PATIENT SAFETY IN PRIMARY HEALTH CARE

Discussion Paper

Draft for Public Consultation

August 2010
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1. Introduction

The field of patient safety emerged following Australian and international research showing that a large number of harmful, but potentially preventable, incidents occur in hospitals.\(^1-3\) This was emphasised by a number of high profile inquiries into incidents at specific hospitals.\(^4-5\) These origins mean that the focus of early patient safety work was mostly on issues that were particularly relevant for acute care settings, and there has been little examination of the patient safety risks that exist in primary health care.

However, most health care in Australia is provided in primary health care settings. Almost one in five people visit a general practitioner (GP), and one in ten visit an allied health professional in any given two week period.\(^6\) Given the size and importance of this sector, it is essential that the care provided in it is safe, and that risks of unnecessary harm associated with the delivery of health care are minimised.

There are a large number of organisations that have a role in quality and safety in primary health care in Australia, and many programs and initiatives are in place to improve care provided in this sector. One of these organisations is the Australian Commission on Safety and Quality in Health Care (the Commission), which was established in 2005 to lead and coordinate improvements in safety and quality nationally.

The Commission’s remit is across the continuum of health care, including primary and acute care, in both the public and private sectors. Many of the Commission’s programs are relevant to primary health care, and the Commission is now keen to build on this work by focusing specifically on patient safety issues in this sector.

The evidence base and research methods regarding patient safety in primary health care are still developing, however, it is clear that there are significant patient safety risks in this field, and that patients can be harmed from the delivery of health care in these settings.

The patient safety solutions that have been applied in primary health care have generally been adapted from the acute care sector, and to date there has been little evaluation of their effectiveness. While some of these approaches may be useful, patient safety risks in primary health care settings differ from those in acute care settings. The type of risks, and strategies used to address those risks, need to be cognisant of the unique characteristics of primary health care. Ideally patient safety tools and resources for use in primary health care settings should be developed specifically for this context, using the knowledge and experience of models that are effective within primary health care.

The purpose of this paper is to stimulate discussion about patient safety in primary health care in Australia. The Commission wants to raise awareness of these issues, and supports coordinated national action to address them. Improving patient safety in primary health care requires a new approach and new thinking that includes a greater emphasis on safety and prevention from harm.

The Commission would like to work with primary health care stakeholders to identify priority areas for improving safety, and to take action to address these priorities. The development of this paper and subsequent consultation process is the first step in this process and the outcomes of the consultation will be used to guide the Commission’s actions to support patient safety in primary health care.
2. **Key concepts**

The terms ‘patient safety’ and ‘primary health care’ are not straightforward and multiple definitions exist. To ensure a shared foundation for discussion, this section discusses the definitions and scope used in this paper.

### 2.1 Quality and safety

The Commission was established as a national body to lead and coordinate improvements in both safety and quality. Although they are frequently used together, these concepts are not synonymous.

**Quality** has been defined as ‘the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge’.\(^7\) The definition of **patient safety** has a different emphasis: ‘the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum’.\(^7\) Safety is often included as one of the components of quality,\(^8\) and many quality improvement activities both improve outcomes and prevent harm (for example, the introduction of information systems and standardised care processes).\(^9\)

The differences between quality and safety are relevant in primary health care. Safety and quality research in primary health care has generally been focused on issues to do with quality, such as access to healthcare services, differences in health outcomes for particular parts of the population and compliance with clinical guidelines. There has been much less research about issues concerning patient safety in primary health care, and ways of preventing unnecessary harm associated with the delivery of care.\(^10\)

Although the Commission has an interest in both safety and quality, the main focus of this paper is on safety, and the prevention of unnecessary harm. There are many organisations in Australia with an interest in quality in primary health care (see Section 6); the gap has been in the specific area of safety – which is core business for the Commission. The range of factors that have been shown to improve safety and prevent harm is broad and includes, but is not limited to, communication, culture, teamwork, reporting of incidents, organisation of services and design of facilities.\(^11\)

### 2.2 Primary health care

The terms ‘primary care’ and ‘primary health care’ are used in many different ways. In this paper the scope used has been selected to align with the National Primary Health Care Strategy, and encompasses services delivered by GPs, nurses, allied health providers, Aboriginal health practitioners and pharmacists both within the public and private sectors.\(^12\) The Commission’s scope also includes safety and quality in dentistry.
Although the scope of this paper covers primary health care broadly, it needs to be noted that much of the quality and safety work in this sector has been limited to general practice. There has been some patient safety work in pharmacy, and to a lesser extent nursing; however there are few studies in other primary health care disciplines.\textsuperscript{13} However there is a considerable body of work about medication safety, focussing on a range of different community settings, including general practices, pharmacies and aged care facilities.\textsuperscript{14} Despite the limited focus of the work that has been done to date, the Commission is interested in primary health care broadly, including patient safety issues that may not yet have been identified in disciplines other than general practice.
What is the problem regarding patient safety in primary health care?

Quality of care has been a significant focus in the primary health care field for some time and this work is associated with considerable improvements in outcomes for patients. Within this field, examination of patient safety has only been emerging as a distinct focus over the last decade. There is an increasing awareness that the risks identified in the acute care sector manifest in different ways in primary health care, and that there are risks to patient safety that are unique to primary health care. Solutions developed in acute care do not necessarily apply here. Primary health care practitioners can learn from the acute care sector, but also need to rigorously examine their own processes and systems to identify specific patient safety risks and possible solutions.

This section summarises what is known about the nature and size of the patient safety problem in primary health care.

3.1 Characteristics of primary health care settings

The characteristics of primary health care affect the way in which care is provided and the nature of the patient safety risks that exist. Some of the characteristics of these settings, differences between acute and primary care settings, and the potential impact of these differences on patient safety, are described below. 9 \textsuperscript{15-17}

- In hospitals, care tends to be provided within the one organisation. While some patients may receive care from only one primary health care provider, many others receive care from primary health care providers in a range of different disciplines, as well as from specialists, and may also need to have tests done at external laboratories and imaging centres. This means that a primary health care practice is part of a dispersed network, and communication with other healthcare providers and sites is particularly complex.

- The types of treatments offered in primary health care tend to be less invasive than those provided in acute care settings. While this may limit the opportunities for harm from the provision of treatment, there is a large number of occasions of treatment in primary health care, meaning that the cumulative risk of harm across the population of patients is still high.

- While the contribution of patients, their families and carers has a significant impact on the outcomes of care in all health care settings, this is particularly important in primary health care. This means that while there are patient safety risks associated with the processes of delivering primary health care services, the actions and knowledge of patients, families and carers can also have a significant impact on safety and quality. For example, lower levels of literacy among patients is associated with a greater misunderstanding of prescription medicine labels, which may affect adherence to medication regimens and the occurrence of adverse drug events.\textsuperscript{18}
What is the problem regarding patient safety in primary health care?

- The nature of the patient safety infrastructure (such as incident reporting, data collection and audit systems) in primary health care settings is different to that in hospitals. While larger private practices may have a practice manager, in many cases the doctors, nurses, allied health providers, pathologists, imaging providers and clerical staff are the only resources available to support patient safety in addition to their existing roles. Relationships with external organisations such as divisions of general practice, professional bodies or the National Prescribing Service may provide some of this infrastructure in different ways. The type of service delivery setting (for example community health centre or private practice) may also influence the nature of patient safety infrastructure.

- Associated with this are the limited options for patients to provide feedback on their experiences in primary health care. While there is a requirement to conduct a patient survey as part of the Royal Australian College of General Practitioners accreditation standards (see Section Four for further information), often there is no systematic process in place in primary health care for the collection, analysis and review of information from patients. Information on patient experience is considered a core component of any comprehensive safety and quality measurement framework.  

3.2 Patient safety incidents reported in general practice

Much of the existing information about patient safety risks in primary health care settings comes from research about reported errors and incidents, including studies that have attempted to develop taxonomies to classify the types of errors and incidents that occur in these settings. These types of studies are generally based on voluntary anonymous or confidential self-reports, and to date have been limited to general practice settings.

Varying definitions of the terms ‘error’, ‘incident’ and ‘report’ have been used in the research described in this section. These different definitions limit the comparability of results, and do not always align with definitions of these terms that have been developed in the patient safety literature. In this paper the term ‘patient safety incident’ will be generally used, which is defined in accordance with the WHO International Classification for Patient Safety, namely: an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

Australia has been one of the pioneers of incident reporting in general practice, and the Threats to Australian Patient Safety (TAPS) study is one of the most comprehensive analyses of patient safety incidents internationally. TAPS and other studies have identified two broad types of patient safety incidents:

- Incidents associated with the processes of care, including administration, investigation, treatment, communication and payment processes. These are the most common types of incidents reported (ranging from 70%-90% depending on the study).

- Incidents associated with the knowledge or skills of the practitioner, including missed or delayed diagnosis, wrong treatment and errors in task execution.

The taxonomy used in the TAPS study is shown in Table 1, which also includes the number of patient safety incidents identified in this study for each category. Although
What is the problem regarding patient safety in primary health care?

Other studies have used different taxonomies and found a different spread of incidents, these results are indicative of the types of patient safety incidents that occur in primary health care, particularly general practice. Examples of some specific incidents from the TAPS study are included in Box 1.

Table 1: Taxonomy used in the TAPS study, including distribution of the 525 patient safety incidents identified in the study from 415 incident reports received

<table>
<thead>
<tr>
<th>Error category</th>
<th>Number (% of total)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Errors related to the processes of healthcare</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 Errors in practice and healthcare systems</td>
<td></td>
</tr>
<tr>
<td>1.1.1 Errors relating to incorrect patient identification</td>
<td>12 (2.3)</td>
</tr>
<tr>
<td>1.1.2 Appointments and message handling errors</td>
<td>15 (2.9)</td>
</tr>
<tr>
<td>1.1.3 Patient record and filing system errors</td>
<td>28 (5.3)</td>
</tr>
<tr>
<td>1.1.4 Recall event and recall systems errors</td>
<td>25 (4.8)</td>
</tr>
<tr>
<td>1.1.5 Computer systems errors</td>
<td>6 (1.1)</td>
</tr>
<tr>
<td>1.1.6 Errors in the maintenance of a safe physical environment</td>
<td>6 (1.1)</td>
</tr>
<tr>
<td>1.1.7 Errors in provision of care after hours or inadequate staff coverage</td>
<td>7 (1.3)</td>
</tr>
<tr>
<td>1.1.8 Errors relating to patient confidentiality issues</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>1.1.9 Practice and healthcare systems errors not otherwise specified</td>
<td>10 (1.9)</td>
</tr>
<tr>
<td>1.2 Investigation errors</td>
<td></td>
</tr>
<tr>
<td>1.2.1 Errors relating to incorrect patient identification</td>
<td>7 (1.3)</td>
</tr>
<tr>
<td>1.2.2 Errors in the process of requesting investigations</td>
<td>12 (2.3)</td>
</tr>
<tr>
<td>1.2.3 Errors in the process of undertaking investigations</td>
<td>9 (1.7)</td>
</tr>
<tr>
<td>1.2.4 Errors in reporting processes or managing investigation reports</td>
<td>35 (6.7)</td>
</tr>
<tr>
<td>1.2.5 Investigation errors not otherwise specified</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>1.3 Medication errors</td>
<td></td>
</tr>
<tr>
<td>1.3.1 Electronic prescription writing or medication charting errors</td>
<td>31 (5.9)</td>
</tr>
<tr>
<td>1.3.2 Other prescription or medication charting errors</td>
<td>16 (3.1)</td>
</tr>
<tr>
<td>1.3.3 Medication dispensing and delivery errors</td>
<td>38 (7.2)</td>
</tr>
<tr>
<td>1.3.4 Patient self-administration of medication errors</td>
<td>11 (2.1)</td>
</tr>
<tr>
<td>1.3.5 Medication errors not otherwise specified</td>
<td>11 (2.1)</td>
</tr>
<tr>
<td>1.4 Treatment errors (non-medication)</td>
<td></td>
</tr>
<tr>
<td>1.4.1 Errors in the process of providing immunisations</td>
<td>11 (2.1)</td>
</tr>
<tr>
<td>1.4.2 Errors in the process of undertaking procedures</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>1.4.3 Non-medication treatment errors not otherwise specified</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>1.5 Communication errors and process errors not otherwise specified</td>
<td></td>
</tr>
<tr>
<td>1.5.1 Errors in general communication with patients</td>
<td>17 (3.2)</td>
</tr>
<tr>
<td>1.5.2 Hospital discharge and other hospital-based communication errors</td>
<td>31 (5.9)</td>
</tr>
<tr>
<td>1.5.3 Errors in referral to other healthcare providers</td>
<td>9 (1.7)</td>
</tr>
<tr>
<td>1.5.4 Errors in general communication with other healthcare providers</td>
<td>8 (1.5)</td>
</tr>
<tr>
<td>1.5.5 Communication and process errors not otherwise specified</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>2. Errors related to the knowledge and skills of health professionals</td>
<td></td>
</tr>
<tr>
<td>2.1 Errors in diagnosis</td>
<td></td>
</tr>
<tr>
<td>2.1.1 Errors in patient history taking</td>
<td>2 (0.4)</td>
</tr>
<tr>
<td>2.1.2 Errors in patient physical examination</td>
<td>11 (2.1)</td>
</tr>
<tr>
<td>2.1.3 Errors in investigations requested or their interpretation</td>
<td>27 (5.1)</td>
</tr>
<tr>
<td>2.1.4 Diagnosis-related errors not otherwise specified</td>
<td>22 (4.2)</td>
</tr>
<tr>
<td>2.2 Errors in managing patient care</td>
<td></td>
</tr>
<tr>
<td>2.2.1 Medication management errors</td>
<td>57 (10.9)</td>
</tr>
<tr>
<td>2.2.2 Knowledge or skills errors in undertaking immunisations</td>
<td>9 (1.7)</td>
</tr>
<tr>
<td>2.2.3 Knowledge or skills errors in undertaking procedures</td>
<td>13 (2.5)</td>
</tr>
<tr>
<td>2.2.4 Errors managing care not otherwise specified</td>
<td>19 (3.6)</td>
</tr>
</tbody>
</table>

6
What is the problem regarding patient safety in primary health care?

Box 1: Examples of reported incidents from the TAPS study

- Accidental incorrect dosage instructions on Actonel prescription resulting in patient taking a weekly medication daily, not corrected by computer prescribing package or pharmacist.
- Iatrogenic pneumothorax resulting from incorrect administration of pain relieving injection for fibromyalgia.
- Attributed abnormal urine result to wrong patient with a similar name, treated wrong patient who was in a nursing home, plus had delay in treating original patient who had the abnormal result.
- Prescribed antimalarials to a patient on antiepileptic medication which could have resulted in serious interaction if patient had not got a second opinion.
- Used incorrect equipment when taking specimen for laboratory testing during minor surgery, resulting in accidental destruction of the specimen.
- Delay in receiving pelvic ultrasound results when radiology practice forgot to send to requesting GP and had confusion over whether patient was to collect or they were to send films to practice.
- Wrong patient responded to call in waiting room, notes were entered into another patient’s file.

3.3 Medication safety risks in the community

There is a considerable body of research regarding medication safety in the community. This broad area includes both medication errors and adverse drug events. The specific area of interest here concerns medication errors, defined as ‘preventable events that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health professional, patient or consumer’. The information in this section is drawn from a systematic review conducted by the National Prescribing Service in 2009.

Medication errors occur during all stages of the medication process, including prescribing, supply, administration, monitoring and documentation. The prevalence of errors varies according to the stage and the method used to collect information. For example the rate of errors associated with the prescribing of medications was up to 32 per 100 prescriptions in international studies, and up to 115 per 100 high risk patients in Australia. Both Australian and international studies show high rates of errors associated with documentation in the transfer of care with 52% to 88% of transfer documents containing a medication error.

Few studies have looked at factors that contribute to the occurrence of medication errors. Of those that have examined this issue, deficiencies in communication was the most common contributing factor. Of particular importance was communication between health professionals and patients, between GPs and pharmacists and at the transfer of care.
3.4 Other possible patient safety risk areas

Apart from those areas described in the previous sections, robust research and evaluation about the nature of risks to patient safety in primary health care is limited. However there is a wide range of areas that have been identified as potentially being associated with an increased risk of harm, including:\(^{13}\)

- administration processes such as recording and filing systems, appointment and communication systems, reporting of test results, recall and reminders, computer systems, patient identification, after hours care, and confidentiality of information
- treatment processes such as maintenance of equipment, including sterilisation equipment, and utilisation of pathology equipment, including collection, storage and handling of pathology specimens
- medication processes including writing, transcribing and dispensing medications including vaccines, work processes within a pharmacy (such as high volume of work, fatigue, interruptions), patient understanding of and compliance with instructions, use of over the counter medications, format of display of consumer medication information, management of medications for multiple conditions and calculation of dosages for children
- communication processes including the communication between the patient and provider (including for patients with limited English and poor health literacy), referrals to hospitals and other providers, hospital discharges, communication between providers
- increased complexity of care such as seeing multiple care providers\(^{31}\) or experiencing complex and/ or co-morbid conditions
- access to services and the safety of alternative models of care such as telephone triage services
- provision of primary health care services in the home environment
- factors associated with delayed or misdiagnosis, including fatigue, high workload, interruptions, complexity and rarity of the problem and the skills of staff.

A broad range of professional quality improvement activities are undertaken in primary health care, however evidence suggests that in many cases these activities are implemented in a disjointed way potentially reducing the patient safety benefits.\(^{32}\)

Linked to this is the issue of clinical governance. Clinical governance is a key driver of successful primary health care quality in Australia. Good clinical governance brings together quality improvement activities in a more consistent and effective way. Consequently, a lack of effective clinical governance could also provide opportunity for risks to patient safety.

It should also be noted that implementation of primary health care reform under the National Health and Hospitals Network and National Primary Health Care Strategy is likely to influence, to some extent, the way in which primary health care is provided, coordinated and monitored. These changes may alter the profile of safety risks within primary health care, and any safety activities should be responsive to this change. Section 6 provides more information on these and other national reform efforts.
3.5 The size of the patient safety problem in primary health care

A number of studies have attempted to estimate the size of the patient safety problem in primary care, usually by counting the number of reported incidents. This has provided a wide range of results, with early studies reporting rates ranging from five to 80 incidents per 100,000 consultations.\(^{20}\)

The TAPS study calculated the incidence of reported incidents based on the number of Medicare item numbers billed and the number of individual patients seen.\(^{28}\) The incidence of reported patient safety incidents per Medicare patient encounter item per year was 0.078% (or one for every 1282 items billed), and the incidence of reported patient safety incidents per patient seen per year was 0.24% (or one for every 417 patients seen).

Another study examined the identification of patients incidents prospectively, and GPs were asked to identify after each consultation whether certain events had occurred (such as missing investigation results, misdiagnosis or communication problems with the patient). Of the 351 patient visits for which data was recorded, 83 (24%) were associated with the occurrence of a patient safety incident, and 117 separate incidents were identified in these visits.\(^{21}\)

There are intrinsic difficulties in using voluntary incident reports to estimate the rate of occurrence of patient safety incidents in the delivery of health care. Issues such as underreporting of incidents, confusion about whether a particular event should be reported, uncertainty on behalf of those providing the reports about the use of the information mean that reported incidents are unlikely to reflect the true extent of actual and potential harm.\(^{11}\) The value of incident reports lies in their capacity to lead to the development of coordinated solutions. Incident reporting is only one method that is needed to understand the extent and nature of harm associated with the delivery of health care.\(^{11,33}\)

3.6 Harm arising from patient safety incidents in primary health care settings

Many of the studies that have analysed and classified patient safety incidents also collect information about the consequences of the incident. These indicate that patient safety incidents in primary health care can be associated with harm to the patient. The proportion of reported incidents associated with some level of patient harm varies considerably, based on factors such as the definitions and methodology used, and can range from 10% to 50% of reported incidents (Table 2).\(^{21,23-27}\) The types of consequences reported include time and financial cost, delay in care, pain, emotional or psychological consequences, temporary physical consequences, unexpected hospitalisation, permanent or very serious damage, and death.
What is the problem regarding patient safety in primary health care?

Research regarding the impact of medication safety risks on patients has been limited to examination of adverse drug events generally, with no studies specifically looking at the harm arising from medication errors. Nonetheless it is worth noting that adverse drug events have a significant impact on the individuals who take medications. In Australian studies that have looked at this issue, it has been found that 5.6% of hospital admissions in the general population are associated with adverse drug events, and 30.4% of admissions for elderly patients.

### Table 2: Summary of studies that have consequences of patient safety incidents and reported rates of occurrence of patient harm

<table>
<thead>
<tr>
<th>Study</th>
<th>Method of collection of incidents</th>
<th>Definition of a patient safety incident</th>
<th>Results regarding consequence of incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dovey et al 2002</td>
<td>Self report</td>
<td>Medical error defined as: …anything that happened in your own practice that should not have happened, that was not anticipated and that makes you say “that should not happen in my practice, and I do not want it to happen again”</td>
<td>96 of 330 reported incidents (29%) had some consequence to the patient: care delayed (21%), care extended (1%), financial / time costs (9%), patient upset or lost trust (12%), onset of illness (7%), did not regain health (2%), admitted to hospital (3%), death (0.3%)</td>
</tr>
<tr>
<td>Makeham et al 2002</td>
<td>Self report</td>
<td>As above</td>
<td>Patient harm recorded in 32% of reported errors Harm considered “very serious” or “extremely serious” in 9% of cases Consequences included hospital admission (4.5%) and death (0.8%)</td>
</tr>
<tr>
<td>Fernald et al 2004</td>
<td>Self report</td>
<td>Practices asked to report: any event you don't wish to have happen again, that might represent a threat to patient safety</td>
<td>62 of 608 reported incidents (10%) had clinical harm now 55 of 608 (9%) had increased risk of clinical harm 39 of 608 (6%) had non-clinical harm</td>
</tr>
<tr>
<td>Elder et al 2004</td>
<td>Self report and interview</td>
<td>Interview about perceived or potential harm associated with reported errors and preventable adverse events (events specified, no general definition)</td>
<td>18 of 76 identified incidents (24%) had harm 53 of 76 (70%) had potential for harm Identified harm believed to be minor</td>
</tr>
<tr>
<td>Rosser et al 2005</td>
<td>Self report</td>
<td>As above</td>
<td>Patient harm recorded in 39% of reported errors Harm considered “very serious” or “extremely serious” in 6% of cases</td>
</tr>
<tr>
<td>Wetzels et al 2009</td>
<td>Self report and medical record review</td>
<td>Adverse event defined as: unintentional occurrence with (actual or potential) adverse health consequences for a patient</td>
<td>16 of 31 identified or reported incidents (52%) had some level of harm: symptoms lengthened or worsened (39%), mental burden (6%), unplanned hospital admission (6%)</td>
</tr>
</tbody>
</table>
3.7 Implications

The research summarised in this section indicates that patient safety incidents can be associated with all aspects of primary health care services, including the administration of a practice, the delivery of treatment, communicating with patients and other services, and the knowledge and skills of the practitioner.

While there are difficulties associated with interpreting counts of self-reported patient safety incidents, it is clear that these events are not exceptional. The rates of reported incidents varies widely according to the methodology used, but there may be up to 80 incidents occurring per 100,000 consultations.20,28

These patient safety incidents are not without consequence to patients. Again, level of reported harm varies considerably. Putting aside the variations in methodology and definition, of the studies reported here, an average of 30% of patient safety incidents were associated with some level of harm to the patient.

The implications of these results are significant. A recent Australian survey indicates that an average general practice has 5 GPs, and each GP sees an average of 130 patients per week (unpublished data held by the Commission from the 2009 Commonwealth Fund international survey of general practitioners). This means that on average there is likely to be at least one patient safety incident per practice per week, and of the 78 incidents that may occur each year, 23 of these are likely to be associated with some harm to the patient.28

The research reported here is limited to two main areas: incidents in general practice and medication safety risks in the community. The patient safety risks may be different in other primary health care disciplines, and the potential for harm may be lower with treatments that do not involve medications. However the issues identified in this research such as practice administration, communication and delivery of treatment are applicable in many primary health care settings. More research is needed across primary health care so that there is understanding of size and nature of the patient safety problem in this sector.
4. **What is being done to address the problem?**

Patient safety solutions are defined as ‘any system design or intervention that has demonstrated the ability to prevent or mitigate patient harm stemming from the processes of health care’. Within this broad definition, patient safety solutions can be broadly based or quite specific, and focus on both clinical or organisational processes. The World Health Organization has identified nine inaugural patient safety solutions, some of which apply in primary health care (including look-alike, sound-alike medication names, patient identification, communication during patient handover, performance of correct procedure at correct body site, assuring medication accuracy at transitions in care, and improved hand hygiene to prevent health care-associated infection).

Robust evaluation and research regarding patient safety solutions in primary health care is limited. In some cases patient safety solutions that have been developed in the acute care sector have been applied in primary health without review and with limited success.

In Australia, the Royal Australian College of General Practitioners (RACGP) has been a leader in developing patient safety resources for general practice. The Australian Government has implemented a number of programs that include consideration of patient safety issues in primary health care to varying degrees. The Commission has also developed a range of frameworks, standards and resources for health care organisations which, though not solely directed at primary health care, are applicable to the sector.

Internationally, a number of patient safety and primary health care organisations have started work in this area. Some of these could be adapted for use in Australia.

This section provides a summary of:

- the current knowledge base regarding effective patient safety solutions in primary health care
- work that has been undertaken in Australia to improve patient safety in general practice
- international activities and resources that could be applicable in Australia.

### 4.1 Evidence base regarding patient safety solutions in primary health care

While the focus on patient safety in primary health care is strengthening, the evidence base about effective patient safety solutions in this context is limited. Many similar approaches that are used in the acute care sector have also been discussed in primary health care settings. These include involvement of primary care providers in incident reporting and analysis of systems, use of information technology, education about patient safety, improving communication and team work and supporting patient self-management. To date evaluation of the effectiveness of these solutions in primary health care has been limited.
There has been research regarding interventions to improve medication safety in the community. The four main types of interventions that have been examined are medication review, medication reconciliation, patient education interventions and e-health interventions (including computerised physician medication order entry and electronic decision support). A systematic review concluded that most interventions within these categories did not demonstrate a significant effect on outcomes including rates of mortality, hospital admissions and re-admissions, emergency department attendances, rates of adverse drug events and quality of life. The complexity of evaluating the impact of these interventions on patient outcomes in the community was identified as a possible reason for these negative results, particularly issues associated with the fragmentation of care in the community and the necessity for active participation of the patient in this setting.

4.2 Australian patient safety solutions

The Commission works on a range of core safety issues with the aim of ensuring safe and high quality health care in Australia. Traditionally the Commission has had a focus on the safety issues within the acute health care sector, however, many of the Commission’s activities have implications and applications for the primary health care sector. These include:

- developing the OSSIE Guide to Clinical Handover Improvement, which can be applied in the primary health care setting
- developing protocols for ensuring correct patient, correct site, correct procedure in radiology, nuclear medicine, radiation therapy and oral surgery
- managing the revision of Australian guidelines for the prevention and control of infection in health care, which will provide national standards for the control of health acquired infections
- developing indicators of safety and quality in primary care as part of the National Indicators of Safety and Quality Project
- funding clinical handover projects such as the Revolving Doors project which aimed to develop effective communication in the handover of mental health patients to community health practitioners.

The Commission has been tasked with developing a National Safety and Quality Framework (the Framework) which is designed to guide improvements in safety and quality in all health care over the next ten years.

The Commission is also leading activities under the national safety and quality accreditation reform including the development of National Safety and Quality Healthcare Service Standards. Section Five provides further information the Framework and the Standards.

Within general practice, accreditation has been in place for some time, with standards set by the RACGP. The current draft 4th edition practice accreditation standards include standards regarding key patient safety issues such as clinical handover, patient identification, medication safety and healthcare associated infection. As well as these standards for general practices, the RACGP has had a specific focus on patient safety in
What is being done to address the problem?

general practice. Outputs of this work include tools and education models on analysing near misses; teamwork, leadership and human factors; infection control; supporting patients to be more actively involved in their care; undertaking procedures; and regaining trust after an adverse event.

The Pharmacy Guild of Australia implements a number of activities with a focus on improving quality and safety including home medicine reviews, medicines use reviews and the Quality Care Pharmacy Program. Under the Community Pharmacy Agreement the Guild also funds discrete research projects such as the Consumer Medicines Index Effectiveness project and the Improving Medication Compliance literature review. The Fifth Community Pharmacy Agreement was signed in May 2010 and includes provision for the continuation of the Guild's research and development program.

The Quality Improvement Commission (QIC) has recently launched the 6th Edition of its Health and Community Services Standards which forms part of its accreditation program. This Edition signals a move towards a single generic set of standards to simplify and streamline assessment, and includes a new standard on safety and quality integration which encourages organisations to have a consistent and accountable approach to safety and quality. QIC have also developed a new set of Interpretive Guides to assist organisations to implement the Standards and prepare for the QIC accreditation program.

Other patient safety solutions for primary health care may have been developed in Australia that have not been described here. The Commission would welcome information about these solutions.

4.3 International patient safety solutions

A number of international patient safety and primary health care organisations have also started work in this area. Table 3 includes a summary of key international organisations, and their work on patient safety in primary health care. Because this is a relatively new field, this table includes activities that are generally targeted at primary health care, even if no specific patient safety solutions have yet been developed. In some cases, however, tools and resources have been developed that could be adapted for use in Australia.

Table 3: Examples of international activities regarding patient safety and primary health care

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activities targeted at primary health care</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Health Organisation Patient Safety Alliance</td>
<td>Overall, the WHO Patient Safety Alliance has had a limited focus on patient safety in primary health care, although activities in areas such as healthcare acquired infection, antimicrobial resistance, handover, learning from adverse events, and involving patients in patient safety are all relevant in this sector. (<a href="http://www.who.int/patientsafety/patients_for_patient/en/">http://www.who.int/patientsafety/patients_for_patient/en/</a>)</td>
</tr>
<tr>
<td>Review of Methods and Measures in Primary Care Research (undated)</td>
<td>The WHO has commissioned a review about research methods regarding patient safety in primary health care that is available from their website. It concluded that there is a need for more robust research methods that can be applied in a wide range of primary care settings, and that more conceptual work was needed regarding measures and outcomes in this field. (<a href="http://www.who.int/patientsafety/research/methods_measures/primary_care_ps_research/en/index.html">http://www.who.int/patientsafety/research/methods_measures/primary_care_ps_research/en/index.html</a>)</td>
</tr>
</tbody>
</table>
Table 3 (cont.) Examples of international activities regarding patient safety and primary health care

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Activities targeted at primary health care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National Patient Safety Agency</strong>&lt;br&gt;Arms length body of the UK Department of Health that leads and contributes to improved patient care</td>
<td>Primary care trusts can report incidents to the UK national safety reporting system, although level of reporting is low. Regular public reports are made from this incident reporting system, including reports from primary care trusts. (<a href="http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/">http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/</a>)</td>
</tr>
<tr>
<td><strong>Significant Event Audit: Guidance for Primary Care Teams (2008)</strong></td>
<td>A significant event audit is a process in which individual episodes (where there has been a significant occurrence either beneficial or deleterious) are analysed in a systematic and detailed way to ascertain what can be learnt about the overall quality of care, and to indicate any changes that might lead to future improvements. (<a href="http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/primary-care/">http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/primary-care/</a>)</td>
</tr>
<tr>
<td><strong>Manchester Patient Safety Framework (MaPSaF) (2006)</strong></td>
<td>A tool to help healthcare organisations and teams assess their progress in developing a patient safety culture. MaPSaF was originally developed for primary health care, and has now been extended to other sectors including acute care, mental health and ambulance services. MaPSaF uses critical dimensions of patient safety and for each of these describes five levels of an increasingly mature organisational safety culture. The dimensions relate to areas where attitudes, values and behaviours about patient safety are likely to be reflected in the organisation’s working practices, and include:&lt;br&gt;1. Overall commitment to quality&lt;br&gt;2. Priority given to patient safety&lt;br&gt;3. Perceptions of the causes of patient safety incidents and their identification&lt;br&gt;4. Investigating patient safety incidents&lt;br&gt;5. Organisational learning following a patient safety incident&lt;br&gt;6. Communication about safety issues&lt;br&gt;7. Personnel management and safety issues&lt;br&gt;8. Staff education and training about safety issues&lt;br&gt;9. Team working around safety issues (<a href="http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796">http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796</a>)</td>
</tr>
<tr>
<td><strong>National Institute of Clinical Excellence</strong>&lt;br&gt;UK organisation provides guidance on promoting good health, preventing and treating ill health</td>
<td>NICE Quality Standards (2010)&lt;br&gt;NICE quality standards are a set of specific, concise, evidence based statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions. Some 150 clinical areas will eventually have their own set of quality standards, with the first three standards published covering the treatment and care of stroke, dementia and venous-thromboembolism (VTE) prevention. (<a href="http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp">http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp</a>)</td>
</tr>
<tr>
<td><strong>Agency for Healthcare Research and Quality</strong>&lt;br&gt;US lead agency responsible for improving quality, safety, efficiency and effectiveness</td>
<td>AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making. AHRQ facilitates the development of, and access to, guides, tools and strategies for health care providers, consumers, Policymakers, purchasers and other health officials on a wide range of topics. (<a href="http://www.ahrq.gov/consumer/safety.html">http://www.ahrq.gov/consumer/safety.html</a>)</td>
</tr>
<tr>
<td>Organisation</td>
<td>Activities targeted at primary health care</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------</td>
</tr>
</tbody>
</table>
| Institute for Innovation and Improvement UK National Health Service Institute to support transformation of health care | The Institute’s Safer Care Program aims to engage, inform and motivate clinical staff and healthcare providers to address the challenge of providing safer healthcare. The program has a specific module on primary health care that includes:  
- Leading Improvement in Patient Safety: training course to help understand, measure and improve patient safety  
- Primary Care Trigger Tool: tool to measure harm caused by health care that involves review of case notes using a structured format to identify “triggers” that may indicate the presence of an adverse event. These triggers relate to medications, general care, DVT/PE, patient transfers, laboratory findings, new key diagnoses and death. (Appendix 2)  
(http://www.institute.nhs.uk/safer_care/primary_care/improving_safety_in_primary_care.html) |
| Joint Commission US healthcare standards and accreditation agency | Develops accreditation standards for ambulatory care facilities, and accredits facilities against standards. Standards cover a range of issues similar to RACGP and other practice accreditation standards in Australia. The Joint Commission sets National Patient Safety Goals that are assessed as part of the accreditation process. Goals relevant to ambulatory care relate to patient identification, healthcare acquired infections, communication, medication safety, falls prevention, prevention of pressure ulcers and identification of safety risks. (http://www.jointcommission.org/AccreditationPrograms/AmbulatoryCare/) |
| Institute for Health Improvement US not for profit organisation that aims to improve health care | IHI works on a wide range of topics and campaigns. Some of the areas of clinical interest are relevant to primary health care (such as diabetes, asthma and HIV), as are the processes and models of improvement that are used (such as the Plan – Do – Study – Act cycle which is being used by the Australian Primary Care Collaboratives program). They also have a specific topic area on office practice, although much of this is focussed on access to services. (http://www.ihi.org/ihi) |
| Health Information Technology for Improving Quality of Care in Primary Care Settings (2007) | Project conducted by IHI for the Agency for Healthcare Research and Quality to distil the best of what is currently known about using health IT for quality improvement in primary health care, and to develop a set of change concepts that could be broadly disseminated to accelerate the adoption of health IT for improvement. (http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_661809_0_0_18/AHRQ_HIT_Primary_Care_July07.pdf) |
| Institute for Safe Medication Practices US not for profit organisation educating the healthcare community and consumers about safe medication practices | ISMP started a voluntary practitioner error-reporting program more than 30 years ago. ISMP’s other initiatives include publishing four "ISMP Medication Safety Alert®" newsletters for healthcare professionals and consumers; presenting educational programs, providing medication safety tools and resources, and providing confidential consulting services to healthcare systems to proactively evaluate medication systems or analyse medication-related sentinel events. (http://www.ismp.org/default.asp) |
| Health Research & Educational Trust, Institute for Safe Medication Practices, Medical Group Management Association Collaboration between three US organisations | Patient safety tools for physician practices have been developed to support safer care in office-based medical practices (general practices). There are two main components:  
- The Physician Practice Patient Safety Assessment: a self assessment tool focusing on key components of patient safety. The self assessment is focussed on: level of adoption of information technology, medication safety, handover and patient transitions, surgery/anaesthesia and sedation and invasive procedures, practice management and culture, patient education and culture (Appendix 3).  
- Pathways for Patient Safety: education modules for implementing patient safety programs in the areas of teamwork and communication, patient safety culture and medication safety (http://www.mgma.com/solutions/landing.aspx?cid=24572&id1=24558&id4l=25180&id4r=25290&id5l=24560&id5r=24562&id6=1&hid=25288&mid=24558) |
5. What is the context for improving patient safety in primary health care in Australia?

There is currently a significant impetus for healthcare reform in Australia, and current reform efforts are emerging and evolving. There are a number of drivers that are particularly relevant to efforts to improve patient safety in primary health care including current arrangements to improve quality use of pathology, diagnostic imaging and medicines, as well as more recent work on the National Safety and Quality Framework, the National Primary Care Strategy, the work of the National Health and Hospitals Reform Commission, and the National Health and Hospitals Network Agreement.

5.1 National Safety and Quality Framework

The National Safety and Quality Framework has been developed by the Commission to provide a vision for co-ordinated safety and quality action across the Australian health system over the next ten years (Table 4). The core themes are that safe, high-quality care is always consumer centred, driven by information and organised for safety.

The Framework provides a basis for strategic and operational safety and quality plans, as well as a mechanism for refocussing current quality improvement activities, reviewing investment in safety and quality and designing goals for implementation.

The Framework has been developed to apply across the health sector, and most of the strategies in the proposed Framework either apply in primary health care, or their implementation would affect practices in primary health care.
### Table 4: National Safety and Quality Framework
(June 2009)

<table>
<thead>
<tr>
<th>Safe, high quality health care is always:</th>
<th>What it means for me as a patient or consumer:</th>
<th>Strategies for action by health systems and providers:</th>
</tr>
</thead>
</table>
| **1. Patient focused**  
This means providing care that is respectful of and responsive to individual preferences, needs and values. It means a partnership between consumers, family, carers and their healthcare providers. Processes of care are designed to optimise the patient experience. | I can access high quality care when I need it. | Develop service models which improve access to health care for patients. |
| | I can obtain and understand health information, so that I can make decisions about my own care and participate in ensuring my safety. | Increase health literacy.  
Involve patients so that they can make decisions about their care and plan their lives.  
Provide care that is culturally safe. |
| | **My health care is co-ordinated because people and systems work in partnership with me.** | Enhance continuity of care.  
Minimise risks at handover.  
Provide case management for complex care.  
Facilitate patient-centered service models. |
| | **I know my healthcare rights**  
This means providing care that is respectful of and responsive to individual preferences, needs and values. It means a partnership between consumers, family, carers and their healthcare providers. Processes of care are designed to optimise the patient experience. | Promote healthcare rights.  
Inform and support patients who are harmed during health care. |
| | If I am harmed during health care, it is dealt with fairly. I will get an apology and a full explanation of what happened. | |
| **2. Driven by information**  
This means enhancing knowledge and evidence about safety and quality. Safety and quality data are collected, analysed and fed back for improvement. Action is taken to reduce unjustified variation in standards of care, and to improve patients’ experiences and clinical outcomes. | **My care is based on the best knowledge and evidence.** | Reduce unjustified variation in standards of care.  
Collect and use data to improve safety and quality. |
| | **My clinical outcomes and experiences are used to build the evidence base for care and for strategies designed to improve care.** | Learn from patients’ and carers’ experiences.  
Encourage and apply research that will improve safety and quality.  
Continually monitor the effects of healthcare interventions. |
| **3. Organised for safety**  
This means that safety is a high priority in the design of health care. Organisational structures, work processes and funding models recognise and reward taking responsibility for safety. | **I know that governments, healthcare managers and healthcare staff take responsibility for my safety.** | Clinicians recognise their responsibilities for safety.  
Managers recognise their responsibilities for safety.  
Governments recognise their responsibilities for safety. |
| | **Our money funds a safe and efficient health system.** | Restructure funding models to support safe, appropriate care.  
Support and implement e-health.  
Design facilities, equipment and work processes for safety. |
| | **I know that when something goes wrong, actions are taken to prevent it happening to someone else.** | Take action to prevent or minimise harm from healthcare errors. |
What is the context for improving patient safety in primary health care in Australia?

5.2 National model for safety and quality accreditation

In November 2006, the Commission commenced its review of national safety and quality accreditation arrangements. This included reviewing current safety and quality systems and standards, and proposing a package of reforms including a national set of standards by which health services could be assessed.

The first stage of implementing the accreditation reform has focused on the development of a preliminary set of National Safety and Quality Healthcare Service Standards. The draft Standards focus on areas that are essential to improving the safety and quality of care for patients by providing explicit statements of the expected level of safety and quality of care to be provided to patients by health services organisations. The Standards also provide a means for assessing an organisation’s performance. Draft Standards have been developed for:

- Governance for Safety and Quality in Health Service Organisations;
- Healthcare Associated Infection;
- Medication Safety;
- Patient Identification and Procedure Matching; and
- Clinical Handover.

An additional five topics are currently under development, these include:

- Blood and blood safety;
- Partnering with Consumers;
- Prevention and Management of Pressure Ulcers;
- Recognising and Responding to Clinical Deterioration; and
- Falls safety.

A range of supporting tools and guidelines for the Standards are being developed in consultation with key stakeholders.

A pilot study of the refined draft Standards was undertaken for the first set of Standards in 2010. The aim of the pilot was to test the Standards, supporting tools and guidelines, and to identify issues for implementation of the Standards. Once finalised the Standards will be provided to Health Ministers for endorsement.

It is intended that all health services that potentially pose a high risk of harming patients be accredited against the National Safety and Quality Health Service Standards. Health service organisations with a lower risk of patient harm should utilise the Standards as part of their internal quality assurance mechanisms.
What is the context for improving patient safety in primary health care in Australia?

5.3 Existing national programs

**Quality Use of Pathology**

The Australian Government funds the Quality Use of Pathology Program (QUPP), which aims to achieve improvement in health and economic outcomes from the use of pathology in health care through the pursuit of better practice amongst referrers, providers of pathology services and consumers.

In consultation with a steering committee made up of pathology, requester and consumer representatives, specific quality projects are undertaken as part of the QUPP. Examples of such projects include a report on evidence-practice gap in GP pathology test ordering, workshops on patient safety and quality related to pathology and best practice requesting, and a system to monitor and analyse errors that occur in patient identification and sample handling on the way to and from the pathology laboratory.

The National Pathology Accreditation Advisory Council also plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. Some aspects of this quality improvement process involve critical linkages with primary care providers.

**Quality and Safety in Diagnostic Imaging**

The Australian Government manages the Diagnostic Imaging Accreditation Scheme (DIAS), which was developed to ensure consistency, across a wide range of practice types, in safety and quality standards across all radiology and non-radiology modalities.

The Department of Health and Ageing is also currently developing a model for the future quality framework for diagnostic imaging, which will be based on the Quality Use of Pathology Program (QUPP) and is expected to commence in 2010-11.

The Royal Australian and New Zealand College of Radiologists (RANZCR) has a strong focus on quality and safety and undertakes a range of quality projects including maintenance of the Radiology Adverse Events Register and development of Diagnostic Imaging Reporting Guidelines.

**National Medicines Policy and Quality Use of Medicines**

The Australian Government also implements the National Medicines Policy (NMP), which is a framework based on 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;
4. Maintaining a responsible and viable medicines industry;

Objectives two and three are the ones most relevant to patient safety in primary health care.
Ensuring objective two is achieved is largely the responsibility of the Therapeutic Goods Administration (TGA), which provides a national framework for the regulation of therapeutic goods in Australia. It also ensures the quality, safety and efficacy of therapeutic goods. The TGA has long-standing rigorous processes to ensure that medicines meet the appropriate standards.

To address objective three, Australia has a National Strategy for Quality Use of Medicines (QUM), which is intended to assist the QUM partners, health care consumers, health practitioners and educators, health care facilities, the medicines industries, the media, health care funders and purchasers, and governments in becoming more aware of the QUM framework and approach.

One of the key issues for QUM is that when receiving care and treatment patients often move between different care providers and settings, which can affect the continuity of medication management. In 2005 the Australian Pharmaceutical Advisory Committee developed the Guiding principles to achieve continuity in medication management to support and encourage continuity of medication management in all areas of the community and health care sector.

Another example of activity under the QUM National Strategy is the provision of a QUMmap (http://www.qummap.net.au/), which provides a comprehensive map of current major QUM initiatives in Australia. The QUMmap provides information on existing resources, expertise and complementary work for people working in the QUM area.

**e-Health**

The National e-Health Transition Authority is responsible for developing guidelines and specifications defining core elements of national e-health infrastructure. E-health information systems can significantly improve how important clinical and administrative information is communicated between healthcare professionals. Consequently, e-health systems have the potential to improve safety and quality of health care in Australia, including primary health care.

Recently, the 2010-11 Budget provided $466.7 million for Australia’s first personally controlled electronic health record and the Healthcare Identifiers Bill was passed in parliament; both of these actions provide a foundation for other e-health activities currently under development such as discharge summaries and referrals and a range of other e-health enhancements.

### 5.4 National Health Reform

**National Health and Hospital Reform Commission**

The National Health and Hospital Reform Commission (NHHRC) presented its final report to the Minister for Health in June 2009. The task of the NHHRC was to develop a long-term health reform plan. In its final report the NHHRC provided 123 recommendations in four broad areas: taking responsibility, connecting care, facing inequities and driving quality performance. A number of NHHRC recommendations addressed the way in which
What is the context for improving patient safety in primary health care in Australia?

Primary health care services are delivered, and a number focused on safety, quality and learning across the health system. Themes that were particularly relevant to improving patient safety in primary health care include:

- ensuring care is focussed on people and families
- improving access to services
- improving integration of services, particularly for people with chronic conditions
- the importance of e-health as a enabler of improvement
- the need to explore options regarding funding mechanisms and incentives
- the need to improve collection and use of data about performance, safety and quality.

Primary Health Care Strategy

In May 2010 the Department of Health and Ageing released Australia’s first National Primary Health Care Strategy, as a key part of the National Health and Hospitals Reform agenda. Safety and quality was recognised as a core direction for change in the National Primary Health Care Strategy. Elements that were identified as part of this direction include:

- access to information on safety, quality and performance that will drive improvement
- the need for tools to allow providers to reflect on the effectiveness of their services
- working within a performance framework that supports peer feedback and comparison as part of continuous quality improvement
- accreditation of publicly subsidised primary care services
- research that is timely, accessible and applicable to policy and service delivery.

National Health and Hospitals Network Agreement

The National Health and Hospitals Network Agreement is the culmination of much of the health reform strategies and reviews noted above. This agreement between the Commonwealth and the States and Territories establishes the Commonwealth government as the majority funder of public hospital services. The Commonwealth government will also have funding and policy responsibility for most primary health care services, including those currently delivered by the States and Territories. The details of this agreement, and the implementation processes associated with it are still being developed. At this stage issues in the agreement that appear to be relevant for improving patient safety in primary health care include:

- the formation of Medicare Locals (independent primary health care organisations) with strong links to local communities and health professionals to provide better services, improve access to care and drive integration between services
- increased investment to ensure access to GP services including expansion and enhancement of the nurse practitioner role, delivering new GP super clinics and upgrades to existing facilities, facilitating access to local after hours services and investment in coordinated care for diabetes patients
What is the context for improving patient safety in primary health care in Australia?

- an emphasis on national clinical quality and safety standards developed by the Commission which will cover safety, quality and appropriateness of care
- publication of performance reports for local hospital networks and the hospitals within them, private hospitals (Hospital Performance Reports) and primary health care organisations (Healthy Community Reports), including reporting on selected clinical quality and safety measures.
Primary health care is a complex and fragmented field. In the discussion paper prepared as part of the consultation process for the draft primary health care strategy, the Department of Health and Ageing noted:

‘The result [of incremental responses to identified issues in primary care] is a primary health care system in Australia characterised by an increasing proliferation of narrowly targeted programs and funding arrangements, and growing complexity and inflexibility for health care organisations, professionals and consumers.’

This means that there are a large number of organisations that have a role in quality and safety in Australia, and that could potentially have a role in improving patient safety. Table 5 includes a summary of the main types of organisations in Australia that have a stake in primary health care, and their role or activities regarding safety and quality. Because of the limited focus on patient safety in primary health care to date, roles in the areas of both safety and quality have been included. Organisations whose primary safety and quality activities are associated mainly with advocacy are not included. The roles of some of these organisations may change with the implementation of the National Health and Hospitals Network Agreement.

<table>
<thead>
<tr>
<th>Type of organisation</th>
<th>Examples of specific organisations</th>
<th>Examples of safety and quality activities performed by these types of organisations</th>
</tr>
</thead>
</table>
| Primary health care providers | Primary health care organisations  
Hospitals which provide primary health care services | Implement local safety and quality policies and frameworks  
Ensure staff are appropriately trained  
Instigate patient feedback processes and protocols |
| Government               | Department of Health and Ageing  
State and territory health departments | Set policy frameworks  
Manage programs that deliver services and support safety and quality  
Regulate activities |
| Colleges                 | Royal Australian College of General Practitioners  
Australian College of Rural and Remote Medicine  
Royal College of Nursing Australia | Vocational training curricula  
Continuing professional development  
Professional standards  
Accreditation standards  
Safety and quality resources |
Table 5 (cont.): Summary of the range of organisations that have a stake in primary health care in Australia

<table>
<thead>
<tr>
<th>Type of organisation</th>
<th>Examples of specific organisations</th>
<th>Examples of safety and quality activities performed by these types of organisations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional organisations</td>
<td>Large number of professional organisations covering nursing and allied health disciplines, including those focussing on delivery of services in specific clinical and geographical areas</td>
<td>Continuing professional development Certification of members Development and maintenance of performance /competency standards Development of clinical guidelines Development and distribution of professional standards</td>
</tr>
<tr>
<td>Consumer organisations</td>
<td>Consumers Health Forum WHO Patients for Patient Safety</td>
<td>Represent consumers interests to government and industry, and supports and provides patient involvement in patient safety programs</td>
</tr>
<tr>
<td>Registration boards</td>
<td>Health professional registration boards, including the new Australian Health Practitioner Regulation Agency New arrangements under the National Registration and Accreditation Scheme commenced 1 July 2010</td>
<td>Registration and certification of health professionals Standards of professional practice</td>
</tr>
<tr>
<td>Accreditation organisations</td>
<td>Practice accreditation organisations (such as QIP/AGPAL, GPA+,QIC, PGA) Training accreditation organisations (such as Australian Physiotherapy Council, Australian Medical Council)</td>
<td>Accredit organisations that deliver primary health care services against relevant standards Provide training to providers and practice staff Clinical standards Accreditation of training programs</td>
</tr>
<tr>
<td>Information organisations</td>
<td>Australian Institute of Health and Welfare National Health and Medical Research Council Primary Health Care Research and Information Service Universities</td>
<td>Reports primary health care information Contributes to the development of indicators Funds research into safety and quality Incorporates National Institute for Clinical Studies, whose role is transform research into practice Develops some clinical guidelines Facilitates the exchange of knowledge and evidence between research, policy and practice Provide undergraduate and postgraduate training Undertake research</td>
</tr>
<tr>
<td>Other organisations</td>
<td>Divisions of General Practice Network</td>
<td>Core divisional programs focus on safety and quality issues Activities include education, development and dissemination of tools and resources, provision of services and liaison and partnerships with local organisations</td>
</tr>
</tbody>
</table>
Who has a role in improving patient safety in primary health care in Australia?

Table 5 (cont.): Summary of the range of organisations that have a stake in primary health care in Australia

<table>
<thead>
<tr>
<th>Type of organisation</th>
<th>Examples of specific organisations</th>
<th>Examples of safety and quality activities performed by these types of organisations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Primary Care Collaboratives</td>
<td>National program to support practices implement solutions to improve patient outcomes</td>
<td></td>
</tr>
<tr>
<td>National Prescribing Service</td>
<td>Provides evidence-based information and services for consumers and health professionals Provides curricula and training Quality prescribing indicators for general practice</td>
<td></td>
</tr>
<tr>
<td>National Primary and Community Health Network</td>
<td>Facilitates the exchange of knowledge and sharing information on primary health care and the role it plays in the Australian health system</td>
<td></td>
</tr>
<tr>
<td>Australian Commission on Safety and Quality in Health Care</td>
<td>Leads and coordinates safety and quality nationally Under implementation of the NHHN additionally: Formulate, promote and support implementation of guidelines, standards and indicators and for safety and quality including monitoring compliance Formulate a national accreditation model for health service organisations</td>
<td></td>
</tr>
</tbody>
</table>
7. **A call to action**

The focus on quality in primary health care in Australia has brought significant gains for patients. For example, in the ten years that data has been collected by the Bettering the Evaluation and Care of Health (BEACH) program, management of conditions such as diabetes, cancer and asthma in general practice has changed in accordance with guidelines, associated with the introduction of government policies and incentives.40

The provision of care that is in accordance with current professional knowledge is necessary, but it is not sufficient for optimal patient outcomes. Care also needs to be safe: patients should not be harmed in the delivery of health care services in primary care settings. We know, however, that patient safety incidents occur in primary health care, and that these can cause harm to the patient.10 Accordingly, having an explicit focus on patient safety and prevention of harm would support and contribute to the longstanding and widespread efforts to improve the quality of primary health care in Australia.

Patient safety in primary care is a relatively new area for Australia, and internationally. The evidence base about the nature of patient safety risks and patient safety solutions in primary health care is weak. Nonetheless, from what is known, it is clear that there is an imperative to act to improve patient safety in primary health care.

In preparing this discussion paper the Commission wanted to raise awareness of these issues and stimulate debate about what needs to be done to improve patient safety in primary health care. More research on this topic is needed. In the meantime, it is also important to identify what actions should be taken now, on the basis of the knowledge that is already available.

This discussion paper is the first step towards a process of developing a nationally agreed action plan to improve patient safety in primary health care. As a result of this paper the Commission wants to identify the current work being undertaken in this area, gaps in this work and priorities for action.
Your Views

The Commission is seeking responses to this discussion paper, and the views and ideas of stakeholders regarding patient safety in primary health care.

Questions of particular interest to the Commission are:

1. What evidence currently exists about patient safety in primary health care?
2. What are the gaps in knowledge that need to be addressed?
3. What are the key patient safety risks/ considerations within primary health care?
4. What solutions could be put in place to address these risks?
5. Where is action urgently needed to improve patient safety in primary health care?
6. What work is currently being done to examine or improve patient safety in primary health care? Who is undertaking this work?
7. What patient safety in primary health care work would benefit from national coordination?
8. What role could the different primary health care organisations take to improve patient safety in primary health care?
9. What would be the key challenges in implementing this type of work in the primary health care sector? How could these challenges be addressed?
10. Are there specific patient populations that should be a particular focus when improving patient safety in primary health care? What are some of the unique challenges for these populations?

The Commission will use the responses to the discussion paper to identify a number of proposed priority areas regarding patient safety that will be the basis for national discussion and development.

Submissions do not have to address these questions and may respond to other issues raised in the Discussion Paper.

All submissions are welcome and will be accepted up to 15 October 2010. Submissions should be marked ‘Patient Safety in Primary Care’ and forwarded to:

Australian Commission on Safety and Quality in Health Care
GPO Box 5480
Sydney NW 2001

or emailed to:
mail@safetyandquality.gov.au
References

17. Wachter RM. Is ambulatory patient safety just like hospital safety, only without the "stat"? Annals of Internal Medicine 2006;145(7):547-49.


Appendix 1

QUICK REFERENCE GUIDE TO THE SEVEN STEPS TO PATIENT SAFETY IN GENERAL PRACTICE


**Step 1: Build a safety culture**
- Carry out an audit to assess your team's safety culture.
- Highlight successes and achievements in improving safety, and be open and honest when things go wrong.
- Apply the same level of rigour to all aspects of safety, including incident reporting and investigation, complaints, health and safety, staff protection, Significant Event Audit (SEA) and clinical quality assurance.

**Step 2: Lead and support your practice team**
- Talk about the importance of patient safety and demonstrate you are trying to improve it by including an annual patient safety summary in your practice report or your Practice Quality Report.
- Include patient safety in in-house staff training, including the use of improvement methods, and ask for it to be part of continuing education outside of the practice.
- Promote safety in team meetings by discussing safety issues and making it a standing agenda item.

**Step 3: Integrate your risk management activity**
- Regularly review patient records (e.g. using casenote review tools) so that areas of common harm such as delayed or missed diagnoses/treatment can be identified.
- Keep a good SEA record that can be used for the General Medical Services (GMS) contract, clinical governance, appraisals and revalidation.
- Involve wider primary healthcare team members in improving patient safety and use information from as many sources as possible to measure and understand safety issues in the practice.

**Step 4: Promote reporting**
- Share patient safety incidents and SEAs with the National Reporting and Learning Service (NRLS) so that learning can be disseminated nationally.
- Record events, risks and changes, and include them in your annual practice report.
- Cascade safety incidents and lessons learned to all your staff and other practices through your primary care organisation.

**Step 5: Involve and communicate with patients and the public**
- Seek patient views, especially on what can be done to improve patient safety, and use complaints as a vital part of a modern, responsive practice.
- Encourage feedback using patient surveys and websites such as NHS Choices.
- Involve your practice population via patient groups, open meetings or by inviting patient representatives to patient safety meetings.

**Step 6: Learn and share safety lessons**
- Hold regular SEA meetings, reflecting on the quality of your care, patient safety and lessons for the future.
- Make the discussion of significant events and the national analyses of patterns of risk everybody’s business, including the wider primary healthcare team as appropriate, and act on your findings.
- Share experiences with other practices by making your patient safety lessons widely available.

**Step 7: Implement solutions to prevent harm**
- Ensure that agreed actions to improve safety are documented, actioned and reviewed, and agree who should take responsibility for this.
- Use technology, where appropriate, to reduce risk to patients.
- Involve both patients and staff as they can be key to ensuring proposed changes are the right ones.
### PRIMARY CARE TRIGGER TOOL

Following is the Primary Care Trigger Tool from the NHS Institute for Innovation and Improvement. The table shows the triggers that should prompt further examination of whether an adverse event has occurred, notes regarding these triggers, examples of situations that would be classified as adverse events, and those that would not.

<table>
<thead>
<tr>
<th>Trigger</th>
<th>Trigger notes</th>
<th>Example adverse events</th>
<th>Not an adverse event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication module</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat medication discontinued</td>
<td>Include only systemic medication (tabs/liquids)</td>
<td>Any side effect requiring the termination of the prescription</td>
<td>Changes made on basis of patient preference without evidence of adverse effects Stopped because no longer required</td>
</tr>
<tr>
<td>Prescribing of opioid analgesia</td>
<td>Any opioid stronger than Co-Codamol 8/500 (Codeine 8mg/Paracetamol 500mg)</td>
<td>Nausea (if required monitoring/change in prescribing) drowsiness, fall, constipation (if resulted in prescribing action)</td>
<td>Stopped because no longer required</td>
</tr>
<tr>
<td>Prescribing oral NSAID/COX2</td>
<td>Even as an acute item Excluding Aspirin 75mg</td>
<td>Vomiting, GI bleed, dyspepsia, peripheral oedema</td>
<td>Stopped as not effective</td>
</tr>
<tr>
<td>Prescribing warfarin</td>
<td></td>
<td>Haemorrhage, bruising (if required monitoring/change in prescribing)</td>
<td>High/low INR without patient harm</td>
</tr>
<tr>
<td>Prescribing insulin</td>
<td>Including Exenatide (Byetta)</td>
<td>Hypoglycaemia, significant lipohyperdystrophy</td>
<td>Insufficiently well controlled hyperglycaemia, complications of disease itself</td>
</tr>
<tr>
<td>Prescribing methotrexate</td>
<td>Including prescriptions issued/dispensed by hospital</td>
<td>Drop in cell count requiring monitoring or change in prescribing, worsening condition resulting from prescribing changes</td>
<td>Failure of condition to respond adequately to medication</td>
</tr>
<tr>
<td>Prescribing amiodarone</td>
<td></td>
<td>Hypothyroidism, dizziness</td>
<td></td>
</tr>
<tr>
<td><strong>General care module</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fall if age &gt;75</td>
<td></td>
<td>Hypotension/drowsiness caused by medication</td>
<td>Falls not caused by or resulting in iatrogenic harm</td>
</tr>
<tr>
<td>Fracture if age &gt;75</td>
<td></td>
<td>Fracture in context of long term steroid use, post-op infection, ?delayed development of neurovascular defect, ?recurrent low</td>
<td>Fracture by itself</td>
</tr>
<tr>
<td>Appendix 2</td>
<td></td>
<td></td>
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<td>----------------------------------</td>
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<td></td>
<td></td>
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<tr>
<td><strong>Patient safety in primary health care: Discussion paper</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Impact fracture without bone protection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pressure sore or ulcer</strong></td>
<td>Including new diabetic ulcer</td>
<td>Any new pressure sore or ulcer</td>
<td></td>
</tr>
<tr>
<td><strong>Seen &gt; once in 3 days</strong></td>
<td></td>
<td>Adverse drug reaction</td>
<td></td>
</tr>
<tr>
<td><strong>Urinary catheter in situ</strong></td>
<td>UTT, blockage, haematuria</td>
<td>Bypassing of urine, A&amp;E attendance for catheter change without complication</td>
<td></td>
</tr>
<tr>
<td><strong>VTE module</strong></td>
<td>Inadequate management of VTE risk, anticoagulation failure</td>
<td>Spontaneous DVT/PE, clinical complications of DVT or PE</td>
<td></td>
</tr>
<tr>
<td><strong>Proven DVT or PE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient transfer module</strong></td>
<td>Consequences of failures in discharge planning, adverse drug events, surgical complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Readmission to hospital within 2 weeks of discharge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Laboratory module</strong></td>
<td>Confusion, lethargy, malaise</td>
<td>Effect of medication requiring monitoring / medication change</td>
<td></td>
</tr>
<tr>
<td><strong>Na+ &lt;130 or &gt;150 mmol/l</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>K+ &lt;3.5 or &gt;5.5 mmol/l</strong></td>
<td>Cardiac dysrhythmia</td>
<td>Effect of medication requiring monitoring / medication change</td>
<td></td>
</tr>
<tr>
<td><strong>INR &lt;2 or &gt;5</strong></td>
<td>Haemorrhage</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Haemoglobin &lt;9g/dl</strong></td>
<td>GI haemorrhage, adverse drug event</td>
<td>Not if the consequence of a disease eg GI haemorrhage with no iatrogenic origin</td>
<td></td>
</tr>
<tr>
<td><strong>MRSA positive</strong></td>
<td>Hospital-acquired complication</td>
<td>Community-acquired</td>
<td></td>
</tr>
<tr>
<td><strong>C.diff positive</strong></td>
<td>Complication of antibiotic use</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Positive wound/skin swab culture</strong></td>
<td>Surgical complication</td>
<td>Complication of a disease process, de novo infection</td>
<td></td>
</tr>
<tr>
<td><strong>eGFR &lt;= 20</strong></td>
<td>Medication complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>End of life module</strong></td>
<td>Complication of medical procedure, adverse drug event</td>
<td>Death from natural causes</td>
<td></td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Key diagnosis module</strong></td>
<td>Complication of care in a vulnerable patient</td>
<td>The event itself</td>
<td></td>
</tr>
<tr>
<td><strong>New diagnosis of CVA/TIA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>New diagnosis of acute confusional state</strong></td>
<td>Complication of medication</td>
<td>Non iatrogenic causes</td>
<td></td>
</tr>
</tbody>
</table>
EXAMPLE OF PHYSICIAN PRACTICE PATIENT SAFETY ASSESSMENT™

Following is the Medication Safety section of the patient safety self-assessment tool developed by the Health Research & Educational Trust, Institute for Safe Medication Practices, Medical Group Management Association. The key to the self-assessment tool is as follows:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>No activity</td>
</tr>
<tr>
<td>B</td>
<td>Considered, but not implemented</td>
</tr>
<tr>
<td>C</td>
<td>Partially implemented in some areas</td>
</tr>
<tr>
<td>D</td>
<td>Fully implemented in some areas</td>
</tr>
<tr>
<td>E</td>
<td>Fully implemented in all areas</td>
</tr>
<tr>
<td>NA</td>
<td>Item not applicable to our practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Rating</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td></td>
<td></td>
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<td>C</td>
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<tr>
<td>D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- A complete medication history, including over-the-counter medications, vitamins and herbal products, is obtained and documented for every patient during each office visit.
- Up-to-date, useful written information about medications is available to patients of the practice who do not speak English.
- Patients are provided with an up-to-date list of all medications they are receiving when leaving the practice or at the end of the encounter (e.g., on a convenient wallet reference card).
- A system is in place to track all patients receiving warfarin therapy that includes notices to patients for periodic laboratory testing of INRs and a documented review of INRs before prescription renewals are approved. (If you do not prescribe warfarin for any patient in your practice then answer this item with NA.)
- All prescriptions are entered into an office-based electronic prescribing system that produces either a computer-generated prescription or electronic transmission of the prescription directly to a pharmacy.
- Indications for medications are included on written and electronic prescriptions.
- A list of high-alert drugs (e.g., warfarin, low molecular weight heparin, oral methotrexate for nononcology use) is established, from a list of drugs often prescribed in the practice, that require direct contact of the physician and pharmacist for phoned-in prescriptions including renewals.
- External medications (e.g., benzoin, podophylline) are labeled “For External Use Only” and are separated from internal-use.
<table>
<thead>
<tr>
<th>Item</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients who are taking medications are asked at each office visit what medications they are currently taking and if they have had side effects. Their responses are documented in their medical record (e.g., “taking medications without problems” or record the nature and type of reaction or interaction).</td>
<td></td>
</tr>
<tr>
<td>All practice staff who prescribe, dispense, administer and provide patient education on medications have easy access to current drug information and other decision support resources. All drug information and clinical decision support resources used in the practice are standardized, maintained and updated at least yearly or whenever a new edition is available.</td>
<td></td>
</tr>
<tr>
<td>All medications, reagents and other products that carry an expiration date are routinely checked (at least quarterly) by a designated staff member and discarded once they have expired.</td>
<td></td>
</tr>
<tr>
<td>All female patients of childbearing age are required to have a documented negative pregnancy test or other notation in the chart before teratogenic medications are prescribed (including refill renewals). Patient education regarding the need for effective birth control while taking these medications is provided.</td>
<td></td>
</tr>
<tr>
<td>A manual or electronic system is in place to document all prescribed drug therapy and anticipated dates of prescription renewals.</td>
<td></td>
</tr>
<tr>
<td>All multiple-dose vials of injectable medications used in the practice (e.g., lidocaine, dexamethasone, prochlorperazine, vitamin B12) are labeled with the date opened and include a date on which the unused product would be discarded (no later than 30 days after opening). (Note: If the practice does not use or stock any injectable medications, even in emergencies, then answer this item with NA.)</td>
<td></td>
</tr>
<tr>
<td>All medications dispensed to patients, including samples, are properly labeled and are documented in the medical record. This labeling and documentation includes the name of the medication, strength, dose, frequency, lot number, expiration date, quantity of medication along with the patient’s name, date dispensed and prescriber information. (Note: If the practice does not dispense any medications, including samples, then answer this item with NA.)</td>
<td></td>
</tr>
<tr>
<td>All vaccines dispensed or administered by the practice are documented in a log that contains the name of the vaccine, lot number, expiration date, patient name, dose, and date administered or dispensed. (Note: If the practice does not dispense any vaccines, then answer this item with NA.)</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Rating</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>The practice does not compound drugs or products and purchases commercially prepared complex / compounded drugs and products or contracts with an outside source to provide these products. (Note: If the practice does not dispense any medications, including samples, then answer this item with NA.)</td>
<td>A</td>
</tr>
</tbody>
</table>