4

Medication Safety

Will adverse drug events be reduced?

Medicines are the most common treatment used in health care and medication is more rigorously tested than almost all other healthcare interventions. Because they are commonly used, medicines are associated with more adverse events than any other aspect of health care. The prevalence of medication errors, where mistakes are made anywhere in the supply of medicines, is of particular concern because most medication errors could be avoided.

Australia is tackling some of the issues associated with medication errors through systems based solutions, such as the standardised National Inpatient Medication Chart, which is helping Australian hospitals reduce the risk of harm to hospitalised patients from medicines. Efforts to reduce harm from medicines in the community are also being implemented through the provision of medication review services, consumer reporting of adverse medicine events and activities to promote quality use of medicines.

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Medicines in Australia

Medications are the most prevalent health therapy in Australia. In any two week period, around seven in ten Australians will have taken at least one medicine. For older Australians, that increases to nine in ten [1].

Australia has a system which generally promotes safe delivery of medicines. Before they reach the market, medicines are assessed by the Therapeutic Goods Administration (TGA). The TGA regulates where and how products can be sold, e.g. prescription only, pharmacy only or freely available. Australia has a highly trained and professional health workforce which prescribes, dispenses and, where appropriate, administers medicines.

Australia also has well established independent sources of information to support appropriate medicine use including Australian Approved Product Information, Consumer Medicine Information, the Australian Medicines Handbook [2], Therapeutic Guidelines [3], Australian Prescriber and RADAR (Rational Assessment of Drugs and Research).

The Commission's work on medication safety

The Commission's medication safety program includes:

- Maintaining the National Inpatient Medication Chart (NIMC), including by conducting a post-implementation review and establishing an online issues register to inform future revisions of the chart.
- Making available a suite of specialist and ancillary standard medication charts in areas of high risk, such as paediatrics and insulin, to complement the NIMC.
- Extending the National Health and Medical Research Council's venous thromboembolism prophylaxis program to the private sector.
- Supporting initiatives to promote systems improvements in medication safety, such as standardising terminologies, abbreviations and symbols used in the prescribing and administration of medicines.

Sometimes people experience harm from medicines

The vast majority of medicines relieve symptoms, improve the quality of peoples' lives and may prevent, or cure, diseases. But like most health care, there is a risk of harm associated with the use of medicines. Harm may occur because of an error in the delivery of medicines, such as the wrong medicine being prescribed or used, or the right medicine being used inappropriately. These types of errors are described as adverse drug events. Harm may also occur because of side effects of medicines (also known as adverse drug reactions).

Most people take medicine at some point during the year; whether it be prescription, over-the-counter or complementary medicines or combinations of these. For some conditions, two or three different medicines taken together are recommended. For people who have more than one disease, this often results in them taking five or more medicines, which increases the likelihood that things can go wrong with medication.

Sentinel event reporting is one way in which serious adverse events are reported to the public. 'Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs' is one of the eight national sentinel events. In 2005–06, five deaths were reported, while in 2006–07, eleven such deaths were reported. Sentinel event reporting only captures a tiny fraction of adverse events attributable to medicines. It is estimated that over 1.5 million Australians suffer an adverse event from medicines each year [4] resulting in at least 400,000 visits to general practitioners and 140,000 hospital admissions. The cost is significant. Cost estimates for medicine related hospital admissions were $380 million in 2002 [5].

The scale of medicine adverse events in Australia

Figure 4.1: Types of medication-related hospital admissions: results from Australian studies (each column represents a study) [5]

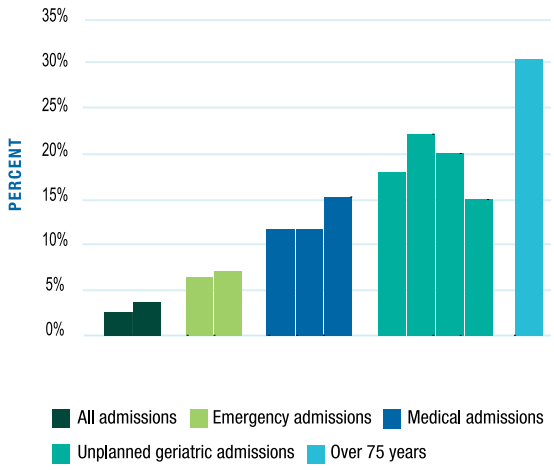
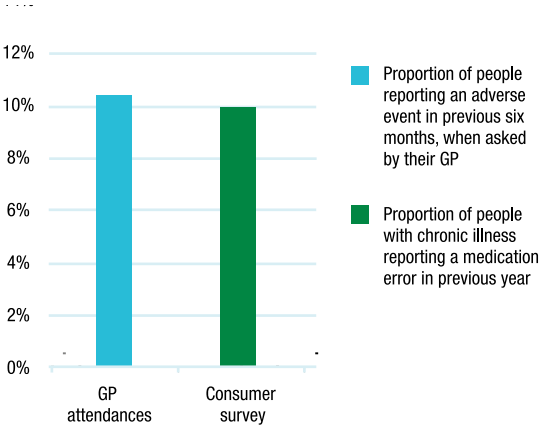


Figure 4.2: Adverse medication event and error rates in the Australian community [6 7]



The reasons for incorrect medication use in acute care

The most common cause of medication error in acute care is a slip error (doing the wrong thing) or a lapse error (not doing something) [8]. Slips by doctors often occur while rewriting drug charts and slips by nurses usually happen when they are checking the name and dose of a drug prior to administration. It has been estimated that between 2% and 5% of Australian drug charts contain prescribing errors, while administration errors occur at a rate of between 5% and 18% [5]. Medication errors are therefore a significant problem for Australian hospitals and there is evidence to show it is also a problem in other settings of care.

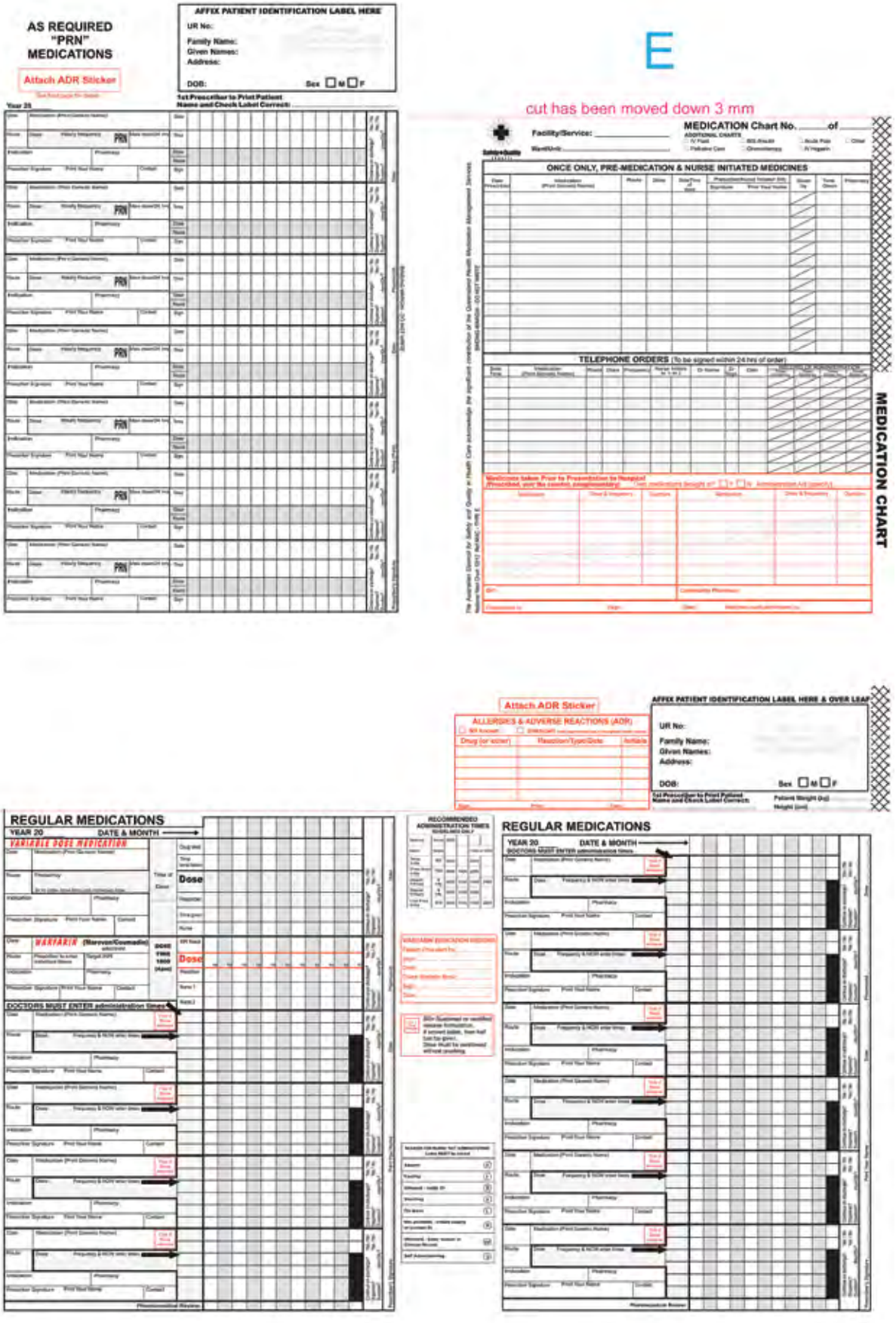
Analysis of medication errors in Australian hospitals showed that failure to read or misreading of charts is the most common causal factor contributing to incidents [9 10]. This is significant given that charts are the main means of communicating medication orders. Other studies confirm that most errors are due to slips in attention that occur during routine prescribing, dispensing and administering, with errors being significantly more frequent out of hours when busy, distracted staff are often dealing with unfamiliar patients [8]. They also confirm that the causes of error are usually multifactorial involving working environment factors as well as team, individual, patient and task factors [11].

Improving systems: The National Inpatient Medication Chart is designed to improve medication safety in acute care

Systems solutions, such as standardisation, or making things as routine as possible, are recognised as the best way to overcome slips and lapses, which are the most common causes of medication errors in acute care [11 12]. In response to this, in April 2004, Australian Health Ministers agreed that all public hospitals should use a common medication chart.

The National Inpatient Medication Chart (NIMC) was implemented during 2006 and 2007, and is now being used nationally in all public hospitals (with some limited variation) and in a large number of private facilities. The NIMC (Figure 4.3) standardises communication of medication information between doctors, nurses and pharmacists, with the aim of reducing harm to patients from medication errors. Pre- and post-implementation audits of charts, conducted by the former Australian Council for Safety and Quality in Health Care, demonstrated both improvement in documentation and reduced risk to patients.

Figure 4.3: The National Inpatient Medication Chart



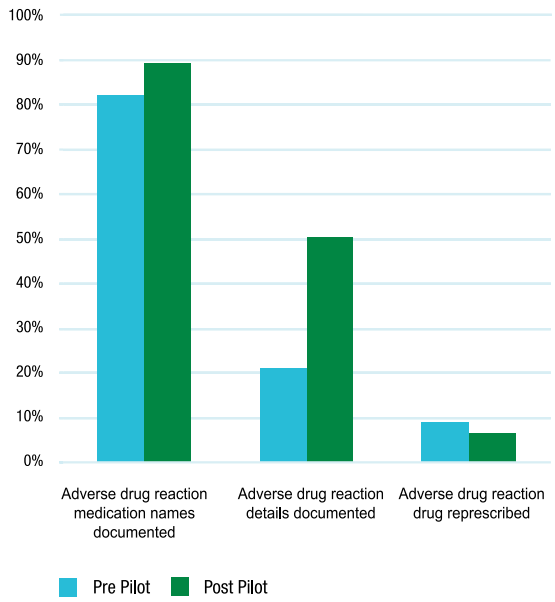
Based on data, prior to the NIMC implementation, comparing 21,000 medication orders at 31 sites with 35,000 medication orders from 300 sites after implementation, the implementation of the NIMC has improved the safety of some important aspects of prescribing in most hospitals.

The NIMC is reducing the risk of patients getting a drug to which they have an allergy

One of the most frequently occurring and avoidable adverse drug events is the re-exposure of patients to medications that have previously been identified as causing an adverse drug reaction (ADR), such as an allergy. The documentation of this information so that it is visible to all prescribers, nurses and pharmacists on patient medication charts is a significant safety feature of prescribing systems.

Figure 4.4 demonstrates that documentation related to adverse drug reactions improved following the NIMC pilot. The recording of medication which had previously caused an ADR improved compared with baseline, while documentation of ADR details also improved. Most importantly for patient safety, the re-prescribing of medicines to which patients had previously experienced an ADR was reduced.

Figure 4.4: Documentation of adverse drug reactions pre and post NIMC pilot



The NIMC results in clearer prescribing

The clear documentation of drug names, forms (especially controlled or sustained release), routes, doses and frequencies are essential for safe and effective communication of prescribing decisions and instructions for nurse supply and pharmacist dispensing.

A designated check box was included in the NIMC to indicate if a sustained or controlled release formulation of medication was to be administered. The inadvertent administration of standard release medication can have adverse effects on a patient. In all but one of the seven jurisdictions which reported this data, the proportion of standard release medications with the formulation indicated had increased to between 31% and 54% of cases from a low of 18% at baseline.

Six of the seven sites that reported the proportion of regular orders with frequency instruction errors found these to be less frequent after implementation of the chart, ranging from 2% to 5% in error from a baseline of 7.2%. In association with reducing the opportunity for administration of a medication at a frequency not intended by the prescriber, prescribers were prompted to enter the administration times, according to a standard administration time guide included on the NIMC. The data indicated that prescribers entered dosing administration times in 33% to 86% of cases with the new chart compared with only 18% at baseline.

The NIMC is improving the administration of 'as required' medications

Medication to be taken 'as required' must be prescribed in such a way that nurses can safely and effectively tailor medication administration to specific patient symptoms. The common classes of medication prescribed as required, or *pro re nata* (commonly abbreviated to PRN), are pain relievers, laxatives and medicines for nausea and vomiting.

From the evidence available, PRN frequency documentation remains an area for concern in many sites with between 13% and 19% of orders not having any frequency of administration indicated.

As extra guidance for safe and effective PRN dose administration, the NIMC prompts prescribers to enter the reason for PRN medicine. The proportion of orders with reason for use was higher in all jurisdictions (14% – 47%) compared with the pre-NIMC pilot (13%). Similarly, the proportion of orders with a maximum dose documented was the same or higher (24% – 40%) than the pre-NIMC pilot (24%) in six of eight sites who reported this data.

As more health professionals use the NIMC, it will continue to reduce the risk of medication errors

Anecdotally, the number of new health professionals presenting in wards and familiar with the NIMC is increasing. For example, all undergraduate medical students at the University of Queensland participate in a safe medication practice program in which they are familiarised with the NIMC [13]. New nursing staff also participate in a medication error awareness raising program [14]. Pharmacists are familiarised with the NIMC during their undergraduate education. This has some important implications both for new staff and for staff rotating between facilities. It will reduce the risk of error caused by inexperienced staff confronting unfamiliar and potentially difficult to read charts (Figure 4.5) in unfamiliar environments, while also often under significant work pressure.

In 2008 the Commission is undertaking the first national quality assurance of the NIMC since its implementation. Implementation has identified some issues which have not yet been resolved within the agreed guidelines for NIMC local management. Inevitably, there is a tension between the requirement for a degree of stability with a national chart and the need to respond to local pressure for customisation especially for elements of the workforce which have been used to the flexibility of a facility-level drug chart.

It is understood and acknowledged that a national chart may 'from time to time' compromise some functionality at a local level. However, any national standardisation is an acknowledgement that the 'public good' of patient safety is to prevail in such situations. The challenge for the Commission is to respond to possible concerns with the NIMC while maintaining stability for users and avoiding frequent altering of the national standard in the absence of pressing safety issues. This will be achieved through quality assurance, including a known timetable for national change considerations.

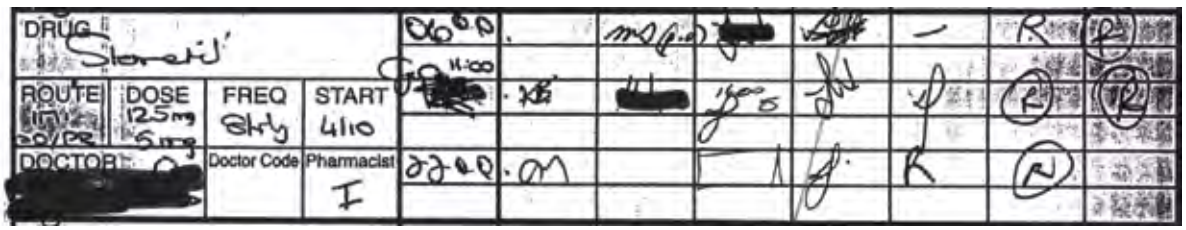
Reasons for medication problems in the community

Consumers report poor communication, lack of information and lack of co-ordination of care as common reasons for problems arising from medicine use. In surveys of Australian adults with chronic illness at least a quarter reported that the side effects of their medicines had never been explained to them, while just under a third said they had never had their medicines reviewed by their doctor [15]. Only four in ten received written instructions or a plan to manage their care at home [7].

One in five chronically ill adults reported they did not follow their doctors' advice. For the majority of these respondents it was because they did not agree with the advice. Half of the respondents found the cost prohibitive, while a similar number thought the advice was too difficult to follow [7].

Doctors, too, have reported that the most common reasons for error are associated with poor communication and co-ordination of care. They highlighted that poor communication between themselves and patients, poor communication with other health professionals and patients seeing other practitioners all contributed to error [17].

Figure 4.5: Idiomatic facility-level chart in use prior to NIMC implementation



Greater risk for people seeing multiple health professionals

- Less than one in twenty people with only one doctor reported receiving an incorrect medicine.

BUT

- Three in ten people who saw four or more doctors reported receiving the wrong medicine or dose in the last year [16].
- One in six reported that they got conflicting advice from different health care professionals [7].
- Only half reported that their regular doctor co-ordinated their care [7].

Greater risk for people moving in and out of hospital

- Nearly half of the chronically ill adults reported that upon leaving hospital they were given a new medicine.
- One quarter also reported that no one asked them about their medicines at the time of their admission [16].

Improving medicine use in the community

Efforts to improve use of medicines and reduce adverse events in the community have focused on improving prescribing and medicine use, enabling consumers to report adverse medicine events, the provision of medicine review services and practice guidelines for medication use in the community and in aged-care facilities.

Ten years ago Australia had none of these services in place, while today robust services are provided based on the rigorous research that underpinned their development [18]. Practice change is difficult and diffusion of innovation in health care notoriously slow [19]. To ensure the diffusion of innovation (in this instance, services to improve medicine use and reduce adverse events) requires uptake by between 15% and 50% of the population [19]. Importantly, the quality use of medicines services provided in Australia has now reached adequate levels of uptake amongst Australia's general practitioners, with half voluntarily participating in quality use of medicines activities such as clinical audits, case studies and academic detailing (educational visits undertaken at doctors' practices) delivered by the National Prescribing Service [20]. The level of engagement among health professionals at all levels provides a strong platform for implementation of strategies specifically focused on reducing adverse medication events and integrating them with the quality use of medicines initiatives.

Medication review services are improving medication use in the community

One significant quality use of medicines initiative, funded by the Commonwealth Government, is the medication review service for those at risk of medication related problems, both in the community and in residential aged-care. Medication review services have been shown to reduce adverse medication events [21-23].

One Australian study involving 1000 consumers at high risk of medication misadventure found over 90% of people who received the service had one or more medication related problem with, on average, each having three problems. Problems included the need for additional medicines or tests, inappropriate selection of medicines, adverse drug reactions and patient confusion about medicines. In 82% of the cases, these problems could be resolved or improved. A systematic review of 22 randomised controlled trials assessing medication review services confirms the effectiveness of the service in improving medication use and surrogate outcomes [22].

Since the initiation of the service over 160,000 home medication reviews have been funded in Australia, with 33,000 conducted in 2007, while over 31,000 collaborative reviews in the aged-care sector were conducted in 2007 [24]. Training and accreditation standards have been established and more than 1775 accredited pharmacists are trained to provide the service. This represents significant diffusion of innovation within the health system, as these services are novel and systems to support their implementation had to be developed. Targeted quality improvement activity will facilitate further improvements in delivery of the services. These services are also being integrated with other elements of the health system and used to facilitate

co-ordination of care when people transfer between health facilities, such as hospital and aged-care. These programs also demonstrate more appropriate medicine use in those receiving the service compared to those who did not [25].

Systems to alert us to problems with medicines are integral to improving medication safety. While Australia has well developed systems for health professionals to report suspected adverse drug reactions, consumer participation in these systems has been consistently advocated [26]. In 2003, the former Australian Council for Safety and Quality in Health Care funded an 18 month national project implementing an adverse medicine event telephone line that provides consumers with advice about the suspected adverse event and collects data on the events which, where appropriate, contribute to national pharmacovigilance. In its first year the service received over 2000 calls, with one in five calls resulting in an adverse reaction report to the Australian Adverse Drug Reactions Advisory Committee. The service is proving successful in contributing to identifying previously unrecognised reactions, as evidenced by consumer reports of adverse events associated with hypnotics [27].

Continuing to improve the safety and quality of medication use in Australia

The demonstrated successes in developing and implementing novel solutions for medication safety in Australia over the last ten years highlight our capacity to reduce the harms that occur with medicines. However, because of the complexity of medicines, their use throughout all aspects of the health care system, the many people involved in their manufacture, distribution, supply and use and evolving knowledge about what works best, there is still much work to be undertaken.

In 2002, the former Australian Council for Safety and Quality in Health Care, in its national report on medication safety, highlighted a number of systems solutions known to be effective in improving medication safety. These included individual patient medication supply systems; clinical decision support systems; adverse drug event alerts; systems that provide adequate checking, such as bar coding; as well as provision of clinical pharmacy services and discharge medication management services. While implementation of some of these systems is occurring at a jurisdictional level, there is still a requirement for national leadership to support widespread implementation of these initiatives and the development of systems to monitor implementation and inform policy development.

Examples of initiatives for further development are:

- Use of ward stock patient supply systems has been associated with administration error rates of 18% compared with individual patient supply systems error rates of 5% to 8% [5]. Currently, the extent of institutions with individual patient supply systems is unknown.
- Scanning medications at the time of dispensing has been shown to reduce errors [5]. It is not a mandatory requirement across the country, although the practice has been implemented in some states. Scanning has also been shown to reduce medication administration errors, but again, the extent of institutions with administration scanning systems is unknown.
- Discharge medication management services have also been shown to be effective [5]. However, the consistency of implementation across all jurisdictions and its integration with other services is unclear.

Additionally, there is also the need for national leadership to support the development of existing resources to further assist efforts to reduce harm from medicines. Details of some existing resources are given below.

Australia has a very successful adverse drug reactions reporting system which identifies previously unrecognised adverse reactions and provides information to all health professionals. The system was developed in the 1970s and relies on spontaneous reporting from health professionals as well as reports from the pharmaceutical industry. It supports global pharmacovigilance efforts and needs to be maintained. In addition, due to information technology, it is now possible to enhance the types of pharmacovigilance studies that can be undertaken in Australia [28].

Australia has two of the richest health information stores in the world: the Pharmaceutical Benefits Scheme data and the Medicare Benefits Scheme data. By linking de-identified data from these two sources with morbidity and mortality data, we would be able to identify problems with medications more quickly, identify previously unrecognised side effects, identify the risk of side effects in groups not included in the clinical trials and assess the appropriateness of medication use in practice.

Timely provision of this information tailored to the needs of all stakeholders would improve medication safety. For example, analyses using the pharmaceutical data set showed that non-steroidal anti-inflammatory drug use increased by 30% in Australia with the introduction of celecoxib [29]. Use increased by the same amount in people who were also dispensed medicines for diabetes and medicines for heart failure, groups in which there is a higher risk of adverse renal events on these medicines [30]. Earlier recognition of this pattern of medicine use may have prevented adverse events in these high risk groups. National leadership is required to support the development of this activity and integration of the outcomes of this work with other quality use of medicines activity.

Finally, as the example of the National Inpatient Medication Chart shows, standardisation of health care is one of the effective ways of reducing medication incidents. However, standardisation, by definition, requires the rigorous work of standards development, as well as agreement by all stakeholders and the integration of the standards into practice. One of the current opportunities for standardisation lies with the information technology systems being developed for health settings. These details are discussed below.

Computerised prescribing ordering and entry systems have been shown to reduce adverse medicine events [5]. However, consumers can be at risk of increased misadventure if systems developed to support improvements in one sector of the health system (e.g. general practice) cannot communicate with systems in another (e.g. pharmacy or hospital). Further, variable results in improvements in care will be seen if adverse drug event alert systems differ between jurisdictions or if presentation of information is inadequate. While the NIMC is an example of a standardised paper based chart, similarly standardised technology alerts and presentation of information in information systems will reduce the potential for errors.

Electronic prescribing systems, especially those systems offering advanced decision support functions, have been shown to reduce risk of medication errors and adverse drug events in hospital settings [31]. Linking prescribing with administration and dispensing information systems further decreases opportunities for error. Currently implementation of electronic medicines management systems in hospitals is low. More research is needed into implementation factors and guidelines developed to assist hospitals implement the technology safely [32].

Conclusion

Many countries are hampered in their efforts to promote safer patient care and improve use of medicines by the lack of a coordinated approach and national strategy. Australia has the advantage of well developed policies and strategic frameworks in place for supporting medicines and quality in health care. Key policies include the National Medicines Policy [33] and its Quality Use of Medicines Strategy [34] and the Commission's program to develop a coordinated national strategy for enhancing medication safety.

The National Medicines Policy advocates systems solutions, the use of data to inform program development and the fundamental need for consumer participation and collaborative, multi-disciplinary activity. The Commission supports these directions, as they provide a strong platform on which to improve medication safety. With coordinated action, improvements in medication safety are underway and are set to continue.

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