systems risks and drive improvement in acute care management of antithrombotic therapy
- Inform development of safe medication practice indicators for all settings of care
- Report on medication distribution systems used and planned in hospitals and residential care settings, including identifying barriers and enablers to introducing safer systems.

6.3 USE OF TECHNOLOGY

The use of information technology in the medication management pathway such as electronic prescribing, computerised decision support, robotic dispensing systems, bar coding checking of medicines and computerised medication administration records have been shown to reduce medication errors.^{19, 37} The United States Institute of Medicine recommends computerised physician order entry (e-prescribing) as a proven method to decrease medication related errors and adverse events in hospital patients.³⁸ The UK Department of Health recommends the wider use of information management and technology in health care to reduce the risk of medication errors.³⁷

6.3.1 Electronic medicines management systems (e-prescribing)

Issue

Electronic medication management systems (eMMS) manage each phase of the medication management process: decision support; computerised physician order entry (electronic prescribing); medication review; dispensing; and recording medicines administration. Despite the evidence of improved medication safety from well designed and well implemented eMMS, there has been limited uptake of the systems in the acute and residential care sectors.

Discussion

At a national level, NEHTA is developing standards, specification and infrastructure requirements for secure, interoperable electronic health information. In addition the Department of Health and Ageing released a report in 2009 on options for the electronic transfer of prescriptions between medical practitioners and pharmacies.³⁹

Acute Care

Clinicians and medicines safety experts expressed concern at the slow pace of eMMS introduction in acute care. The Northern Territory is the only jurisdiction implementing eMMS while NSW and Victoria have pilot sites. This problem is not unique to Australia. Encouraging the use of technology in the acute care sector was considered a priority. Technologies include electronic medicines management systems for prescribing, dispensing, and administering medicines with advanced decision support and links to key hospital information systems and safety alerts.

There is a risk of introducing new errors if the implementation of eMMS systems is not well planned, if there is no inbuilt decision support and safety features and if the system is not linked with other key hospital information systems.

“Poorly designed applications and a failure to appreciate the organisational implications associated with their introduction can introduce unexpected new risks to patient safety”.¹⁹

Research into eMMS implementation in Australian health care settings is limited. Some research is occurring in Australia on safety and the effectiveness of hospital e-prescribing systems, the impact on the work of health professional and the way technology can unintentionally generate new types of errors, mostly at the Health Informatics Research and Evaluation Unit (University of Sydney) and the Centre for Health Informatics (University of NSW). Guidance to assist Australian hospitals implement and evaluate technology safely for use in adult and paediatric settings would make an important contribution to medicines safety. This approach is supported by the U.S. literature.⁴⁰

Community

While the uptake of e-prescribing by general practitioners has been high, it has been very low by specialist clinicians. This is a gap that will need to be addressed for the safety gains of a complete medicines history in the consumer's e-health record to be realised.

The NPS evaluation of the safety, quality and usefulness of general practice clinical software was noted as was the low interoperability of the systems.⁴¹

It was considered important that all prescribers, including non-medical prescribers, had access to safe prescribing systems with clinical decision support.

Identified gaps and needs

- Implementation of eMMS in acute care sector
- Implementation of e-prescribing amongst specialist clinicians
- Guidance on requirements for safe e-systems and guidelines for implementation
- Interoperability between systems especially between community and acute care, and between community practitioners
- Data on effect of eMMS on workflow and workforce in Australia
- Linkage between e-prescribing and pharmacy systems in all sectors
- Access for clinicians to online clinical decision support material at point of prescribing and administering medicines.

6.3 USE OF TECHNOLOGY

(continued)

Use of technology – Options for national action

- Introducing e-medicines management systems with e-prescribing throughout all sectors
- Preparing guidance on safe e-systems requirements and safe implementation of electronic medication management systems including safety alerts, clinical decision support systems and migrating the safety features of National Inpatient Medication Chart
- Developing principles to evaluate technology for assessing safety in design.

Key organisations with a role in the actions

National Prescribing Service Ltd, National E-Health Transition Authority, National Electronic Health Information Principal Committee, E-Health Branch, Department of Health and Ageing, State and Territory governments, Pharmacy Guild of Australia, Software companies providing prescribing, administering and pharmacy information systems

Recommended actions for the Commission

- Advocate the safety and quality benefits of implementing electronic medication management systems in all care settings
- Work with NEHTA and DOHA E-Health Branch to improve the interoperability of systems between healthcare sectors
- Develop a guidance document on the requirements for safe e-medication management systems (including safe design features, use of safety alerts, clinical decision support systems) and the safe introduction of the technology into workplaces
- Advocate access for all professionals with prescribing responsibility to systems that support safe prescribing (including decision support tools).

6.3.2 Use of bar code checking to improve patient safety

Issue

Bar code checking has been shown to substantially decrease dispensing errors and errors in administering medicines in hospitals by enabling healthcare professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time.⁴²⁻⁴⁴ In the United States, bar codes have been mandatory for all medicines used in hospitals since April 2006.⁴⁵

No published studies have been undertaken in the Australian setting to assess the effect of bar code checking on medication errors in acute care.¹ As with other technology, careful implementation is required to maximise safety benefits.

Discussion

It was noted that the New Zealand Quality Improvement Council has decided to implement bar code checking of medicines through to the bedside as a patient safety strategy.

The Committee noted that most pharmacy boards in Australia have mandated, or are in the process of mandating, the use of bar code checking in dispensing. Guidelines are being developed by the Australian Pharmacy Council on implementing the technology within pharmacies. The need for an active approach to the use of bar code technology in the administration of medicines was identified.

Identified gaps and needs

- Use of bar code checking technology in the medication administration process in hospitals and aged care facilities
- Use of bar code checking in dispensing processes nationally
- Legislative requirement for labels for prescription medicines to include a bar code to unit of use level.

Use of machine readable or bar codes to improve patient safety – Options for national action

- Developing technical standards for bar codes in Australian health environment
- Advocating mandatory requirement for bar codes on all medicines to unit of use level
- Developing guidelines for implementing bar code checking in medication management pathway.

6.3 USE OF TECHNOLOGY

(continued)

Key organisations with a role in the actions

Therapeutic Goods Administration, National E-Health Transition Authority, Pharmacy boards, Pharmaceutical manufacturers, Barcode industry.

Recommended actions for the Commission

- Advocate the safety and quality benefits of bar code checking systems in the medicines management pathway
- Coordinate the development of guidelines for implementing bar code checking in the medication management pathway
- Advocate a mandatory requirement for bar codes on all medicines to 'unit of use' level (i.e. to the point of patient administration)
- Promote industry awareness of the need for bar codes on products to support safe medication management systems in health care.

6.4 INCIDENT MONITORING AND SHARING THE LESSONS

Issue

Lessons from incident reports are an important way to reduce the 50% of medication errors that are considered preventable. Sharing those lessons, and learning from them, can reduce the risk of harm to patients from adverse medicines events. Using incident data to identify problems and develop strategies to prevent similar errors recurring forms an important component of the work of national safe medication practice centres around the world (see Appendix 3).

Discussion

Incident monitoring

Clinicians and medication safety experts consulted for this report unanimously supported a national focus for incident monitoring, analysis and use of data to identify causes of error and developing strategies to prevent recurrence of serious errors. This was seen as a major gap in the national coordination of medication safety. It was recognised that any national approach to incident monitoring should involve the TGA.

Concerns were expressed at the lack of systems for reporting and monitoring medication incidents in the community and residential care facilities and the lack of knowledge about the causes of errors and adverse medicines events in these settings. Similarly there was little known about the incidence and causes of adverse medicines events in mental health services. Improving the reporting of adverse medicines events and “near miss” incidents was cited as an important component for a national strategy to reduce adverse medicines events in mental health services.⁴⁶ It was noted that there was funding, through the Fourth Community Pharmacy Agreement, to undertake a large scale implementation trial enabling community pharmacists to record interventions on medication errors in dispensing software .

There was also a need to enhance consumer reporting with many consumers unaware that they could report adverse medicines events, including medicines errors, through the Adverse Medicines Events Line.

The States, Territories and private hospital sector have incident monitoring systems in place. It was agreed that incident data were generally handled well at hospital and area health service levels by Drug & Therapeutics and Medication Safety Committees, but that further use of information differed across jurisdictions. The lack of a national system for managing error data from all health sectors (jurisdictional acute care sector, private sector, community sector (including residential care) and consumer reporting) was considered a major gap and common systemic, issues were therefore not identified and addressed.

Committee members proposed that a national approach be taken to medicines incident reporting and data analysis using incident reports from all settings, including consumer reports, professional indemnity insurers, professional boards and coronial communiqués. Enabling practitioners in the community to contribute to incident reporting would be an important component of any national program.

Sharing the lessons

Medication safety committees and groups at State and Territory levels currently issue safety alerts resulting from hazards identified in their own databases or through overseas medication safety organisations. Dissemination of these alerts is limited to the jurisdiction. Nationally, the Society of Hospital Pharmacists of Australia publishes a medication safety section in the Journal of Pharmacy Practice and Research and posts it on their website. Circulation of the journal is limited and is mainly read by hospital pharmacists.

A national approach is recommended to sharing lessons from medicines incidents. Results of data analysis and investigation could be used to formulate and disseminate recommendations for systems changes and liaise with key agencies to facilitate the change. This could include:

- Developing and disseminating medicines safety information through bulletins and safety alerts
- Developing and distributing learning packages, implementation tools and audit tools
- Promoting system improvements developed overseas.

This would build on work already undertaken by State and Territory safe medicines committees and equivalents, reducing the duplication of effort that is currently occurring and effect the dissemination of information nationally across all health care sectors.

6.4 INCIDENT MONITORING AND SHARING THE LESSONS

(continued)

Identified gaps and needs

- Coordination of incident reporting or sharing of data nationally to recognise error risk outside of individual facilities and jurisdictions
- Systems for incident reporting and monitoring in community and residential care sectors
- Knowledge of errors and adverse medicines events in community, residential care facilities and mental health services
- Use of analysed data to investigate causes of error and identify trends or underlying systems failures and develop solutions nationally
- Highlight issues and potential systems improvements nationally through preparing and disseminating alerts drawn from Australian incident monitoring systems and international information
- Development and distribution of medication safety information, learning packages and implementation tools for managing systems changes
- Promotion of safer systems developed overseas.

Incident monitoring and sharing the lessons – Options for national action

- Identifying a national approach to incident reporting and monitoring
- Coordinating incident report collation and data analysis from all sectors including consumer reports, professional indemnity insurers, professional boards and coronial communications
- Using results of data analysis and investigation to formulate and disseminate recommendations for system changes and liaise with key agencies to facilitate the change
- Implementing a national approach to:
 - Formulating and disseminating recommendations for systems changes and working with key agencies to implement change;
 - Sharing lessons nationally through generation of alerts, bulletins and working with relevant key stakeholders.

Key organisations with a role in the actions

Jurisdictions, Therapeutic Goods Administration, National Prescribing Service Ltd, Pharmacy Guild of Australia, Professional Registration Boards, Professional indemnity insurers, Australian Coroners Society, Medical Colleges, Health Faculties at Universities.

Recommended actions for the Commission

- Identify a national approach to medication incident reporting, data analysis and investigation
- Work with stakeholders on a coordinated approach to using medication incident and adverse event data to identify and develop national safety solutions including:
 - a. Formulating and disseminating recommendations for systems changes;
 - b. Developing implementation tools and audit tools;
 - c. Liaising with key agencies on implementing change.
- Share lessons nationally through generation of alerts and bulletins and by working with stakeholders
- Network with overseas safe medication practice centres.



7. HEALTHCARE PROFESSIONALS

7.1 GAPS IN PRACTICE

Issue

Clinical guidelines can improve clinical decision making and patient outcomes. However studies have shown that clinical guidelines use in clinical practice is suboptimal and important gaps in practice continue to exist.⁴⁷ Non-adherence to guidelines can have far reaching consequences:

“The emergence and selection of resistant bacteria driven by inappropriate antimicrobial use and subsequent transmission among hospital patients has a significant impact on morbidity, mortality and treatment costs.”⁴⁸

There are also guidelines that promote evidence based safe medication practices such as medication reconciliation on admission to hospital^{10, 12} and indicators for measuring performance.⁴⁹

Discussion

There was concern at the slow uptake of evidence-based and best practice guidelines into clinical practice. Examples given included the management of acute coronary syndromes post-discharge and safe and effective use of antibiotics. Examples of inconsistent national implementation of guidelines and standards for safe use of medicines included the APAC *Guiding principles for continuity of medication management* and the former Council safety alert requiring removal of potassium ampoules from intensive care and paediatric settings.

Significant activity was noted in the community and hospital sectors to address gaps in practice. Examples included: the National Institute for Clinical Studies collaborative projects; the NPS programs for general practitioners, pharmacists and consumers, drug usage evaluation projects in the acute care sector, and the publication of indicators for measuring safe and quality use of medicines and driving practice improvement in general practice and hospitals (*Indicators for Quality Prescribing in Australian General Practice*.⁵⁰ *Indicators of Quality Use of Medicines in Australian Hospitals*⁴⁹ *The Australian Council on Healthcare Standards*⁵¹). The Commission's National Indicator Project was also noted. To effect change nationally, and to improve health outcomes and patient safety, the Committee agreed that a coordinated approach was needed to implementing interventions and measuring performance.

Setting goals for reducing medication errors in hospitals and improving medication management systems were important drivers used by the U.S. Joint Commission for improving safe medicines practice in that country.⁵² There was support amongst the jurisdictional committees for a similar approach in Australia.

Identified gaps and needs

- Professional accountability for following evidence-based, best practice guidelines
- Process for developing nationally agreed priorities to address practice gaps
- National systems for monitoring uptake and implementation of guidelines
- Indicators for measuring safe medication practice
- Implementation tools and audit tools to address important gaps in safe medication practice.

Gaps in practice – Options for national actions

- Incorporating guidelines into prescribing decision support systems at point of care
- Increasing access and links to Medicare Australia data to identify gaps in practice and measure the effect of guideline implementation
- Setting and monitoring national indicators for quality use of medicines and safe medication practice
- Developing and disseminating alerts and implementation and audit tools to address important gaps in quality use of medicines including safe medication practice.

Key organisations with a role in the actions

National Institute of Clinical Studies of the National Health and Medical Research Council, National Prescribing Service Ltd, Council of Australian Therapeutic Advisory Groups, NSW Therapeutic Advisory Group, NSW Clinical Excellence Commission, Department of Veterans' Affairs.

Recommended actions for the Commission

- Set nationally agreed priorities for addressing gaps in quality use of medicines and safe medication practice and monitor outcomes through the use of indicators
- Develop safe medication practice indicators
- Develop and disseminate alerts, implementation and audit tools to address important gaps in safe medication practice.

7.2 COMPETENCIES IN SAFE MEDICATION PRACTICE

Issue

Health professionals with responsibilities for prescribing, administering, dispensing and monitoring medicines need to be familiar with the principles of safe medication practice and be competent in their area of practice.

Discussion

There was unanimous agreement that health professionals should be required to demonstrate competency in safe medication practice within their respective scope of practice such as the prescribing, dispensing, administering of medicines and clinical pharmacy. This applied to staff working in all health sectors, such as enrolled nurses administering medicines in acute and residential care facilities and unqualified staff in hostels administering medicines, as well as to complementary and alternative medicines practitioners. It was noted that the detail, as opposed to the general principles, of medication safety practice is not always evident in medical, nursing and pharmacy curricula.

Demonstration of competency by those prescribing, administering, dispensing and clinically reviewing medicines, as part of health professional registration, was agreed to be an important element of medication safety. In addition, competency based training in safe medication practices for all health practitioners with medication management responsibilities was also agreed to be important.

As poor communication is a major cause of error in hospitals and the community, training programs for safe medicine practice should include communication and team work skills. It was agreed that a national advocate for these propositions was necessary. Currently available tools, such as the National Prescribing Service on line prescribing curriculum and on line NIMC learning tool,⁵³ should be more widely promoted. It was noted that competency to practice could come within the scope of national registration of health professionals currently being progressed by the Council of Australian Governments. There was an opportunity for the Commission to advocate for the inclusion of competencies for safe medicines practice into the professional registration requirements relating to scope of practice. For example, competencies to prescribe could be included in the registration requirements for all prescribers, including non-medical prescribers.

It was noted that all States and Territories will review legislation affected by proposed changes during implementation of national registration, in particular drugs and poisons legislation. This may reduce the jurisdictional inconsistencies in policy and regulations which currently impede standardised medication safety education for health professionals and nationally consistent scopes of practice.

Identified gaps and needs

- National approach to assessment of the competency of health professionals who prescribe, administer, dispense and clinically review medicines
- Competency-based training in safe medication practice for all health practitioners with medication management responsibilities including training in communication and working in teams
- Professional accountability for following evidence-based and best practice guidelines and standards (clinical and safe medication practice).

Competencies in safe medicines practice – Options for national actions

- Including safe medication practice in curricula for health professionals
- Including professional accountability for adhering to best practice guidelines and standards in credentialing requirements
- Requiring competency in safe medicines practice for registration of health professions with medication management responsibilities.

Key organisations with a role in the actions

Professional organisations, health professional education councils, university faculties and schools, professional registration bodies, jurisdictions, hospitals and other facilities, National Prescribing Service Ltd, Council of Australian Governments, National registration bodies.

Recommended actions for the Commission

- Advocate inclusion of safe medication practice in curricula for health professionals
- Advocate competency in safe medication practice as a registration requirement for health professions with medication management responsibilities.

“An integrated comprehensive approach to medicines error is a national imperative”
Cliff Hughes AO, CEO, Clinical Excellence Commission, NSW.⁵⁴

While this scoping study found that there is much activity occurring in Australia in medication safety and the quality use of medicines, it also identified a number of important patient safety activities that were not occurring or being implemented inconsistently. It was agreed that there is an important role for the Commission in leading and co-ordinating these activities if measurable, system-wide improvements are to occur in the safe and quality use of medicines. The role for the Commission is to reduce patient harm by providing national leadership and strategic direction for practice change and systems improvement.

The following section of the report proposes a national approach to achieve measurable improvements in the safety and quality of medicines use. There are three components to the approach, recommending:

1. Actions for prioritisation by the Commission;
2. Actioning prioritised recommendations;
3. Working with key stakeholders;
4. Identifying a unit within the Commission to provide a national focus for safe medication practice.

The proposed national approach to medication safety and quality requires the Commission, in partnership with key stakeholders, to prioritise and action the activities identified in the scoping study. It is important that the Commission's medication program informs, contributes to and aligns with the National Medicines Policy and its new implementation structure.



8. NATIONAL APPROACH TO MEDICATION SAFETY AND QUALITY

8.1 RECOMMENDED ACTIONS FOR THE COMMISSION

A range of national activities to improve patient safety in relation to medication were identified in the previous chapters. Those recommended for action by the Commission have been collated and listed in Table 1.1 which is reproduced below.

Recommendation 1

The Commission accept the report and prioritises the recommendations in Table 1.1.

Table 1.1 Recommended actions for the Commission

1. The patient's journey through the health system		c. Improving communication about medicines and access to HMR/discharge liaison services in rural and remote areas and communities.
1.1 Consumer access to information		2. Product Safety
1. Advocate the safety and quality benefits of the proposed e-health record for medicines.		2.1 Enhancing post-marketing pharmaco-vigilance
2. Work with NEHTA and DOHA E-Health Branch on the e-health record for medicines.		16. Advocate the safety and quality benefits of enhancing post-marketing pharmaco-vigilance through linking data from existing data repositories.
3. Recommend implementation of the APAC <i>Guiding principles for medication management in the community</i> .		2.2 Packaging and labelling as contributors to error
4. Liaise with NPS on a communication strategy for consumers and health professionals to promote available options for accessing current medicines lists.		17. Work with TGA to improve the safety of labelling and packaging including giving prominence to the active ingredient equal to the brand name.
5. Consult with consumer organisations on consumer information needs, including CMI, and communicate preferred enhancements to key information providers.		18. Work with TGA to establish a process for identifying and addressing reports of errors and patient harm caused by poorly designed labelling and packaging.
6. Advocate increased access and review of the content, and format, of CMI and the mechanisms for delivery.		19. Work with pharmacy organisations to develop standards for improving labelling on dispensed products.
1.2 Continuity of care		20. Work with key stakeholders to establish and implement standards for user applied labels for medicines in hospitals.
7. Lead advocacy for the safety and quality benefits of a national approach to an e-health record for medicines.		3. Medication management systems
8. Work with NEHTA and DoHA E-Health Branch to assist development and implementation of the e-health record for medicines in all care settings.		3.1 Systems improvements through standardisations
9. Advocate interoperability of systems between healthcare providers.		21. Develop additional standard medication charts for residential and community care and high risk drugs in acute care.
10. Recommend implementation of the APAC <i>Guiding principles for continuity of medication management</i> .		22. Facilitate the development of an National Inpatient Medication Chart that can be generated by GP e-prescribing systems.
11. Promote medication reconciliation at care transition points including identifying resources (tools, models) to support implementation of medication reconciliation.		23. Develop a guidance document on the requirements for safe e-medication management systems including safe design features, use of safety alerts, and clinical decision support systems.
12. Lead advocacy for the safety and quality benefits of a national approach to the funding of pharmaceuticals.		24. Lead the identification and development of standardisation initiatives to improve medication safety.

8.1 RECOMMENDED ACTIONS FOR THE COMMISSION

(continued)

3.2 Medication distribution systems
25. Recommend national adoption of <i>Medication Safety Self Assessment for use in Australian Hospitals</i> to identify risks in acute care medication management systems and drive improvement.
26. Recommend national adoption of <i>Medication Safety Self Assessment for Antithrombotic Therapy in Australian Hospitals</i> to identify risks and drive improvement in acute care management of antithrombotic therapy.
27. Inform development of safe medication practice indicators for all settings of care.
28. Report on medication distribution systems used and planned in hospitals and residential care settings, including identifying barriers and enablers to introducing safer systems.
3.3 Use of technology to improve medication safety
29. Advocate the safety and quality benefits of implementing electronic medication management systems in all care settings.
30. Work with NEHTA and DOHA E-Health Branch to improve the interoperability of systems between healthcare sectors.
31. Develop a guidance document on the requirements for safe e-medication management systems (including safe design features, use of safety alerts, clinical decision support systems) and the safe introduction of the technology into workplaces.
32. Advocate access for all professionals with prescribing responsibility to systems that support safe prescribing (including decision support tools).
33. Advocate the safety and quality benefits of bar code checking in the medicines management pathway.
34. Coordinate the development of guidelines for implementing bar code checking in the medication management pathway.
35. Advocate a mandatory requirement for bar codes on all medicines to 'unit of use' level (i.e. to the point of patient administration).
36. Promote industry awareness of the need for bar codes on products to support safe medication management systems in health care.

3.4 Incident monitoring and sharing the lessons
37. Identify a national approach to medication incident reporting, data analysis and investigation.
38. Work with stakeholders on a coordinated approach to using medication incident and adverse event data to identify and develop national safety solutions including: <ol style="list-style-type: none"> Formulating and disseminating recommendations for systems changes; Developing implementation tools and audit tools; Liaising with key agencies on implementing change.
39. Share lessons nationally through the generation of alerts and bulletins and by working with stakeholders.
40. Network with overseas safe medication practice centres.
4. Healthcare professionals
4.1 Addressing gaps in practice
41. Set nationally agreed priorities for addressing gaps in practice in quality use of medicines and safe medication practice and monitor outcomes through the use of indicators.
42. Develop safe medication practice indicators.
43. Develop and disseminate alerts, implementation and audit tools to address important gaps in safe medication practice.
4.2 Competencies in safe medicines practice
44. Advocate inclusion of safe medication practice in curricula for health professionals.
45. Advocate competency in safe medication practice as a registration requirement for health professions with medicines management responsibilities.

The Committee acknowledges that the list is extensive. The environment in which medicines are regulated, prescribed, supplied, administered and monitored in Australia is complex and involves many stakeholders, government and non-government, at national and state/territory level, including health professionals and consumers and carers. The breadth of the recommendations reflects the complexity of the task required to improve medication management practices and reduce preventable harm from medicines across all sectors of care. The Committee agreed that the actions recommended for the Commission would need to be prioritised and a work plan developed.

Recommendation 2

The Commission action the priority recommendations.

8.2 WORKING WITH STAKEHOLDERS

A national approach to medication safety and quality requires the Commission to work with key stakeholders. Working together, the Commission and key stakeholders will prioritise and advise on national strategies to improve medication safety and the quality use of medicines.

Recommendation 3

The Commission establish an expert Medication Reference Group to advise on national strategies and priorities for medication safety and quality.

The Medication Reference Group

Committee members recommend that the Commission establish a Medication Reference Group. The Committee considers the Commission, with the support of an expert group representing key stakeholders, is best placed to advise on national priorities for improving medicines safety and quality in all settings and addressing gaps in practice with a clear focus on reducing patient harm.

Setting goals for reducing medication errors in hospitals and improving medication management systems are important drivers used by the U.S. Joint Commission, for improving safe medicines practice in that country.⁵²

The Medication Reference Group will work with the Commission's other standing committees to advise on priorities for action and implementation.

It is expected that the Committee's activities will contribute to the work of the National Medicines Policy Executive and its associated fora.

The main roles of the Medication Reference Group will be to:

- Advise the Commission on national strategies for medication safety
- Assist in implementing the strategies
- Recommend national priorities for action
- Recommend and monitor national standards and indicators for Quality Use of Medicines and safe medication practice
- Recommend research priorities for safe medication practice
- Recommend strategies for translating evidence into practice.

Membership will include representatives from

Consumers' Health Forum
Clinicians involved in medication safety
National Medicines Policy Committee (Chair)
Department of Health and Ageing
Therapeutic Goods Administration
National Prescribing Service
Academia/Centre for Research Excellence in Patient Safety
National Health and Medical Research Council/National Institute for Clinical Studies
Department of Veterans Affairs
Pharmaceutical Industry
Pharmaceutical Benefits Advisory Committee
State and Territory health departments
National Electronic Health Transition Authority

8.3 A NATIONAL FOCUS FOR MEDICATION SAFETY AND QUALITY

A national focus for medication safety is a prerequisite for leading and coordinating systems improvements throughout the health sectors, and to implement the recommended activities identified in the study.

Recommendation 4

The Commission identify a National Medication Safety Unit within the Commission

1. To effect the recommended actions (listed in Section 8.1)
2. As a national focus for medication safety and quality.

National Medication Safety Unit

Committee members recommend that a National Medication Safety Unit be identified in the Commission. Committee members do not make this recommendation lightly but do so primarily to provide a national focus for medication safety fully conscious of the current fragmented arrangements. Fragmentation works against coordinated national action which can improve patient safety. Committee members agreed that the Commission is best placed to lead and coordinate the range of activities identified in the study, providing a national focus for reducing the risk of harm from medicines use.

A national medication safety unit was considered an essential component of a national strategy to reduce preventable adverse medicines events and effect measurable improvements in patient safety in all Australian health settings. It would:

- Manage the Commission's medication safety work program;
- Integrate with the Commission's broader work and the National Medicines Policy; and
- Work with existing bodies to implement key medication safety and quality improvements nationally.

The Steering Committee considered the option of a unit being outside the Commission, either as an entity on its own or housed within another organisation that had expertise in implementing programs and change, such as the National Prescribing Service. However the Steering Committee recognised that the Commission is the only organisation with:

- A remit to lead and coordinate activities for improving patient safety across all health settings
- Links into all health settings through its committees (Inter-Jurisdictional, Private Hospital Sector and Primary Care Committees) to inform policy development and overcome structural barriers to change

- The role of identifying policy direction and providing strategic advice to Health Ministers on best practice thinking and implementation strategies to drive quality improvements.

The proposal to create a national focus for medicines safety within the Commission was supported very strongly by those stakeholders with involvement in medication safety in the acute hospital sector.

Working with existing organisations

It is recommended that the National Medication Safety Unit work with existing national, State and Territory medication safety and quality use of medicines organisations to implement programs. This is because existing organisations have specific remits and capacities which should not be replicated. It is also because the Commission's role does not include implementation and therefore use must be made of existing authorisations, expertise and resources available in the wider medicines community to develop and deliver programs and materials. Work could be undertaken in partnership with organisations with expertise in specific areas of safety and quality.

For example:

- Further developments of the Medication Safety Self Assessment Tool could be undertaken in collaboration with NSW Therapeutic Advisory Group and the Clinical Excellence Commission
- Further medicine charts designed with the Safe Medication Practice Unit in Queensland Health
- Improving the access of consumers to medicines information or introducing initiatives for safe prescribing with the National Prescribing Service
- Working with the Therapeutic Goods Administration to reduce adverse medicines events resulting from naming, labelling and packaging and to coordinate dissemination of medication safety messages.

Overseas models of national centres for medication safety

Prior to recommending identification of a national medication safety unit in the Commission, members considered existing national medicines safety and quality arrangements in other developed countries. It was agreed that the absence of similar national arrangements in Australia to those in other developed countries diminished our ability to lead and coordinate the systematic changes required to improve patient safety in relation to medicines use.

8.3 A NATIONAL FOCUS FOR MEDICATION SAFETY AND QUALITY

(continued)

Establishing a national medication safety unit would bring Australia into line with the U.S.A., Canada, the United Kingdom and other European countries which have established national safe medication practice centres to focus national medication safety and quality activity.

In 2006 the Council of Europe Committee of Ministers recommended that “A recognised national focus point for safe medication practices should be designated in each country in a collaborative and complementary way with pharmaco-vigilance systems for reporting medication errors, analysing causes and disseminating information on risk reduction and prevention”.⁵⁵

In the United Kingdom, the safe medication practice unit is housed within the National Patient Safety Agency, similar to the model proposed for Australia. Details of some of the national safe medication practice units that have been established overseas are listed in Appendix 3. Apart from New Zealand, these centres operate discretely from national pharmaco-vigilance programs.

The advantages of a national medication safety unit within the Commission.

The following advantages of a National Medication Safety Unit were identified by the Committee.

1. It will provide nationally coordinated management of key medication safety and quality improvements.
2. There will be a coordinated approach to medicines safety developments and sharing lessons nationally that will reduce the duplication of effort currently occurring across jurisdictions thus providing efficiency gains.
3. Maximum use will be made of existing expertise and resources available in the wider medicines community to develop and deliver programs.
4. The Commission's Primary Care, Private Hospital Sector and Inter-Jurisdictional Committees will advise and assist on structural changes required to overcome barriers to safe and quality use of medicines in different health care settings.
5. The agency responsible for patient safety will also be responsible for medication safety.
6. Work can be done in partnership with organisations with expertise in specific areas of safe and quality use of medicines.
7. The Commission will be better placed to fulfil its mission of leading and coordinating the medicines element of safety and quality and delivering measurable improvements in the safety and quality of health care.

A good example of the effectiveness of a national safety and quality organisation as a change agent is development and implementation of the National Inpatient Medication Chart nationwide in all public and most private hospitals. It is an exceptional innovation which was developed cooperatively and implemented relatively smoothly, and remains unique internationally.

On the contrary, and without the engagement of a national body, the Australian Pharmacy Advisory Committee *Guiding principles for continuity of medicines management* has been inconsistently implemented and the benefits not fully realised despite the good evidence and cost effectiveness data to support their use. As a result patients continue to be at risk of adverse medicines events particularly at transitions of care.

8.4 SUMMARY

The scoping study found a need for a national approach to reducing medicines related adverse events and medication error in Australia. Although there is much activity occurring in the area of medication safety and quality use of medicines, a number of important patient safety activities were identified as not occurring or being implemented inconsistently.

The Commission was considered to be the appropriate agency for providing national leadership and strategic direction for a national approach to reducing patient harm from medicines.

To enable the Commission to lead and coordinate the national activity required to improve the safety and quality of medicines use across all health settings it was recommended the Commission establish an expert medication reference committee that works with the Commission's other standing committees to:

- Advise priorities for action and implementation and monitor the outcomes of activities; and
- Contribute to the activities of National Medicines Policy Executive.

Finally it was recommended that the Commission identify a national medication safety unit in the Commission that provides a national focus for medication safety and works with the Commission's current committee structures and existing medication safety and quality organisations to effect the recommended actions.



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APPENDICES

APPENDIX 1

Organisations consulted

Organisation	Persons interviewed
ACT Health QUM Reference group	Mr Neil Keen, Mr Andrew Matthews
Adverse Medicines Events Line	Dr Treasure Maguire
(Former) Australian Pharmaceutical Advisory Council	Dr John Aloizos (Former Chair)
Australasian College of Physicians	Ms Mary Osborn Dr Madlen Gazarian
Australian and New Zealand College of Anaesthetists	Dr John Biviano, Dr Penny Briscoe, Dr Felicity Hawker
Australian Medical Association (Therapeutics Committee)	Adjunct Associate Professor John Gullotta, Dr John Aloizos, Dr M Steiner
Australian Pharmacy Council	Ms Elizabeth Frost
Australian Nursing Federation	Ms Julianne Bryce
Australian Patient Safety Agency	Professor William Runicman
Bettering the Evaluation and Care of Health	Dr Helen Britt, Dr Graeme Miller
Council of Australian Therapeutic Advisory Groups	
Children's Hospitals of Australasia	Ms Joanna Holt, Dr Madlen Gazarian
Clinical Excellence Committee (NSW)	Professor Clifford Hughes AO
Consumer Health Forum	Ms Joy Russo
Centre for Research Excellence in Patient Safety	Dr Sue Evans
Department of Veterans Affairs	Mr Robert Peck
Drug and Therapeutics Information Service (DATIS)	Ms Deborah Rowett
Drug Utilisation Subcommittee of Pharmaceutical Benefits Advisory Committee (DUSC)	Ms Maxine Robinson
eHealth Branch, Department of Health and Ageing	Dr Christopher Mount, Ms Janine Bevan
Generic Medicines Industry of Australia	Ms Di Ford

Organisation	Persons interviewed
Health Quality Complaints Commission (Queensland Government)	Dr Danielle Stowasser
Department of Health & Ageing	Mr David Learmonth, Ms Rosemary Huxtable, Ms Sue Campion
Medication Services, Queensland Health	Ms Di Aldous
Medicines Australia	Ms Elizabeth de Somer
Monash University – Centre for Medication Safety	Professor Roger Nation, Associate Professor Michael Dooley
National Institute of Clinical Excellence	Dr Sue Phillips
National Prescribing Service	Dr Lyn Weekes, Ms Karen Kaye, Ms Margaret Williamson
National Electronic Health Transition Authority	Ms Kate Ebrill, Ms Colleen Brooks
NSW Health Chief Nursing Officer	Adjunct Professor Debra Thoms
NSW Therapeutic Advisory Group	Ms Karen Kaye
Royal Darwin Hospital	Ms Bhavini Patel
Former Pharmaceutical Health and Rational use of Medicines Committee	Professor Ric Day AM
Pharmaceutical Society of Australia	Mr Grant Martin, Ms Kay Sorimachi
Pharmacy Guild of Australia	Ms Erica Vowles, Ms Katherine Baverstock, Ms Jenny Bergin, Mr Stephen Armstrong
Quality & Safety Branch NSW Health	Mr Kelvin Genn, Mr Daniel Lalor, Dr Ric Day
Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute, University of South Australia	Associate Professor Andrew Gilbert

APPENDIX 1

(continued)

Organisation	Persons interviewed
Reducing Adverse Medication Events in Mental Health Services Working Party	Dr Rowan Davidson
Office of Aged Care Quality and Compliance, Department of Health and Ageing	Dr Susan Hunt
Royal Australian & NZ College of Psychiatrists	Dr Sharon Brownie
Royal Australian College of General Practice	Mr Ian Watts
Royal College of Nursing, Australia	Associate Professor Elizabeth Manias
South Australian Government Health Department, Quality and Safety Unit	Ms Naomi Burgess
Safe Medication Practice Unit, Queensland Health	Dr Tony Hall, Dr Ian Coombes
Society of Hospital Pharmacists of Australia	Ms Yvonne Allinson,
Society of Hospital Pharmacists Of Australia, Committee of Speciality Practice in Medication Safety	Ms Rosemary Burke
Therapeutic Goods Administration, Department of Health and Ageing	Dr Rohan Hammett
Unit for Medication Research and Outcomes, University of Tasmania	Professor Gregory Peterson
Victorian Medicines Advisory Group	Ms Helen Leach
Government of Western Australia Health Department, Office of Safety and Quality	Mr Mark Scully
Western Australia Medicine Safety Group	Professor Alasdair Millar, Dr Margherita Veroni
Medication safety expert	Ms Penny Thornton,
Medication safety expert	Ms Melita van de Vreede

APPENDIX 2

Organisations with roles in improving safe and quality use of medicines

The following table lists organisations at international, national and state and territory levels that have a role in improving the safety and quality of medicines use in Australia. The Australian content of the table was mainly derived from interviews held with personnel from the organisations during the consultation process. Some of the details have been augmented with information from the relevant organisation's website or from the discussion paper produced by the *National Prescribing Service Medication safety in Australia: Status at November 2007*.⁵⁶

Scope

There are many organisations and people with responsibilities for medicines in Australia including consumers and carers, health professionals, institutions and organisations. Only those organisations which have a specific focus on improving safe use of medicines have been included in the table.

Content

The description of the roles of the organisations has been limited to those relevant to safety and quality of medicines use. Column three of the table provides a brief description of activities currently occurring in the area of medication safety.

Table of organisations with roles in improving safe and quality use of medicines

Body	Roles	Examples of Activities
International		
World Health Organisation – World Alliance for Patient Safety www.who.int/patientsafety/en	Raise awareness and promote political commitment to improve safety of health care. Formulate global patient safety challenges. Develop Patient Safety Solutions.	Current solutions include: <ul style="list-style-type: none"> • Look alike, sound alike names. • Control of concentrated electrolyte solutions. • Assuring medication accuracy at transitions of care.
International Network of Safe Medicines Practice Centres www.intmedsafe.net/	Optimise medication safety through information exchange, address common issues, global initiatives to minimise harm from medicines.	Global report on medication safety centres' activities. Collaborating with World Health Organisation and Joint Commission International on patient safety solution to Look alike, sound alike names. Solutions to prevent risk with opioid patches.
NATIONAL – Government		
Therapeutic Goods Administration A division of the Commonwealth Department of Health and Ageing responsible for administering the <i>Therapeutic Goods Act 1989</i> and the Regulations. www.tga.gov.au	TGA ensures therapeutic goods available in Australia are of an acceptable standard. It does this through a range of assessment and monitoring activities including: <ol style="list-style-type: none"> a. Product registration (includes approval of product labelling, packaging, product information and assessing consumer medicines information meet criteria within the regulations). b. Pre-market assessment. c. Licensing of manufacturers. d. Post market vigilance. e. Recall of unsafe and defective medicines. The Office of Medicines Safety Monitoring monitors adverse drug reactions. The Adverse Drug Reactions Advisory Committee (ADRAC), formed in 1970, provides advice to the TGA on the safety of medicines.	Conducting pre-market risk assessments and post marketing pharmaco-vigilance activities. (The TGA is currently enhancing pharmaco-vigilance activities). Managing the adverse drug reactions reporting system. Issuing medicines alerts and advisories. Developing a repository of consumer medicines information and product information to be available on its website in 2009. Maintaining a data base of adverse drug reactions and contributing to identification of previously unrecognised reactions. Publishing the Australian Adverse Drug Reactions Bulletin bi-monthly.

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
NATIONAL – Government		
National Prescribing Service (NPS) An independent, non-profit organisation primarily funded by the Commonwealth Department of Health and Ageing. www.nps.org.au	NPS provides medicines information and resources for consumers, health professionals, members and stakeholders involved in Quality Use of Medicines. Supports quality prescribing and provides services and programs nationwide.	Many NPS programs incorporate medication safety messages and work towards improving medication safety. They include: <ol style="list-style-type: none"> Consumer section on website providing medicines information and access to Consumer Medicines Information. Curricula and training through on line prescribing modules, training module for the National Inpatient Medication Chart. Quality prescribing indicators for general practice. Phone line services for health professionals, consumers seeking information and for consumers to report adverse medicines events.
Pharmaceutical Benefits Division A division of the Commonwealth Department of Health and Ageing responsible for achievement of Departmental outcome 2 – access to pharmaceutical services. www.pbs.gov.au/html/home	The Pharmaceutical Benefits Division aims to provide all Australians with access to cost-effective and high quality pharmaceutical services. Policy implementation including National Medicines Policy and the National Strategy for Quality Use of Medicines. Various advisory and program entities including: <ol style="list-style-type: none"> National Medicines Policy Executive and associated Committee and Forum. Paediatric Medicines Advisory Group. Consumer Medicines Information – Quality Reference Advisory Group. Drug Utilisation Subcommittee of Pharmaceutical Benefits Advisory Committee. Expert Advisory Panel on medicines in indigenous health settings. Activities under the 4th Community Pharmacy Agreement. 	Quality assures Consumer Medicines Information. Hosting website reports of QUM research and projects through Queensland University. Monitoring usage of Pharmaceutical Benefits Scheme (PBS) listed drugs to ensure safe and effective use of PBS drugs. Funding: <ol style="list-style-type: none"> Pharmacy services. Dose administration aids. Patient medicines profiles. Residential Medicines Management Program Home medicines review program. Research projects on Quality Use of Medicines and medicines safety.
National Institute for Clinical Studies An institute of the National Health and Medical Research Council (NHMRC). www.nhmrc.gov.au/nhics/asp/index.asp	Improve health care by closing important gaps between best available evidence and current clinical practice.	Publish on identified gaps in clinical practice. Develop evidence based guidelines, intervention strategies to close the gaps. Run collaborative projects to address gaps in practice eg. VTE prophylaxis project in private sector in collaboration with ACSQHC. Provide fellowships to support future leaders in the science and practice of evidence implementation.
Department of Veterans Affairs Commonwealth Government Department responsible for carrying out Government policy and implementing programs to fulfil Australia's obligations to war veterans and their dependants. www.dva.gov.au	Provide pharmaceutical benefits and services for Australian veterans and their dependants.	Fund: <ul style="list-style-type: none"> Home medicines reviews. Drug administration aids. Veterans Medicines Advice and Therapeutic Education Services (Veterans MATES).

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
NATIONAL – Government		
Council of Australian Therapeutic Advisory Groups National forum for State Therapeutic Advisory Groups.	Develop national positions on issues relating to access, safety and quality use of medicines.	Develop national guidelines for use in Australian hospitals <ul style="list-style-type: none"> • Guiding principles on use of complementary and alternative medicines. • Guiding principles for off-label use of medicines.
NATIONAL – Non-Government		
Consumers' Health Forum Organisation that advocates for consumer health issues www.chf.org.au	Advocate for consumer health issues including safe and appropriate use of medicines.	Partnership with NPS on Community Quality Use of Medicines Project 2007–07 to provide consumers with knowledge on sourcing information on how to use medicines safely and appropriately.
Medical Colleges	Deliver training, college fellowship programs. Accredite hospitals and training programs. Publish evidence based clinical practice guidelines. Develop standards of practice. Provides continuing professional development.	Royal Australasian College of Physicians <ul style="list-style-type: none"> • Position statement on e-prescribing. • Incorporate Quality Use of Medicines principles including medication safety, into clinical qualities curriculum. • Consultation with TGA on process for updating Product Information. Royal Australian College of General Practitioners Develop patient safety resources and initiatives: <ul style="list-style-type: none"> • Allergy documentation. • Causal analysis model for use by general practitioners for internal reporting of adverse events and reactions. Australian and New Zealand College of Psychiatrists Develop evidence based guidelines, that include medicines information, for health professions and for consumers and carers for a range of mental health disorders. Australian and New Zealand College of Anaesthetists Quality and Safety Committee established. Safety alert section on website.

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
NATIONAL – Non-Government		
<p>Pharmacy Organisations (Society of Hospital Pharmacists of Australia, Pharmaceutical Society of Australia)</p> <p>Professional organisations for pharmacists.</p> <p>www.shpa.org.au</p> <p>www.psa.org.au</p>	<p>Publish standards of practice, guidelines.</p> <p>Provides continuing professional development.</p> <p>Develop competency standards for pharmacy profession.</p>	<p>Society of Hospitals Pharmacists of Australia Journal of Pharmacy Practice and Research – Medication Safety section.</p> <p>Medication Safety Committee of Speciality Practice.</p> <p>Medication safety seminars.</p> <p>Advocacy for safe and effective use of medicines across the continuum.</p> <p>Pharmaceutical Society of Australia Competency standards for pharmacists in Australia 2003.</p> <p>Guidelines for Pharmacists on Providing Medicines Information, CMI to Patients</p> <p>Guidelines for managing pharmacy systems for quality and safety.</p> <p>Guidelines for pharmacists in providing services to people with impaired vision.</p> <p>Dose Administration Aids Service – Guidelines and Standards.</p>
<p>Pharmacy Guild of Australia</p> <p>National employers' organisation for Pharmacy Owners.</p> <p>www.guild.org.au</p>	<p>Develop and implement policy.</p> <p>Develop accreditation standards and accredit community pharmacies.</p> <p>Manage community pharmacy research program funded through Community Pharmacy Agreement.</p>	<p>Promoting community pharmacy initiatives to support safe and effective use of medicines including:</p> <ul style="list-style-type: none"> • Drug administration aids. • Patient medication profiles (Trial). • CMI provision. <p>Research grants funded through 4th Community Pharmacy Agreement include:</p> <ul style="list-style-type: none"> • Warfarin management in community. • Continuity of care from hospital to residential care facility.
<p>Australian Nursing Federation</p> <p>National union for nurses and professional nursing organisation.</p> <p>www.anf.org.au</p>	<p>Develop policy in nursing.</p> <p>Represents nursing on quality use of medicines projects, national bodies.</p>	<p>Publishes features on medicines, reports on NPS activities in Australian Nursing Journal, Australian Journal of Advanced Nursing.</p> <p>Development of Informatics Competency Standards for the nursing profession in Australia.</p> <p>Updating guidelines for medicines management in nursing homes in collaboration with RCNA.</p> <p>National standards for nurse practitioners – medicines management and prescribing.</p>
<p>Royal College of Nursing, Australia</p> <p>The peak national professional organisation for Australian nurses.</p> <p>www.rcna.org.au</p>	<p>Provide educational services, publications, and networks for nurses.</p> <p>Administer scholarship schemes funded through DoHA.</p>	<p>Updating guidelines for medicines management in nursing homes in collaboration with ANF.</p>

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
NATIONAL – Non-Government		
Children's Hospitals of Australasia Organisation representing Children's Hospitals. www.wcha.asn.au	Develop tools to assist with systems change in paediatric acute sector. Advocate for improvements in quality and safety of medicines use in Paediatrics.	Medication Safety Committee. Information on oral syringes. Implementation guidelines and audit tool to assist with introduction of the paediatric national inpatient medication charts.
Australasian Patient Safety Foundation	Subsidiary of APSF, Patient Safety International, markets the Advanced Incident Management System (AIMS).	Incident reporting software used in public hospital sector in SA, WA, NSW & NT.
Pharmaceutical Industry Groups Organisations representing Pharmaceutical Industry (Medicines Australia, Generic Medicines Industry of Australia). www.medicinesaustralia.com.au www.gmia.com.au	Post marketing pharmaco-vigilance. Conduct of clinical trials. Labelling and packaging design.	Participate in the CMI Quality Assurance Reference Advisory Group. Medication safety viewed as an individual company responsibility.
Australian Council on Health Care Standards Independent not for profit organisation for improving quality of healthcare. www.achs.org.au	Assess and accredit health services. Set standards and indicators for measuring performance.	Standard 1.5.1 Medications are managed to ensure safe and effective practice. Performance indicators for medication management.
Professional indemnity insurers Organisations that provide professional indemnity insurance. www.the-pda.org	Provide information to health professionals to reduce risk of error.	Pharmacy Defence Ltd – guidelines for safe dispensing, Look alike, sound alike names causing error. News Bulletins.

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
STATE AND TERRITORIES		
Registration boards for medicine, nursing and pharmacy	<p>Set requirements for registration, register professionals to practice.</p> <p>Manage complaints about professionals, their conduct and professional performance.</p> <p>Establish standards of education, accredit teaching programs.</p> <p>Distribute information bulletins.</p>	<p>Medication safety messages in bulletins.</p> <p>Pharmacy Board requirements for mandatory barcode checking in the dispensing process in some States and Territories.</p>
Safety and Quality Branches and Councils	<p>Strategic role, report directly to ministers on safety and quality issues.</p> <p>Manage incident monitoring systems.</p>	<p>Issue safety alerts within their jurisdictions.</p> <p>WA Office of Quality and Safety on Health Care have published Pharmaceutical review policy, audit tools.</p> <p>South Australia planned implementation of APAC Guiding principles for continuity of medication including development of indicators to measure performance.</p> <p>NSW Clinical Excellence Commission collaborated with NSW TAG to produce Medication Safety Self Assessment (MSSA) Tools for Australian Hospitals, MSSA for Antithrombotic Therapy in Australian Hospitals and QUM Indicators for Australian Hospitals. Hosts website for sites reporting MSSA data.</p> <p>Northern Territory implementing information technology solutions.</p>
<p>Medication safety committees and bodies</p> <p>Victorian Medicines Advisory Group.</p> <p>WA Medication Safety Group.</p> <p>NSW Medication Safety Strategy Committee.</p> <p>ACT Health QUM reference Group.</p> <p>Queensland Health Safe Medicines Practice Unit.</p>	<p>Monitor incidents, root cause analyses and identify actions.</p> <p>Issue safety alerts on drugs and practices.</p> <p>Monitor QUM indicators.</p> <p>Evaluate interventions.</p>	<p>Develop strategic plans for medication safety.</p> <p>Develop strategies to manage high risk drugs.</p> <p>Issue safety alerts e.g. NSW and Oxycodone, Victoria and oral dispensers.</p> <p>Recommend indicators for monitoring.</p> <p>Develop charts, tools to support practice changes e.g. Queensland Health Safe Medicines Practice Unit's specialist medicines charts, medicines action plan.</p> <p>Queensland Health Safe Medicines Practice Unit projects on:</p> <ul style="list-style-type: none"> • Medicines review. • Medicines at interfaces of care (admission, discharge). • Electronic solutions to transfer medicines information. • Tele-pharmacy to provide medicines review in rural hospitals. • Training and competencies in safe medicines practice.

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
STATE AND TERRITORIES		
<p>Therapeutic advisory groups, drug and therapeutics committees</p> <p>NSW TAG, SATAG, Vic TAG Queensland Hospitals Drug Advisory Committee, Tasmanian State wide Drug and Therapeutics Committee.</p>	<p>Support State/territory QUM programs and networks.</p> <p>Support Drug and Therapeutic Committees.</p>	<p>NSW TAG collaborative with Clinical Excellence Commission on Medication Safety Self. Assessment tools and Quality use of Medicines Indicators for Australian Hospitals.</p>
<p>Health care complaints commissions</p>	<p>Manage health care complaints. May involve medicines.</p>	<p>Queensland Health Quality Complaints Commission sets and monitors performance against standards including some relating to QUM e.g. AMI management on and post discharge, VTE prophylaxis.</p>
RESEARCH & EDUCATION		
<p>Centre for Research of Excellence in Patient Safety (CREPS)</p> <p>www.crepatientsafety.org.au</p>	<p>Established to design, conduct, promote and promulgate high quality multi-centre research to improve quality, safety, efficiency and effectiveness of health care for Australians.</p>	<p>Research projects in medication safety:</p> <ul style="list-style-type: none"> • Medication error in the recovery room. • Warfarin management in the community.
<p>Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute, University of South Australia</p> <p>www.unisa.edu.au/sansominstitute/research/activities/groups/qumprc.asp</p>	<p>Develop, implement and evaluate national medicines policies and programs through research, consultancy and training.</p>	<ul style="list-style-type: none"> • Develops, evaluates and implements policy on quality use of medicines. • Involved in Pharmaco-epidemiological research, teaching and training. • Research into traditional and complementary medicines.
<p>Centre for Medication Safety (Monash University)</p> <p>www.monash.edu.au/research/cmus</p>	<p>Optimise and address the safe and effective use of medicines.</p> <p>Develop, implement and evaluate new models and systems of health care practice, with the ultimate goal of optimising the safe and effective use of medicines.</p>	
<p>Health Informatics Research and Evaluation Unit (University of Sydney)</p> <p>www.fhs.usyd.edu.au/hireu</p>	<p>Conduct innovative research aimed at understanding and improving the way in which health care delivery and patient outcomes are enhanced through the effective use and exchange of information.</p> <p>Evaluates health informatics interventions for effectiveness, efficiency and safety using quantitative research methods grounded in epidemiological techniques and qualitative techniques such as video observational studies and social network analyses.</p>	<p>Research Projects include:</p> <ul style="list-style-type: none"> • The safety and effectiveness of hospital e-prescribing systems: a controlled time series study. • The impact of electronic medication administration records (e-MAR) on medication administration safety and nurses' work. • Impact of electronic health record systems on health professionals' patterns of clinical work. • The role of clinical communication loads in contributing to medication administration errors and task scheduling errors. • Online evidence retrieval systems supporting clinical decision-making.

APPENDIX 2

(continued)

Body	Roles	Examples of Activities
RESEARCH & EDUCATION		
<p>Unit for Medication Outcomes Research and Education – University of Tasmania</p> <p>www.pharmacy.utas.edu.au/UMORE.htm</p>	<p>Provides information, education and collaborative research in the assessment and improvement of medication outcomes.</p>	<p>Research projects include:</p> <p>Information systems solutions to improve the safety and quality use of medicines e.g. quality use of medicines between hospital and community, evaluation of medication incidents and clinical interventions software for community pharmacy. Management of anticoagulant medicines.</p>
<p>Pharmacy School, Queensland University</p> <p>www.uq.edu.au/pharmacy</p>	<p>Prepare graduates for the contemporary role of the pharmacist in society ensuring that patients optimise medication usage.</p> <p>Research projects in quality use of medicines.</p>	<p>Website hosts the QUMMAP – a comprehensive map of current major quality use of medicines (QUM) initiatives in Australia.</p>
<p>Centre for Health Informatics, University of NSW</p> <p>www.chi.unsw.edu.au</p>	<p>Research on safety models and standards for information technology in healthcare.</p>	<p>Develop technologies to provide on-line access to clinically relevant information to support decision making by clinicians and consumers.</p> <p>Research into ways information technology can unintentionally generate new types of error.</p> <p>Use accident models to design safe electronic medication management systems.</p>
<p>Paediatric Therapeutics Program, School of Women's and Children's Health, University of New South Wales and Sydney Children's Hospital</p>	<p>Multidisciplinary and collaborative research in: knowledge translation and health services; policy and practice interface in health care; and pharmcoepidemiology and medication safety.</p>	<p>Development of model for systematic evaluation and improvement of medication safety (including errors and harm) in hospitalised children.</p>

APPENDIX 3

Overseas models of safe medicines practice centres

	US ISMP	Canada ISMP – CA	UK – National Patient Safety Agency – Safe Medication Zone	NZ – National Safety and Quality Use of Medicines Group	Netherlands Institute for Proper Use of Medicines – ISMP Affiliate
Funding source	Mainly subscriptions.	Contracts with Federal and Provincial governments.	National Patient Safety Agency (NPSA).	District Health Boards.	60% Ministry of Health, 40% from professional organisations.
Government Organisation			Yes	Yes	Yes
Report to	ISMP Board.	ISMP Board.	NPSA Board.	District Health Board Chief Executives Group.	Institute reports to Ministry of Health. ISMP Affiliate to be set up in November 2008. Will have own Board of Trustees.
Committees/reference groups Advisory groups		Stakeholder committee (medical, nursing and pharmacy) review top drugs causing errors and assist with identifying solutions.	NPSA Hospital Pharmacists' Reference Group. Advisory groups/panels formed for specific pieces of work e.g. design for patient safety initiatives, publications.	The Safety & Quality use of medicines Group is the clinical leadership group for medicines safety and quality in NZ. Steering Committees formed to implement specific projects. Each Committee has a District Health Board representative.	Steering committees and reference committees of opinion leaders oversee programs.
Staff No.	32	8	4	0.4FTE	50 Institute staff in total – approx. 50% time associated with medication safety activities. 35 staff dispersed throughout the country.
Staff composition	Mainly pharmacists and nurses.	Pharmacists, nurses, data analysts.	Pharmacists, Pharmacy Technician.	Part-time coordinator (Pharmacist).	Medical, nursing, pharmacy, management.

APPENDIX 3

(continued)

	US ISMP	Canada ISMP – CA	UK – National Patient Safety Agency – Safe Medication Zone	NZ – National Safety and Quality Use of Medicines Group	Netherlands Institute for Proper Use of Medicines – ISMP Affiliate
Role	<p>The remit of ISMP is to learn about medication errors, understand their system based causes and disseminate practical recommendations that can help health care providers, consumers and the pharmaceutical industry prevent errors.</p> <p>Work collaboratively with a range of government, regulatory, standards setting, licensing and accreditation agencies/organizations to influence medication safety.</p>	<p>Similar to ISMP US.</p> <p>Work closely with Ontario Government to lead medication safety initiatives in that province.</p> <p>Funded by Federal Gov't to work with Institute for Health Information to develop Pan Canadian medication error reporting system for hospitals.</p>	<p>The role of NPSA Safe Medication Practice Team is to review and take action regarding medication incidents reported in the National Reporting and Learning Systems, and information concerning medication risks from other national and international sources.</p>	<p>Implementation of national medication management projects funded by NZ government.</p>	<p>Work with professional bodies to effect changes to improve quality and safe use of medicines. Safety was added to activities in late 1990s.</p>
Activities undertaken	<p>Medication error reporting data collection and analysis to identify high risk drugs, systems problems, labelling and packaging issues.</p> <p>Issue alerts on high risk drugs, solutions for preventing errors.</p> <p>Disseminate learning from errors to health professionals and consumers - bulletins, journal columns, website, monitored message board.</p> <p>Develop/support medication safety tools – e.g. MSSAs for range of settings.</p>	<p>Medication error reporting development, management, data analysis and follow up. Identify strategies to prevent errors.</p> <p>Receive reports from acute, community & residential care sectors.</p> <p>Identify top 10 drugs – do environmental scan to see if problem elsewhere and if work already done.</p> <p>Issue regular bulletins to alert health professionals.</p> <p>Issue resource kits e.g. on high alert drugs.</p>	<p>Analyse and report on medication incidents reported through national reporting system, defence and litigation org'ns.</p> <p>Issue alerts directives, tools & guidance re high risk medicines/systems.</p> <p>Design for patient safety – graphic design guides for packaging/labelling of oral medicines, injectables, dispensed medicines.</p> <p>Rapid response reports on emerging medication safety issues e.g. Oral cytotoxics.</p> <p>Collaborate with NICE – Guidance documents.</p>	<p>Currently no national system for incident monitoring. Done at District Health Board Level.</p> <p>No data from community.</p> <p>Plan is for a central repository for medication errors/incidents. The SQM Committee will be looking at data analysis, investigation to identify strategies for change.</p> <p>Runs high risk medicines alerts program across primary and acute care.</p> <p>Including alerts in dispensing systems for high risk drugs e.g. methotrexate.</p>	<p>Institute undertakes broad range of activities including: improving continuity of care, implementing guidelines, research into “off label” use of medicines in children, website for consumers.</p> <p>Medicines error reporting and management systems are handled at hospital level, with hospitals sharing the data.</p> <p>Plan to implement ISMP-US activities in the Netherlands.</p> <p>The Netherlands pharmaco-vigilance system, LAREB has a working relationship with the Institute. LAREB accepts reports of adverse drug reactions from consumers.</p>

APPENDIX 3

(continued)

Activities undertaken	US ISMP	Canada ISMP – CA	UK – National Patient Safety Agency – Safe Medication Zone	NZ – National Safety and Quality Use of Medicines Group	Netherlands Institute for Proper Use of Medicines – ISMP Affiliate
	<p>Provide consultancies/ education on error investigation for institutions. (RCA, FMEA).</p> <p>Liaise with industry on labelling and packaging.</p> <p>Lead improvements in medication safety system e.g. A national approach to implementing barcode checking in medication management pathway.</p> <p>Research.</p> <p>Provide postgraduate fellowship in medication safety.</p> <p>Subsidiary organisation. Med-ERRS programs. For profit organisation.</p> <p>Tests names and packaging for safety for pharmaceutical Industry.</p>	<p>Provide education in RCA, FMEA.</p> <p>Support Canadian versions of MSSAs – host reporting facility on their website.</p> <p>Develop standards, run workshops for Canadian accreditation body.</p> <p>Run collaboratives e.g. Medication reconciliation for Canadian Patient Safety Institute.</p> <p>Co-ordinating development of best practice guidelines for implementing bar code checking.</p> <p>Inform development of medication safety indicators.</p> <p>Research.</p> <p>Provide postgraduate fellowship in medication safety.</p>		<p>Operationalising national medication management projects including bar-coding initiative to support bedside verification, medicines reconciliation, national hospital drug chart, national formulary.</p> <p>Activities in e- transfer of information from GPs to hospital and e-discharge summaries into GP software.</p> <p>Have expert advisory group working on “look alike, sound alike” drugs, packaging and labelling. Linking PHARMAC (the entity the manages NZ Pharmaceutical Benefit scheme) into the process.</p> <p>New Zealand’s Pharmacovigilance centre is run by Otago University . They reports to SQM and the Medicines Adverse Reactions Committee (Run by the regulator).</p>	

APPENDIX 4

List of acronyms

ACSQHC	Australian Commission on Safety and Quality in Health Care
ADR	Adverse drug reaction
ADRAC	Adverse Drug Reaction Advisory Committee
AHMAC	Australian Health Ministers' Advisory Committee
AHMC	Australian Health Ministers' Conference
AIMS	Advanced Incident Monitoring System
AME	Line Adverse Medicines Events Line
AMSI	Australian Self-Medication Industry
APAC	Australian Pharmaceutical Advisory Committee
APSF	Australian Patient Safety Foundation
ATSI	Aboriginal and Torres Strait Islander
Boards	Professional registration boards
CATAG	Council of Australian Therapeutic Advisory Groups
CEC	NSW Clinical Excellence Commission
CHF	Consumers' Health Forum
CMI	Consumer Medicines Information
COAG	Council of Australian Governments
CREPS	Centre for Research Excellence in Patient Safety
DOHA	Department of Health and Ageing
DVA	Department of Veterans' Affairs
Health pros	Health professions
HIREU	Health Informatics Research and Evaluation Unit
HMR	Home medicines review
IIMS	Incident Information Monitoring Systems
IJC	Inter-Jurisdictional Committee
Industry	Pharmaceutical industry
INSMPC	International Network of Safe Medicines Practice Centres
IS Prog	Information Strategy Program
ISMP	Institute for Safe Medical Practice
Med Industry Software Assoc	Medicines Industry Software Association

NEHTA	National Electronic Health Transition Authority
NHMRC	National Health and Medical Research Council
NICS	National Institute of Clinical Studies
NIMC	National Inpatient Medication Chart
NIMCOC	National Inpatient Medication Chart Oversight Committee
NMP	National Medicines Policy
NPS	National Prescribing Service
NSW TAG	NSW Therapeutic Advisory Group
PCC	Primary Care Committee
PGA	Pharmacy Guild of Australia
PHARM	Pharmaceutical Health and Rational Use of Medicines
Pharmacy boards	Pharmacy registration boards
Pharmacy orgs	Pharmacy professional, representative and registration bodies
PHSC	Private Hospital Sector Committee
Prof boards	Professional registration boards
Prof bodies	Representative bodies
Prof indemnity insurers	Professional indemnity insurers
Prof orgs	Health professional, representative and registration bodies
PSA	Pharmaceutical Society of Australia
QUM	Quality use of medicines
RACGP	Royal Australasian College of General Practitioners
SHPA	Society of Hospital Pharmacists of Australia
SMPU	Safe Medication Practice Unit
States	Australian States and Territories
TAG	Therapeutic Advisory Group
TGA	Therapeutic Goods Administration, Department of Health and Ageing
UMORE	Unit for Medication Outcomes Research and Evaluation
VMAC	Victorian Medicines Advisory Committee

APPENDIX 5

Glossary of terms

Administration The process of giving a medicine to a patient or a consumer taking a medicine. (ACSQHC)

Adverse drug event A particular type of adverse drug event where a drug or medication is implicated as a causal factor in the adverse event. This encompasses both harm that results from the intrinsic nature of the medicine (an adverse drug reaction) as well as harm that results from medication errors or system failures associated with the manufacture, distribution or use of medicines. (ACSQHC)

Adverse drug reaction A response to a drug which is noxious and unintended, and which occurs at doses normally used or tested in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. (WHO)

Adverse event An incident in which unintended harm resulted to a person receiving health care. (ACSQHC)

Automated dispensing devices Automated dispensing devices are computer-based devices that store and dispense medications and maintain records of medication use. (ACSQHC)

Clinical decision support systems Clinical decision support means the provision of relevant, objective accurate and balanced up-to-date information that is accessible to practitioners. It can include a variety of resources such as guidelines or protocols for prescribing and administration of medication (either as print or electronic copies). It can also include information services such as drug information and advisory services or poisons information services. (ACSQHC)

Complementary medicine Vitamins, mineral, homeopathic, aromatherapy and herbal preparations. These may be practitioner only or non-prescription medicines. In Australia these products are regulated as therapeutic goods. (ASMI)

Computerised prescriber order entry A computer based system of ordering medications. Prescribers directly enters orders into a computer system. Also known as “e-prescribing”. (International Network of Safe Medicines Practice Centres)

Consumer medicines information Brand specific leaflets produced by pharmaceutical company, in accordance with the Therapeutic Goods regulations, to inform consumers about prescription and Pharmacy Only medicines. Available as an enclosure in the medicine package or a leaflet or computer printout from a pharmacist, and from other sources such a doctor, nurse, hospital, pharmaceutical manufacturer or via the internet. (APAC)

Discharge liaison service This intervention involves counselling before discharge from hospital followed by a pharmacist and a nurse visiting a patient’s home after discharge from hospital to optimise the management of the patient’s medication, identify any early deterioration in the patient’s condition and facilitate medical follow up if required. (ACSQHC)

Dispensing To put up and distribute medicine, especially on prescription. (ACSQHC)

Generic name The established name of the medicine. The name of the product itself, not the brand name. (ISMP)

Harm Death, disease, injury, suffering, and /or disability experienced by a person. (ACSQHC)

Home medicines review The home medicines review (HMR, also known as DMMR – Domiciliary Medication Management Review) is a consumer-focused, structured and collaborative health care service provided in the community setting, to optimise quality use of medicines and consumer understanding. It involves the consumer, their general practitioner, their pharmacy, and other relevant members of the health care team. (PGA)

Incident An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or complaint, loss or damage. (ACSQHC)

Incident monitoring A method of collecting detailed qualitative data about any unintended incident, no matter how seemingly trivial or commonplace, which could have or did harm anyone, patient, staff or visitor. (ACSQHC)

Individual patient supply Medication that is dispensed in a package that is labelled with the patient’s name.

Machine readable coding Encoded identifying mark e.g. bar code representing data that can be read with a computerised reading device such as a scanner or imager. (International Network of Safe Medicines Practice Centres)

Medication action plan A continuing plan for use of medicines, developed by the health care professional in collaboration with the consumer, to identify and document (in a working document): actual and potential medication management issues (problems and needs, including risk assessment) identified during the assessment process; medication management goals; actions or strategies needed to address the issues and achieve the medication management goals. The medication action plan (MAP) is to be shared and used by all members of the health care team (institutional and community) and the consumer. The plan could form part of other institution’s documents or be incorporated in other processes. (APAC)

APPENDIX 5

(continued)

Medication distribution system Those steps of the medication management pathway (see below) that relate to the issue, distribution and storage of medicine, including medicines procurement and materials management.

Medication error Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in control of the healthcare professional, patient or consumer. Such events may be related to professional practice, healthcare products, procedures, systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use. (The U.S. National Coordination Council for Medication Error Reporting and Prevention)

Medication incident An incident associated with medication. (ACSQHC)

Medication list A complete and comprehensive list of medicines where there is sufficient information to fully identify all products. Key elements include the name(s), strength, and dose form and indication for use. (APAC)

Medication management pathway Also described as the medication management cycle.

The nine steps and three background processes that describe the cognitive and physical steps involved in the use of medicines. The nine steps described are: decision to prescribe medicine, record of medication order/prescription, review of medicine order/prescription, issue of medicine, provision of medicines information, distribution and storage, administration of medicine, monitor for response, transfer of verified information. Background processes are medicines procurement and materials management, reporting and quality safety audit review, communication. (SHPA)

Medication management review service A service which included a review of individual patient's medication undertaken by a pharmacist, and liaison between the pharmacist and the patient's medical practitioner. (Includes home medicines reviews see above). (ACSQHC)

Medication reconciliation The formal process of obtaining a complete and accurate list of each patient's current medications and comparing the clinician's admission, transfer or discharge orders with that list. (Department of Human Services, Victoria)

Medication safety Freedom from preventable harm with medication use. (ISMP Canada)

Over the counter medicines Health care products that can be purchased without a prescription. (ACSQHC)

Pharmaceutical review The systematic appraisal of all aspects of a patient's medication management to optimise patient outcomes. (Department of Health, WA)

Pharmaco-vigilance The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines. (WHO)

Ward stock Medications stored in areas of healthcare facilities outside of the pharmacy that are not labelled or stored for a specific patient. This includes medication stored in medication rooms, cupboards automated dispensing devices. (International Network of Safe Medicines Practice Centres)

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