CLINICAL
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Patient Safety Research

A review of the technical literature

A review for the Clinical Excellence Commission

The Centre for Clinical Governance Research in Health undertakes strategic research, evaluations and research-based projects of national and international standing with a core interest to investigate health sector issues of policy, culture, systems, governance and leadership.

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Preface

This monograph has been prepared as part of a program of research on safety and quality undertaken for the Clinical Excellence Commission (CEC) in New South Wales by the Centre for Clinical Governance Research at University of New South Wales. It seeks to assess the patient safety literature and suggest a way forward for clinical teams in providing safer health care.

It is one of a series. Other monographs scheduled for release over 2004 to 2006 concern related topics such as what the formal inquiries into poor patient safety have found, and how agencies responsible for promotion of patient safety operate and perform.

Other components of the program are empirical. In one study we are designing and administering a questionnaire on the safety climate of health organisations. A second study with CEC will run focus groups throughout New South Wales in order to secure the views of stakeholders on patient safety.

The team responsible for this research with CEC includes A/Professor Jeffrey Braithwaite, Dr Rick Iedema, Professor Don Hindle, A/Professor Johanna Westbrook, A/Professor Mary Westbrook, Ms Jo Travaglia, Ms Nadine Mallock, Dr Christine Jorm, and Mr Peter Nugus. This monograph was designed and written by Professor Hindle, A/Professor Braithwaite and Dr Iedema.

1 Summary

Recent literature was reviewed for the purpose of addressing two issues. First, we wanted to determine the level of avoidable harm, and the ways in which it is manifested.

We found that it is consistently high in Australia and similar countries from which there is reliable information. Poor quality of care and outcomes are present in virtually every part of the health care system, and avoidable morbidity and mortality take a wide variety of forms. It appears unlikely that any part of the system is free of error to an acceptable degree.

Second, we attempted to understand the causes and found that the literature tends to group them under three headings: errors of individual clinicians, errors that are a consequence of poor teamwork at the point of delivery of care (including failure to establish rules and processes for collaboration and communication), and errors that are a consequence of environmental factors. By environmental factors, we mean those that are external to an individual clinician or clinical team. They include the level of financial and other incentives and sanctions provided by external agencies such as regulators and health care purchasers, the levels of accountability, and the degree to which care settings have been designed in ways that affect the risks of error (such as workplace ergonomics). This is not to deny there are many people doing good things. But there are practice and cultural constraints that impede progress.

The literature suggests a wide variety of corrective measures. They include legislation, financial incentives, establishment of new agencies to be responsible or accountable for improvements in safety, education, improved access to information about safety risks and corrective measures, external auditing, internal audits, consumer involvement, new technologies, improvements in organisational culture, improvements in clinical teamwork, and more and better research.

Little evidence exists regarding the cost-effectiveness of the large majority of these measures. Indeed, most of them have already been widely applied but appear to have had only marginal or local effects. Although there are exceptions, there appears to have been little improvement as a whole. Where there have been

successes, they appear to be associated with multiple interventions within the framework of a comprehensive plan to which all concerned parties are committed.

Some commentators argue there is little to be gained by establishing information systems that routinely measure and analyse events in which there was potential or actual harm. The literature suggests that, for the most part, circumstances exist that are common to all complicated human-machine systems where communication is poor: problems are obvious to almost everyone, solutions can be easily defined that are cost-effective and require no additional resources, no-one is sure as to where the responsibility lies for taking action, and therefore everyone is a prisoner.

We conclude that the patient safety movement adds little to the ideas and techniques of clinical practice improvement that have long been promoted under headings like quality assurance or total quality improvement. However, it can have some benefit to the extent that it emphasises a greater degree of accountability for patient wellbeing and promotes some tools (such as human factors engineering) and clinical team building that have been paid too little attention to date.

Our recommendations concentrate on actions that might be initiated by an individual clinician or clinical unit that is interested in achieving change. We define the attributes of a provider tackling patient safety in a systematic and intelligent way, building on experiences in the application of ideas like learning organisations and soft systems methods.

Finally, we briefly outline one type of process that might be easily applied by individual care provider organisations that wish to strengthen their existing activities directed at improvements in patient safety. It concentrates on encouraging care teams to identify and openly discuss the way they work together, with a view to reducing the cultural constraints to clinical practice improvement.

2 Definitions

The literature contains a variety of definitions of patient safety and related concepts. In some cases, there are precise and measurable criteria (such as the boundary above which a patient can be said to have been harmed).

However, we will deliberately avoid addressing the differences of emphasis or the technical details to minimise the risk of adding confusion. The core ideas can be simply expressed and are already well understood, and imprecision of definitions is an unimportant contributor to harm.

By patient safety, we mean the extent to which patients are protected from avoidable harm. We say that patient safety was low or poor if patients are not in fact adequately protected.

By harm, we mean a loss of health outcomes as a consequence of the way that an episode of care was provided.

Avoidable harm is that which is a consequence of the care providers having worked in a sub-optimal way. This is equivalent to the idea of affordable best practice: we are indicating that better care could have been provided within the limits of reasonable resource availability.

Finally, it is worth making a distinction between potential and actual harm. By potential harm, we mean the situation in which care was provided that did not harm the patient – but where care practices were deficient to the extent that we believe there is a high probability of harm in the future. An example is where the wrong drug was given but it had no measurable effect on the patient's health status.

It is usual to refer to quality of care here: the process of care is such that it creates the potential for good care and improvement.

By actual harm, we mean the situation in which care was provided that did in fact cause harm to the patient. In this case, we usually refer to health outcomes: there was a lower level of health status relative to what would have occurred if the methods of care had been adequate.

Patient safety is clearly concerned with methods of care that create both potential and actual harm. We would, however, wish to distinguish between poor quality of care (that creates potentially harmful situations) and poor outcomes (where there was a measurable loss of outcomes).

Outcomes may be poor, even where the best possible care was provided: some health problems cannot be resolved. On the other hand, outcomes might be excellent in spite of poor patient safety – such as where the wrong drug was given but it had no measurable effect on the patient's health status. There was potential harm, as indicated by poor quality of care.

Incidentally, the definitions presented above are more or less consistent with those issued by the US Institute of Medicine (IOM). Safety is defined as freedom from accidental injury. Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care. The IOM says that not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition of the patient. However, not all adverse events are preventable – that is, they are not all attributable to errors.

3 Review of the technical literature

We undertook a review of articles listed in four databases: Medline, the Cumulative Index to Nursing and Allied Health (CINAHL), the International Bibliography of the Social Sciences (IBSS) and Sociological Abstracts. The search was undertaken in February 2004, and was restricted to publications between 1995 and the date of the search.

We searched the keywords field in these databases. The searched phases were 'patient safety', 'clinical harm', 'harm reduction', and 'patient plus harm'.

We identified 358 articles, of which 243 are examined in this monograph and are listed in Appendix A. They may be categorized in many ways, but we have chosen a simple structure that is based on the idea that decision makers and other interested parties might be expected to ask three sets of meta-question in this order:

Is patient safety a major problem? Should I worry about it now, given that there are so many other matters that could consume my time? What types of avoidable harm are common? What types of avoidable harm have the most serious effects on health status? Which categories of patients are most likely to be affected?

What are the underlying causes of avoidable harm? Who is most to blame? Is there individual or collective blame?

What should we do about it? How many resources should we apply, over what time period, and what changes do we need to make in the way that health care is provided?

There are logical links between these questions. Moreover, each article may address between zero and three of them. Where an article is relevant to more than one question, we have cited it the same number of times. If

an article did not provide particular additional insight into any of the questions, it is listed in Appendix A but not cited in the text.

In this section, frequent mention will be made of a report by the US Institute of Medicine. In 1998, the Institute of Medicine established a Committee on Quality of Health Care in America, and asked it to develop a strategy "… that will result in a threshold improvement in quality over the next ten years." The Committee decided it was necessary to take early action to draw the attention of governments, clinicians, insurers, and the community at large to one aspect of quality of care that it believed was a critical matter: patient safety.

This led the Institute of Medicine to publish a report in 2000 titled 'To err is human: building a safer health system' (Institute of Medicine, 2000). The report, which we will abbreviate to the 'IOM study' here, has perhaps been the most frequently cited document worldwide in the last four years. It therefore merits being the first-referenced text.

In response to the IOM report, the Clinton administration instructed government agencies that conduct or oversee health-care programs to implement proven techniques for reducing medical errors, and created a task force to find new strategies for reducing errors. Congress held hearings on patient safety, and in December 2000 it appropriated $50 million to the Agency for Healthcare Research and Quality to support a variety of efforts targeted at reducing medical errors. The IOM went on to develop a second, companion report titled 'Crossing the quality chasm: a new health system for the 21st century' (Institute of Medicine, 2001) which called for fundamental changes to improve the quality of health care.

3.1 The magnitude of the problem

The purpose of this section is to review the literature that gives an indication of the order of magnitude of the problem of patient safety, and the way that it is distributed across the health care systems in Australia and similar countries. As will be evident from the literature cited below, the overwhelming view is that the problem is large, is greater than many people have previously assumed, and does not seem to be responding rapidly to increased interest and effort. There are, however, important minority views – including an argument that the number of avoidable errors has been over-estimated and that there are dangers in over-emphasising patient safety (and thereby diverting attention from other causes of loss of health).

3.1.1 Number of incidents that indicate poor safety

The IOM study (Institute of Medicine, 2000) involved taking data from two analyses of adverse events and extrapolating them to estimate US national rates. The first was the Harvard Medical Practice Study (Brennan, Leape, Laird, Hebert, Localio, Lawthers et al., 1991; Leape, Brennan, Laird, Lawthers, Localio, Barnes et al., 1991) that found a rate of adverse events of 3.7% in hospitals in New York of which 13.6% resulted in death. The second was conducted in hospitals in Colorado and Utah, which found that adverse events occurred in 2.9% of hospitalisations of which 6.6% led to death (Thomas, Studdert, Burstin, Orav, Zeena, Williams et al., 2000). In both studies, over half of the adverse events resulted from medical errors that could have been prevented.

The IOM study extrapolated these results to the 33.6 million hospital admissions in the USA in 1997, and concluded that the Colorado and Utah studies gave an estimate of 44,000 deaths per year (Thomas, Studdert, Newhouse, Zbar, Howard, Williams et al., 1999) whereas the New York data gave an estimate of 98,000 deaths per year (American Hospital Association, 1999). The IOM study compared these rates with other causes of death and noted that adverse events were more significant by far than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS

(16,516). It was estimated that medication errors alone, occurring either in or out of the hospital, resulted in at least 7,000 deaths per year (Occupational Safety and Health Administration, 1998).

We note in passing that the results of the New York study had been known for many years. It is a point to which we will return when presenting our conclusions. The IOM study argued it was necessary "… to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort."

It was also noted that the findings of the New York study have been corroborated by other studies, and yet "… few tangible actions to improve patient safety can be found. Must we wait another decade to be safe in our health system?" The absence of progress has been noted by Forster et al (2004). They found that, in a sample of Canadian hospitals, 25% of discharges had experienced an adverse event, of which half were judged to be preventable.

The IOM study notes that most of the work to date has concerned hospital inpatient care, but increasingly complex care is being provided in ambulatory settings, in nursing homes, and in private homes. It may be that some types of errors (such as those relating to drugs) are at least as significant outside hospitals.

Figure 1: common types of errors reported by the Harvard Medical Practice Study

Diagnostic	**Treatment**
Error or delay in diagnosis	Error in the performance of an operation, procedure, or test
Failure to employ indicated tests	Error in administering the treatment
Use of outmoded tests or therapy	Error in the dose or method of using a drug
Failure to act on results of monitoring or testing	Avoidable delay in treatment or in responding to an abnormal test
	Inappropriate (not indicated) care
Preventive	**Other**
Failure to provide prophylactic treatment	Failure of communication
Inadequate monitoring or follow-up of treatment	Equipment failure
	Other system failure

SOURCE: Leape, Lawthers, Brennan et al (1993).

In total, the IOM study admitted that much remains to be noted and understood. However, enough was known already "… to recognize that a serious concern exists for patients. Whether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself. This report is a call to action to make health care safer for patients." The authors believed that health care was ‘a decade or more’ behind other high-risk industries including aviation in ensuring there was adequate safety for its customers. "Although health care may never achieve aviation’s impressive record, there is clearly room for improvement."

In passing, we would argue that the comparison is not particularly useful in view of the significant differences between the health care and airline industries in terms of culture, context, and production methods. However, there is good reason to believe actual performance of the health care sector is far behind what most people believe is feasible with the available resources.

Runciman and Moller examined the available information about patient safety in Australia. They concluded that iatrogenic injury occurs in at least 10% of admissions to acute-care hospitals in Australia, which are associated with a potentially preventable adverse event. They argue that there are ethical, humanitarian and financial imperatives to find out what is going wrong, collate and analyse the information and devise and implement strategies to better detect, manage and prevent these problems. It may be estimated that as much as half of this burden to society may be removed within 5-10 years if the necessary investments are made in a systematic approach to this problem. Failure to do this will result in escalating costs, as the factors contributing to iatrogenic injury will become more prevalent, not less, in the coming years.

Kizer (2001) reports the views of the National Quality Forum in response to work it has been asked to undertake by the US Federal government. Membership of the NQF includes a wide array of public and private health agencies, healthcare provider organizations, consumer groups, healthcare purchasers, and research and quality improvement organizations. The NQF reviewed the literature and held discussions with organizations known to be knowledgeable on the topic, including the Harvard University Executive Session on Medical Error, the VA National Patient Safety Centre, the Joint Commission on Accreditation of Healthcare Organizations, the National Patient Safety Foundation, and the IOM. The NQF concluded that "… there is an urgent need to reduce healthcare errors". However, it relied almost entirely on the IOM study as the basis for estimation of the magnitude of the problem.

Bender (2000) quotes the main results of the Harvard study, but argues that "… many errors in health care are unknown and the total number may be unknowable." He quotes Leape et al (1991) and claims that this and other studies show that, in 95% of the cases, errors are not the result of carelessness or lack of concern. The worst errors are sometimes made by the best doctors and nurses. He says that, even though error is not a popular problem in health care, if not critically tackled, it will get worse in the future.

Berman (2000) reports discussions during the first national conference to respond to the IOM study. There was a wide acceptance of the seriousness of the problem, but several speakers believed that more research was needed in order to assess its magnitude.

Some authors have doubts about the accuracy of the available statistics. One cause of confusion is the changes in methods of reporting, including an apparent trend towards increased reporting (Habal, 2000).

Runciman, Webb, Helps et al (2000) attempted to understand why the rates of adverse events (AEs) were higher in the Quality in Australia Health Care Study (QAHCS) (Wilson, Runciman, Gibberd, Harrison, Newby, & Hamilton, 1995) than in the Utah-Colorado Study (UTCOS) after methodological differences had been accounted for.

The adverse events were assigned to 98 exclusive descriptive categories and the relative rates compared between studies, and rated with respect to severity and death. They found that, for 38 categories accounting for 67% of UTCOS and 28% of QAHCS AEs, there were no statistically significant differences. For 33 categories, representing 31% and 69% respectively, there were seven times more AEs in QAHCS than in UTCOS. Rates for major disability and death were very similar (1.7% and 0.3% of admissions for both studies) but the minor disability rate was six times

greater in QAHCS (8.4% versus 1.3%). The authors concluded that a similar 2% core of serious AEs was found in both studies, but for the remaining categories six to seven times more AEs were reported in QAHCS than in UTCOS. They hypothesized that this disparity was due to different thresholds for admission and discharge and to a greater degree of under-reporting of certain types of problems as AEs by UTCOS than QAHCS reviewers. The biases identified were consistent with, and appropriate for, the quite different aims of each study. No definitive difference in quality of care was identified by these analyses or a literature review.

Classen and Kilbridge (2002) say that "… controversy about the exact size of the medical error problem continues, but there is little debate about the enormous opportunity for improvement in the safety and reliability of health care." This is witnessed in part by the steady stream of high-visibility medical accidents that keeps patient safety on the front page of health care. They note that significant progress has been made in some areas, including the large reductions in maternal mortality. They argue that "… this level of reliability is on par with the best safety records in other industries and far below those in the rest of health care. Achieving such a level of safety across health care will require considerable effort on the part of health care delivery systems and integration of physicians into such efforts."

Classen and Kilbridge (2002) pointed out the significant improvements that have occurred in some parts of obstetrics, and suggested safety performance there is equal to the best "… in other industries and far below those in the rest of health care." This suggests improvements in all fields of health care are possible if the right approach is taken.

Petty (2002) compared the results of one Australian and two US studies of adverse events in anaesthesia. They argue that methodological problems mean that "… the true frequency of anaesthetic mortality is unknown." However, the three studies suggested that respiratory events were the most common form of injury and that substandard care frequently was involved. One of the American studies found that death or brain damage occurred in 85% of respiratory cases, 72% of which were deemed preventable.

Runciman (2002) examined the available data on adverse events in Australian hospitals with the aid of a new classification model termed ‘principal natural categories’ (PNCs). An index of expected resultant cost was developed that was largely based on extended length of stay. A measure of clinical severity was also applied.

The subsequent analysis showed that most resource use (60%) was by AEs which led to minor disabilities, some (36%) was by those which led to major disabilities, and a smaller level (4%) by those associated with death. Most of the events with serious clinical outcomes fell into fewer than 50 PNCs; only seven of these PNCs had more than six cases resulting in serious outcomes. They concluded that, if interventions for AEs were triggered only by serious outcomes, most problems would not be addressed. In particular, the large number of mundane problems that consume the majority of resources might be overlooked. Both serious and mundane problems should be addressed.

The experiences of paediatric cardiac surgery at the Bristol Royal Infirmary in the UK have been widely reported. The anaesthetist who tried to encourage corrective actions, Stephen Bolsin (1998), reported that problems of poor care were known for many years. For example, he presented statistics that showed children undergoing cardiac surgery were three times more likely to die than the national average, and one surgeon had 20 times higher mortality rates for some procedures. An enquiry resulted after eight years’ delay, when there was no alternative in view of publicity in the mass media. The General Medical Council found three paediatric cardiac surgeons guilty of serious professional misconduct.

Douglas, Robinson and Fahy (2001) presented a review of the problems at the King Edward Memorial Hospital in Perth Australia arising from their conduct of a formal inquiry into alleged poor care. They noted that, although the hospital was a tertiary referral hospital specialising in high-risk obstetric and gynaecological cases, the level of errors was extremely high. Junior doctors often gave complex care to high-risk patients without supervision. Post-operative shock and haemorrhage, as well as fluid and electrolyte balance were poorly managed. Case reviews revealed inadequate management of antepartum haemorrhage, ruptured uterus in labour, major post-partum haemorrhage, hypertensive crisis and newborn resuscitation. Similar problems existed in nursing: non-specialist nurses were often left to deal with highly complex, sometimes life-threatening situations.

Clinical errors were very common, the most frequent being “failure to recognise a serious and unstable condition” and “inappropriate omissions”. One or more clinical errors occurred in 47% of a sample of high risk cases. In 24% of the cases, the errors were very serious. Junior medical staff made errors in 76% of the cases, mid-level doctors 65%, midwives 60%, and senior doctors made mistakes in 30% of the cases. Compared with national averages, the hospital had higher rates for stillbirths and obstetric interventions, hysterectomies following post-partum haemorrhage, maternal deaths and deaths following gynaecological procedures, and transfers to the special care unit following laparoscopic procedures and hysterectomy.

Finally, most authors argue that the magnitude of the problem is much the same in countries with similar health systems. For example, Smallwood (2002) quotes the few reasonably comparable multi-national studies and concludes there are probably few differences between the USA, Australia and England. Nicklin and McVeety (2002) described the results of conducting focus groups comprising Canadian nurses with regard to patient safety in hospitals. Nurses overwhelmingly responded that the health care environment in which they provide care presents escalating risk to their patients.

3.1.2 Estimates of costs

There is frequent mention of the high cost of avoidable harm, in terms of loss of wellbeing for the patients and their families, and in other ways. However, there is seldom any precise measurement of those costs, presumably because it is assumed they are high and that almost any intervention is likely to represent a justifiable investment (Alhand, 2001; Arceci, 2003).

An exception is the IOM study, which made reasonable estimates of the costs of poor patient safety. The estimated total costs were between US$17 billion and US$29 billion per year. Health care costs accounted for about half of the total, and other costs related to lost income of patients, lost household production, and disability (Johnson, Brennan, Newhouse, Leape, Lawthers, Hiatt et al., 1992; Thomas, Studdert, Newhouse et al., 1999).

Other costs were noted but not estimated. They included cost penalties as a result of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals, increased physical and psychological discomfort for patients who experience a longer hospital stay or disability as a result of errors, and loss of morale and frustration at not being able to provide the best care possible among health care professionals. Employers and society in general pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

Runciman and Moller (2001) estimated that iatrogenic injury in Australia results in direct medical costs of over $2 billion per year and that the total lifetime cost of such preventable injury may be twice that amount. They also note that there is a heavy toll in human costs on both those who

are harmed and those who care for them. Furthermore, medical misadventure consumes over half the amount spent on compensation and insurance by State Treasury Departments.

Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly. Bates and colleagues (Bates, Spell, Cullen, Burdick, Laird, Petersen et al., 1997) studied experiences at two prestigious teaching hospitals, and found that 2% of admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital. The IOM generalised these results to the US health system and concluded that the increased hospital costs alone of preventable adverse drug events affecting inpatients are about $2 billion per year.

3.1.3 Local studies of particular types of care

Many papers report the levels of potential and actual harm in small studies, but there is often an inadequate basis for comparison. Astion et al (2003) described a study of problems in a pathology laboratory in the USA. They established an incident report classification system, and applied it retrospectively to 129 incident reports occurring during a 16-month period. Incidents were classified by type of adverse event (actual or potential), specific and potential patient impact, nature of laboratory involvement, testing phase, and preventability.

They found that 95% of the incidents were potential adverse events, and 73% were preventable. The most common specific impact was delay in receiving test results (85%). “The laboratory alone was responsible for 60% of the incidents; 21% were due solely to problems outside the laboratory’s authority. The laboratory function most frequently implicated in incidents was specimen processing (31%). The pre-analytic testing phase was involved in 71% of incidents, the analytic in 18%, and the post-analytic in 11%. The most common pre-analytic problem was specimen transportation (16%)”, where the majority of the problems were judged to be easily preventable. In sum they found that “of the 94 preventable incidents, 30% involved cognitive errors, defined as incorrect choices caused by insufficient knowledge, and 73% involved non-cognitive errors, defined as inadvertent or unconscious lapses in expected automatic behaviour.”

Miller, Elixhauser & Zhan (2003) analysed paediatric hospitalisations to assess the magnitude and nature of problems of patient safety. They used patient safety indicators (PSIs) as the basis for counting and classification. PSIs are algorithms developed by the Agency for Healthcare Research and Quality to identify potential inpatient safety problems using administrative data. They found a high rate of patient safety events, of which the most significant was birth trauma at 1.5 cases per every 100 births. The majority of these events for birth trauma consisted of long bone and skull fractures, excluding the clavicle. Compared with records without PSI events, discharges with PSI events had 2 to 6 times longer lengths of stay, 2 to 18 times higher rates of in-hospital mortality, and 2 to 20 times higher total charges. The authors concluded that the prevalence of birth trauma and other potential patient safety events for hospitalised children is high and comparable to hospitalised adults.

Tsilimingras et al (2003) discuss patient safety in geriatrics. They argue that the work done thus far (including that which led to and followed from the IOM report in the USA) did not specifically address the implications of safety for elderly patients. They argue that elderly patients might be particularly susceptible to errors. They recommend several actions including the detection and reporting of geriatric syndromes, identifying system failures when geriatric syndromes occur, establishing dedicated geriatric units, improving the continuity of care, reducing adverse drug events, and improving geriatric training programs.

Schenkel (2000) reports national studies including that by the IOM and argues that about 3% are associated with care in emergency departments. In emergency medicine (EM), error detection has focused on subjects of high liability: missed myocardial infarctions, missed appendicitis, and misreading of radiographs. Some system-level efforts in error prevention have focused on teamwork, on strengthening communication between pharmacists and emergency physicians, on automating drug dosing and distribution, and on rationalizing shifts.

Gournay (2000) reviewed 31 cases of suicide and self-harm in inpatient psychiatric units. They found that, of the 12 deaths, there were "… environmental factors that, arguably, could be simply addressed. There was a considerable variation in the content and quality of observation policy and practice. The results … provide evidence requiring urgent action by the Department of Health regarding the setting of national standards."

There may be particularly high risks of harm for elderly patients or those in palliative care. Myers and Lynn (2001) and Myers and Lynn (2002) argue that the overwhelming majority of palliative care specialists believe error rates are high but largely unreported in patients nearing the end of life with serious illness. They are particularly vulnerable to medical errors and other lapses in patient safety for three reasons: (1) substantially increased exposure to the possibility of medical errors; (2) more serious effects from errors because they cannot protect themselves from risks and have less reserve with which to overcome the effects; and (3) pervasive patterns of care that run counter to well substantiated evidence-based practices. A national research agenda on preventing medical errors and increasing patient safety must include a focus on how to improve shortcomings affecting these vulnerable patients.

Finally, Cook, Woods and Miller (1998) presented several individual examples of errors that made the mass media simply because they were newsworthy as horror stories. They included the case of a distinguished health journalist who died from an overdose during chemotherapy, and an 8-year-old boy who died during minor surgery due to medication error.

3.1.4 The rate of progress

Many authors believe that progress has been highly unsatisfactory (Dickey & Ley, 2000). Jacott (2003) accepts that patient safety has been given increased attention, but questions whether there is any system-wide evidence of progress. Manasse (2003) believes that small victories are being achieved, but the current phase is that of learning there are no simple answers. Vincent and Knox (1997) claim that the methods of addressing the problem are misguided, and have had little impact on iatrogenic injury.

Millenson (2002) notes that "… the problem of patient safety has been repeatedly identified in the medical literature since the mid 1950s, but regular revelations about patient deaths and injuries resulting from treatment have had almost no effect on the actual practice of medicine. Only very recently has the medical profession made a systematic effort to reduce or eliminate the many preventable deaths and injuries that occur in hospitals each year."

There are fewer authors who recognise the severity of the problem but are satisfied with the rate of improvement. This is often deduced from evidence that care providers are setting up reporting systems, conducting education programs, and so on rather than from measurement of the levels of avoidable harm (Hagland, 2003).

The Commonwealth Fund (2000) reported a survey of the views of 400 generalist physicians and 100 specialists in each of Australia, Canada, New Zealand, the United Kingdom, and the United States. In the UK, 45% of GPs and 49% of specialists believed the quality of care had declined in the previous five years, and there were similar negative views from other countries.

Few doctors believed the situation would improve in the foreseeable future. There were general concerns for patient safety.

3.1.5 Overstatement of the problems

Some authors argue that the problems have been overstated. For example, Dunn (2000) compares the results of the 1999 Institute of Medicine study (IOM) with those from patient safety research in Texas by the Texas Medical Foundation (TMF). He concludes that the Texas work, which is based on routine peer review audits as part of care provider payment claims processing, shows a much more positive picture "… that has been ignored too often in the current debate". The Texas studies show "… low rates of significant injury and death caused by any medical care or hospital care safety or negligence problems."

Morello, Colon, Fredricks, Iverson and Singer (1997) studied the level of patient safety in ambulatory surgery facilities. They distributed an anonymous questionnaire to 418 facilities and obtained a response rate of 58%. They found that significant complications (hematoma, hypertensive episode, wound infection, sepsis, hypotension) were infrequent, occurring in less than 0.5% of 213 cases. Return to the operating room within 24 hours and preventive hospitalisation were less frequent. The death rate was 0.0017%. The authors concluded that the overall risks were much the same in all types of ambulatory surgery facilities (whether an accredited office, free-standing or hospital ambulatory surgical facility). The main weakness of this study is, of course, that it largely involved the subjective assessments of people, some of whom may have an interest in under-reporting the problems.

3.1.6 Overemphasising patient safety

Woolf (2004) expresses the view that patient safety is important, but there are other causes of loss of health that are more important. An excessive concern for patient safety may mean that other problems may be neglected even though they pose a greater threat to health.

He refers to studies that have shown that hundreds of thousands of Americans die because of inadequate treatment of cardiovascular disease, cancer, and other conditions. He notes that the failure to address extant risks (such as the use of beta-blockers after acute myocardial infarction) results in 4300 to 17,000 lives each year. Many more deaths (potentially more than 700,000 per year) result from gaps in screening, immunizations, and reducing risk factors (for example, obesity and unhealthy diet) in the population (Woolf, 1999). Tobacco use alone accounts for more than 400,000 deaths per year.

This matters because getting the balance wrong can cost lives. For example, poor control of blood pressure or serum lipid levels accounts for more deaths than do illegible drug prescriptions (Chyka, 2000; LaRosa, He, & Vupputuri, 1999). Therefore a quality improvement program that is preoccupied with computerized prescription entry but ignores the large proportion of patients with uncontrolled hypertension or hyperlipidemia costs more lives than a program with reverse priorities.

Patient safety experts who redesign systems to reduce drug errors, catheter sepsis, or anaesthesia mishaps do good work. However, by not addressing larger deficiencies in quality, they may fix problems in the branches and twigs while preserving proximal disease in the trunks. They may reduce accidents but leave deeper defects in place, making health care safer (less likely to add new risks) but still ineffective in caring for extant risks.

The greatest good for the health of the population comes from a global perspective that views the system as a whole, judges its performance by its effect on population health rather than on

parochial domains, and prioritises interventions in a rational scheme to optimise outcomes. Such an approach, albeit rational, faces potent challenges. Individual diseases, not global health outcomes, are what motivate policy and medical leaders. The dramatic changes that a global approach demands would be resisted by power centres that face financial, political, and administrative consequences.

Methodological tools for such an approach are also limited. A global approach for prioritising interventions requires a common metric for contrasting the relative effect of interventions on health. Quality-adjusted or disability-adjusted life-years can serve this purpose, and policymakers have used these tools to prioritise the relative importance of preventive and other services. However, the methods and data sources for applying this metric across diverse health care interventions are not straightforward. Nonetheless, the path toward overcoming these challenges begins with the proper vision.

Thus patient safety can be seen as a subcategory of medical errors, which also include mistakes in health promotion and chronic disease management that cost lives but do not affect "safety." These errors are in turn a subset of lapses in quality, which result not only from errors but also from systemic problems, such as lack of access, inequity, and flawed system designs. Finally, lapses in quality are a subset of deficient caring, which encompasses gaps in therapeutics, respect, and compassion that are undetected by normative quality indicators.

Ensuring such rational prioritisation requires policy and medical leaders to eschew parochialism and take a global perspective in gauging health problems. The public's well-being requires policymakers to view the system as a whole and consider the potential effect on overall population health when prioritising care improvements and system redesigns.

Over-investment in patient safety might divert resources from other potentially more useful changes. Simple arguments are made by several authors including Zorab (2002) who says that "… patient safety is more important than efficiency." This argument is fundamentally flawed, because efficiency and health outcomes are inseparably associated with each other. If excessive resources are used to maximise patient safety for one group of patients, they will be diverted from other areas of endeavour (such as health promotion) where they would have done more good.

3.2 The causes of poor patient safety

There are two main views on this subject – although they overlap to a considerable extent and both may be applied in the same article. The first is that individual care providers make mistakes as a consequence of such factors as fatigue, lack of knowledge, or carelessness. The second is that the large majority of errors have little to do with the behaviour of individuals, but are largely the inevitable consequence of underlying factors that present barriers to effective teamwork.

It is difficult to classify the causes because many are closely related or subsets of each other. We have decided to use the IOM study's main categories for convenience. In some cases, particular articles mention two or more causes, in which case we mention the articles more than once.

3.2.1 Fragmentation of the health care system

The IOM study criticises the high degree of fragmentation that results in poor communication, competition rather than collaboration, opportunities to transfer responsibilities elsewhere, absence of clear lines of accountability, and so on. Technical problems include difficulties in ensuring care providers have access to complete information for reasons of insularity of many

clinicians (and a consequent lack of commitment to sharing information). The problems are exacerbated by incompatible technologies (such as data definitions and software) that are mostly incapable of providing timely access to complete patient information.

There are many important discontinuities, such as those between GPs and hospitals, and between the formal and informal health care systems. Errors are more likely to occur in patients who need care across multiple settings over prolonged periods of time.

Bender (2000) notes the problems of errors between care settings, and argues that a major factor is the inherently greater complexity of health care compared with other industries. Poor communications between and among health care providers and patients are one of the consequences of complexity that lead to errors.

Gui, Cheruvu, Subak-Sharpe, Shiew, Bidlake and Fiennes (1999) discuss weaknesses in the communication between hospital and general practitioners after day case surgery, and point out that they often lead to patient safety problems. Cook, Render and Woods (2000) argue that fragmentation leads to poor continuity of care and this is a major cause of problems of patient safety. Gunn (2000) suggests that the main causes of errors are systems problems rather than the mistakes of individuals.

3.2.2 Fragmentation of care teams within a single care setting

The IOM study noted that there are problems even within hospitals, because there are "… rigidly-defined areas of specialization and influence." This may lead to problems such as an unwillingness for one doctor to question the practices of another, the shifting of responsibilities for diagnostic testing from the emergency department to the ward for the sake of shifting of the costs, and differences of understanding regarding accountability for functions like discharge planning.

Shapiro, Croskerry and Fisher (2002) give an example of a patient with significant respiratory distress secondary to a left-sided pleural effusion that mandated an urgent thoracentesis. An adverse event occurred when the physician performed the procedure on the incorrect side of the patient. There were simple solutions to this kind of problem, but their implementation was constrained by poor communications and confusion about responsibilities.

Beach, Croskerry and Shapiro (2003) describe the case of a patient presenting at the emergency department (ED) with the chief complaint of "panic attacks." In total, he was evaluated by 14 faculty physicians, 2 fellows, and 16 residents from emergency medicine, cardiology, neurology, psychiatry, and internal medicine. These multiple transitions were responsible, in part, for the perpetuation of a failure to accurately diagnose the patient’s underlying medical illness. The case illustrates the discontinuity of care that occurs at transitions, which may threaten the safety and quality of patient care.

Reeder (2001) reviewed safety in perioperative nursing and argued that the main causes of nursing error are inadequate training and poor multidisciplinary teamwork. Nursing tended to function in isolation from medicine, excepting that junior doctors and senior nurses worked together well at an informal level.

Cassirer, Anderson, Hanson and Fraser (2000) argue that there can be high levels of abusive behaviour between clinicians. This weakens the willingness and ability to work together effectively, and this in turn is a cause of errors that prejudice patient safety. The most common abusers are administrators and doctors, and the most common victims are female nurses and allied health professionals.

3.2.3 Poor written and oral communications

Many authors have argued that the importance of communication between clinicians has been under-rated, as have the consequential problems of patient safety. Benjamin argues that most medication errors are a consequence of poor methods of sharing of information. In some cases, the cause is a complicated and poorly understood chain of communication. In other cases, errors occur as a result of elementary weaknesses such as failure to involve the patient as a quality control check, poor handwriting on prescriptions, and the use of the elitists' arcane Latin words and shorthand abbreviations that are subject to misinterpretation.

Beyea (2002) argues that many errors are made in the tracking of medical devices as a consequence of poor rules regarding records. These may be inadequate in terms of indicating responsibilities, poor form design, and failure to monitor compliance.

Heard, Roberts, Furrows, Kelsey, Southgate et al (2003) discussed problems in establishing standards for microbiological record keeping. In a survey in the UK, it was found that at various times 65% of respondents used a daybook, 62% used the back of the clinical request card, 57% used a computer record, and 22% used an index card.

Parisi (2003) emphasised the importance of correct communication of patient identifiers. She noted that many health care facilities have had difficulties in developing standard methods of identification for various reasons, including an underestimation of the risks.

3.2.4 Few financial incentives to manage safety

The IOM study argues that purchasers of health care typically make few demands for improvements in safety. Most purchasers "… provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality."

Morath (2003) noted that purchasing behaviour in the USA has typically been ineffective in some respects. Problems have included a lack of consistency of approaches across the various purchasing agencies, and a focus on short-term efficiency gains.

Blewett, Parente, Peterson and Finch (2003) also analysed purchaser behaviour in the USA. They concluded that a major problem was the absence of standard methods of measuring and monitoring health care quality and safety across public and private payers. Constraints to the establishment of standard methods included difficulties in reaching agreement on sharing of the costs of data collection, the diversity of the units of data collection, data privacy, and limitations of administrative data elements.

Classen and Kilbridge (2002) noted that most of the incentives provided to doctors concern productivity and financial performance in general, rather than quality of care. Cost savings that might be generated by reduced complications or avoidance of waste are more likely to go to the hospital or the insurer than to the doctors.

3.2.5 Ineffective educational interventions

Ferlie and Shortell argued that efforts to improve patient safety through the education of individuals alone have succeeded in only marginal ways in a few contexts. This may be because patient safety depends to a significant extent on interactions (patient care usually requires a team approach). Moreover, there has to be strong motivation for wanting to learn and subsequently to change one's own practices, and this might not be present if (as is largely the case in medicine) the basis for evaluation of performance is largely in terms of individual performance rather than patient outcomes.

Davis, Thompson, Oxman et al (1995) demonstrated that little had been gained from traditional continuing medical education, or from the more up-to-date approach of dissemination of clinical practice guidelines. Similar views were expressed by Greco and Eisenberg (1993) and Griffiths and Feder (1999). Individual learning seems to be an essential component of improved patient safety, but is not by itself a significant stimulus to change. It may facilitate choice of a new approach but is unlikely to be the catalyst.

The reports of the enquiries regarding paediatric cardiac surgery at the Bristol Royal Infirmary in the UK (Bolsin, 1998) and the King Edward Memorial Hospital in Perth, Australia (Douglas, Robinson, & Fahy, 2001) both noted that the poor quality of care could not be directed at a lack of trained staff. Most of the changes that were needed were technically simple, and could be designed and then subjected to continual improvement by even the most inexperienced of clinical teams. The problem was that training did not adequately address knowledge and attitudes that might improve patient safety.

Petty, Kremer and Biddle (2002) compared the results of one Australian and two US studies of adverse events in anaesthesia. They found that respiratory events were the most common form of injury and that substandard care frequently was involved. In total, they argued that patient acuity and procedure complexity may be less significant contributory factors to anaesthesia risk than are provider vigilance and clinical decision making.

The IOM study pointed out that there were many obvious problems with simple solutions, and the reasons for failure to address them were systematic. For example, it argued that "… the majority of medical errors do not result from individual recklessness or the actions of a particular group – this is not a “bad apple” problem." More commonly, errors were caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. "For example, stocking patient-care units in hospitals with certain full-strength drugs, even though they are toxic unless diluted, has resulted in deadly mistakes."

3.2.6 Inadequate involvement of consumers

The IOM study argues that consumers are poorly informed about the risks and therefore they typically fail to recognise danger signals. For the most part, they believe they are protected, and media coverage seldom helps because it focuses on assigning blame – and promotion of the view that there are few inadequate care providers who are uncovered and removed in due course.

Schwartzberg (2002) studied health literacy among patients, and noted that patients with low literacy skills were twice as likely to be hospitalised and twice as likely to report poor health. She argues that low health literacy may cost $73 billion annually in excess hospitalisation days alone. Much depends on improving the ability of patients (with help from their families) to carry out complex health instructions on their own.

3.2.7 Cultural aspects: blame, concealing errors, and culture clashes

The IOM study claims there is a widespread culture of blame. The authors argue that "… building safety into processes of care is a more effective way to reduce errors than blaming individuals." The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error (Deming, 1993).

Kizer (2001) reports the views of the National Quality Forum in response to work it has been asked to undertake by the US Federal government. The NQF noted that there were many barriers to progress including widespread misunderstanding about why healthcare errors occur, the prevailing culture of "name and blame" surrounding these events, lack of user-friendly error-reporting mechanisms, and fear of litigation if errors are acknowledged and reported.

Etchells and Bernstein (2001) argue that there is a "… dark culture of blame" that discourages clinicians from admitting errors. This culture is promoted in medical school and continued in the teaching hospital.

Goode, Clancy, Kimball, Meyer and Eisenberg (2002) note that many efforts to improve quality involve a systems-level approach, and physicians are often viewed as obstacles to improvement programs. By contrast, physicians may view population- or systems-based approaches to health care as interfering with the delivery of care to specific patients. There are ineffective processes for developing a common understanding.

Reeder (2001) noted the common view that healthcare organizations need to promote a patient safety culture, and to banish the blame and shame culture and "conspiracy of silence" – which are the traditional approaches within organizations when reacting to errors. Culture change arises when physicians, pharmacists, nurses and other self-regulated professionals are encouraged and expected to report errors without fear of retribution. A culture of patient safety will evolve in healthcare organizations and regulatory agencies only if leaders demonstrate their commitment to change by making it a personal priority to assimilate new knowledge about medical errors and human behaviour. Leaders must also promote strategies to integrate patient safety into every process that supports the system of patient-care delivery. Similar views are expressed by Perry (2002).

The Institute for Safe Medication Practices lists several causes of medication errors. It gives particular emphasis to the culture of blame, and the related problem of lack of leadership. It noted that there was a need to establish a voluntary reporting system whereby practitioners could share information on errors – and therefore gain more knowledge of the causal factors underlying medication errors. However "… there is enough knowledge and information about medication errors to permit our putting prevention strategies into practice without delay."

The reports of the enquiries regarding paediatric cardiac surgery at the Bristol Royal Infirmary (Bolsin, 1998) and the King Edward Memorial Hospital (Douglas, Robinson, & Fahy, 2001) both noted there was a corporate culture that promoted a view of excellence, discouraged admission of errors, allocated blame, and failed to encourage and reward effective teamwork. It also promoted (or at least accepted) the view that patients were a nuisance. They were often told only what the clinicians wanted them to know, and were expected to feel grateful and humble at being given the best possible care by the best hospital around.

One negative effect in both hospitals was an inability to communicate effectively and work as a team. The different clinical professions (and especially medicine and nursing) did not know how to work together – as witnessed by the absence of shared documentation. Junior doctors could not communicate with senior doctors, partly because of the culture of paternalism within the medical profession.

Most clinicians were reluctant to report errors, and they did not see errors as opportunities to improve. Admitting mistakes or admitting a lack of knowledge were viewed as signs of weakness rather than strength. People who raised problems or who criticized the quality of work were traitors, troublemakers, and not welcome.

3.2.8 External auditing

The IOM study is critical of licensing and accreditation processes because they have failed to pay sufficient attention to patient safety. Moreover, the responsible bodies have often been weak in the face of unreasonable opposition from care providers.

The limitations of current methods have been illustrated by several of the recent reviews of poor quality of care such as the Bristol Royal Infirmary in Britain (Bolsin, 1998) and the King Edward Memorial Hospital in Australia (Douglas, Robinson, & Fahy, 2001). The care providers found to be responsible for harmful clinical practices had all been licensed or accredited in various ways.

3.2.9 Medical liability and incentives to conceal errors

The IOM study notes that many care providers perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors (Leape, Brennan, Laird et al., 1991). Admission of errors may lead to legal proceedings that can destroy the care provider.

Noble and Brennan (2001) considered the impact of patient safety activities on the operation of managed care in the USA. They argue that the most disappointing aspect of the IOM study is that it "… did not endorse change in malpractice liability, which consistently puts the impetus for reducing medical error on the individual provider rather than the system as a whole."

The authors noted that the intersection of managed care, litigation, and patient safety has been largely overlooked. Managed care incentives are part of the system of health care, they are intended to affect physicians' behaviour in favour of more cost-effective approaches to care, and they could presumably increase the occurrence of errors. Financial incentives to limit care may also create a situation of greater vulnerability for patients. Consequently, the focus in managed care litigation has increasingly been on the system of financial incentives. Suits against managed care organizations should lead to changes in this system of incentives, and hence be one place where error reduction and litigation can act in concert.

On the other hand, litigation against MCOs could also lead to eliminating methods and procedures that systematically reduce cost. Here, the trade-off between cost and quality becomes relevant, and courts are a poor forum for making delicate compromises between cost and quality. Litigation against managed care organizations may inadvertently discourage quality-enhancing behaviour by them and discourage innovation in the field. Litigation that brings about system changes in the area of managed care could frustrate similar changes in the traditional care of patients by leaking new theories of malpractice into health care, thereby increasing the intensity of malpractice litigation and potentially driving physicians away from quality improvement.

Liang and Cullen (1999) note that there is an inevitable tension between the legal system and patient safety. The legal system is designed to assign blame whereas continuous quality improvement is most effective when care providers are ready to identify errors. Lang (2001) and Liang and Coulson (2002) make similar points.

Liang (2003) studied differences in the perceptions of laypersons and doctors about the appropriateness of jury verdicts in malpractice litigation. He found that laypersons showed significantly better agreement with actual jury verdicts on clinical assessment and success in jury verdict prediction than doctors. However, both doctors and laypersons perceived a similar bias towards plaintiffs. The author concluded that "… the malpractice system may be inducing behaviour that has a negative impact on patient safety."

Sage (2002) stated that political debate over medical malpractice reform seldom takes meaningful account of its policy context, including the emerging concern for patient safety. Stakeholders on both sides use the rhetoric of patient safety to support entrenched positions on proposals such as capping damages and limiting access to information about errors.

In the survey of doctors by The Commonwealth Fund (2000), there was a general concern for patient safety. Most doctors believed their hospitals were doing little to identify and address potentially harmful errors. A third of specialists in the United States, and half of those in the other four countries, rated hospitals' medical error tracking or correction systems as only fair or poor. In fact, many doctors said they are not encouraged to report errors. In Canada, New Zealand, and the United States, 64%, 46%, and 44% of specialists said they were discouraged – or at least not encouraged – from reporting medical errors.

3.2.10 Resource shortfalls

The IOM study made little reference to resource shortfalls, on the grounds that the challenge is to make better use of the available resources no matter how limited. However, there are many papers that mention the adverse effect of resource shortfalls on patient safety.

Nicklin and McVeety (2002) conducted focus groups comprising Canadian nurses, and found they were overwhelmingly of the view that risks to patient safety were increasing. The main factors were increased workloads and nursing shortages, and communication problems between clinical professions and with patients.

Cavorous (2003) describes some of the evidence of increased risks to patient safety as a consequence of fatigue among clinicians. Gaba and Howard (2002) express similar views and propose early action.

Several authors refer to shortages of supplies and equipment including disposables. For example, Nye and Wilson (1998) reported some of the risks to patient safety associated with reusing medical devices labelled by the manufacturer for single-use only.

Hildebrandt, Westfall and Smith (2003) analysed the processes whereby after-hours access was provided in primary care. They found that most after-hours call systems in primary care offices impose barriers that may delay care. All clinical patient calls should be sent to appropriately trained medical personnel for triage decisions. All clinicians that use an answering service should re-examine their policies and procedures for possible sources of medical error. Hickner (2003) believes there has been a significant increase in risks to patients in recent years as a consequence of reduced willingness of family doctors to operate a 24-hour on-call service.

Knox, Kelley, Hodgson, Simpson, Carrier and Berry (1999) argue that inadequate resources may be applied to the management of changes in the health care agencies (and particularly changes that involve significant 'downsizing' or 're-engineering'). The changes are usually defined to meet only productivity goals, and patient safety is largely ignored.

Finally, the survey of doctors by The Commonwealth Fund (2000) reported a high degree of concern over the adequacy of hospital resources. Lack of nursing resources was the most common concern.

3.2.11 The special role of doctors

Classen and Kilbridge (2002) emphasised the role of doctors in patient safety, and explained why doctors are limited in their ability to take corrective actions. They noted that doctors develop their attitudes in medical school and "… it is hard to imagine how changing the education of

physicians with respect to patient safety would be successful without corresponding changes in the environment and culture of the health care delivery systems in which they train."

In fact, they train in an environment that focuses on error and mistakes. An example is the traditional morbidity and mortality conference, which is a commonly used teaching venue that has the main aim of pointing out individuals' mistakes and vilifying the responsible doctor in the presence of peers. This approach institutionalises the idea that mistakes are not tolerated and that mistakes are caused by individuals rather than systems. At a higher level, credentialing and peer review might also focus on assignment of blame and can be painful and intimidating processes.

Oversight at the local and national levels tends to be speciality-driven. This leads to great resistance on the part of doctors to accept and participate in team-based care, despite the evidence that team-based care can improve patient safety. In total, while the doctors' role is central to improving safety, they are presented with many pressures from the medical profession that deter them from doing so.

3.2.12 Innovation and change

Liang (2002) points out that patient safety has sometimes been prejudiced by changes in legislation regarding the confidentiality of patient information. He presents several case studies from the USA where legislation on confidentiality has caused difficulties for some care providers. Tang (2000) discussed the difficulties that have arisen in the USA as a consequence of incompatibilities between legislation on privacy and security of patient data and the need to provide better information to measure and manage patient safety.

Miller, Brayman and Abramowicz (1998) examined errors in the context of obstetric ultrasonography. They noted that the epidemiologic record of diagnostic ultrasound is exemplary in terms of foetal and maternal outcomes, but the available evaluation statistics were based on use of clinical devices whose outputs were relatively low compared with current practice. This creates additional opportunities for error, and changed legal requirements now place greater responsibility on the diagnostician.

Patterson, Cook and Render (2002) examined the potential for new risks to occur as a consequence of introducing bar coding in medication administration. They found five types of potentially dangerous side-effects: nurses confused by automated removal of medications by BCMA, degraded coordination between nurses and physicians, nurses dropping activities to reduce workload during busy periods, increased prioritisation of monitored activities during goal conflicts, and decreased ability to deviate from routine sequences.

Smith, Mort, Goodwin and Pope (2003) studied the use of electronic monitoring in the context of anaesthetic practice through workplace observation and interviews with anaesthetists and other anaesthetic staff in the UK. They found that, while anaesthetists are mostly well informed about theoretical principles and performance specifications of devices, they often 'disbelieve' monitoring information in practice. They call on and integrate other sources of knowledge about the patient, especially from their clinical assessment. The ability to distinguish 'normal' and 'abnormal findings is vital. Confidence in electronic information varies with experience, as does the degree to which electronic information may be considered 'redundant'. They concluded that electronic monitoring brings new dimensions of understanding but also the potential for new ways of misunderstanding. The tacit knowledge underlying the safe use of monitoring deserves greater acknowledgement in training and practice.

Finally, Coombes (2002) discusses the trends towards increased freedom for nurses to practise in other countries, especially in the European Union. She argues that this will create additional possibilities for poor patient safety.

3.3 Actions

As was the case for causes, there is no easy way to categorise remedial actions. Most papers present more than one category of solution, and most solutions address more than one kind of problem. We have presented 21 categories, but they could usefully be aggregated.

3.3.1 Systems, strategies, and mixed designs

Several articles in the literature emphasise the need to use many kinds of interventions simultaneously. This is supported by the IOM study: its authors argue that there are both internal and external factors that can encourage improvements in patient safety. External factors include generation and dissemination of knowledge and tools, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements. Internal factors (those within health care organizations) include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

None of these factors is sufficient by itself, and a comprehensive approach is needed. The IOM study said that "… there is no 'magic bullet' that will solve this problem (because) large and complex problems require thoughtful, multifaceted responses." There needs to be a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations. No single action represents a complete answer, nor can any single group or sector offer a complete fix to the problem.

However, the authors of the IOM study believed that changes in the external environment were the first priority: external agencies must "… create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety."

Small and Barach (2002) presented a historical review of patient safety in health policy. They argued that the main challenge has been to achieve a balance between learning and control in complex systems with technical, social, and organizational components. Efforts to improve learning are marked by better information flow, discovery, flexibility in thinking, embracing of failures as learning opportunities, and core incentives to promote voluntary participation of all stakeholders in the process. Efforts to improve accountability are traditionally marked by public disclosure, meeting of certain widely disseminated standards, availability of performance measures, exposure to legal liability, and compliance with mandated directives (statutes, regulations, accreditation requirements).

They observed that, in some sense, these directions are mutually exclusive. Although a more collaborative regulatory-improvement model would be helpful in creating an industry-wide safety culture, it is likely that learning and accountability functions will follow separate tracks. An exception would be policy that stimulates organizations to comply with regulation by showing how well and by what methods they are learning and how others can profit from these experiences. Any approach to improving patient safety should, at a minimum, include a non-punitive in-depth mechanism for reporting incidents, post-incident evaluations for identification of system changes to prevent subsequent occurrences, and state-guaranteed legislative protection from discovery for all aspects of information gathered to improve patient safety.

Affonso and Doran (2002) developed a framework for designing a patient safety program. The main actions are arranged under four headings: building technological tools to create safer ways for dealing with drugs and devices, applying human factors design to create safer work environments, reforming organizational culture (to create the conditions for critical thinking, ethical practice, and opportunities for learning), and delivering processes to optimise safe care. They proposed four evaluation criteria: quality care, optimal communications and working relationships, evidence-based practice to transform current clinical services, and establishment of learning environments for educating a new generation of health scientists and health providers accountable to patient safety.

Shojania, Wald and Gross (2002) presented a model of patient safety improvement that has two components. The first, termed qualitative, is inspired by research in cognitive psychology and the lessons of accident investigation in other industries. It involves the use of qualitative methods for anticipating errors, documenting critical incidents, and responding to them in a blame-free and structured manner. Using these methods, doctors can generate meaningful strategies for preventing similar occurrences in the future. In hospital care, the strategies might involve promoting a culture of safety by championing incident-reporting initiatives and participating in multidisciplinary teams that analyse adverse events and promote change.

The second, termed quantitative, involves applying the results of quantitative clinical research to reduce some of the common hazards of hospitalisation. Hospital-based doctors also have an important role to play in this arena because many of the safety targets and the associated clinical practices (such as early enteral nutritional support and fall prevention) are not often considered by hospital-based specialists. In both circumstances, doctor participation in collaboration with nurses, pharmacists, nutritionists, and other health care professionals could produce important improvements in patient care. Doctor involvement would also contribute visible leadership in promoting a culture of patient safety in hospitals and in health care.

3.3.2 Patient safety and related management models

Patient safety has become a major theme in health care research and operations, but it is obviously not a new issue. It has always been of concern to most health professionals, albeit with less interest and concern on the average than is presently the case. Many other research activities, programs, projects, and so on have addressed similar concerns.

Miller and Bovbjerg (2002) argued that safety is an aspect of quality (the same tools, decision making, interventions, and monitoring apply), and safety management benefits from prior efficiency management (similar skills and culture of innovation).

There are clear links between the methods proposed for the purpose of improving patient safety, and methodologies directed at other aspects of performance improvement. The links between evidence-based health care and patient safety are obvious, and there are increasing numbers of articles that make this point. Leape, Berwick and Bates presented an overview of the links. A similar review was conducted by Shojania, Duncan, McDonald and Wachter (2002).

Pakpahan, Balas and Boren (2002) reviewed the literature on child health care to identify the most significant risks and how they might be avoided. They conducted systematic searches of MEDLINE and the Cochrane Database of Systematic Reviews and found the knowledge to create 41 child health safety modules for medications and procedures.

The relationships between patient safety and risk management are also easily seen, and many papers that address risk management now also make reference to patient safety. In principle,

risk management is a process that covers more than patient safety. In practice, the core of both has been identical in most of the technical literature over the last two or three years.

For example, Youngberg (2001) described the application of risk management ideas to improvements in patient safety. McElhinney and Heffernan (2003) described experiences in clinical risk management at a hospital in Ireland with an emphasis on improving patient safety. The interventions were as described in many patient safety programs: making an explicit commitment to the principles of a learning organisation including: blame free risk reporting, providing education and awareness training to promote understanding of clinical risk management locally, and developing a clinical incident/near miss reporting system to address clinical risk in both a proactive and reactive way.

3.3.3 Dedicated agencies, bodies, and committees

The IOM study recommended there should be a single designated government agency devoted to improving and monitoring safety throughout the health care delivery system. Therefore, Congress should create a Centre for Patient Safety that would set national safety goals and track progress in meeting them, develop a research agenda, define prototype safety systems, disseminate and evaluate tools for identifying and analysing errors, develop methods for educating consumers about patient safety, and recommend additional improvements as needed.

The IOM study argued that funding should be at least $100 million per year, and this would represent a small investment "… relative to the consequences of errors and to the resources devoted to other public safety issues." In the event, funding was provided to the Agency for Healthcare Research and Quality shortly after the IOM study was published. The AHRQ has already has made progress in several areas including:

- developing and testing new technologies to reduce medical errors
- conducting large-scale demonstration projects to test safety interventions and error-reporting strategies
- supporting new and established multidisciplinary teams of researchers and health-care facilities and organizations, located in geographically diverse locations, that will further determine the causes of medical errors and develop new knowledge that will aid the work of the demonstration projects
- supporting projects aimed at achieving a better understanding of how the environment in which care is provided affects the ability of providers to improve safety
- funding researchers and organizations to develop, demonstrate, and evaluate new approaches to improving provider education in order to reduce errors
- advising consumers on actions they can take.

Kern (1998) described the National Patient Safety Foundation in the USA, and explained how it could be relevant to surgeons. The UK Department of health has established the National Patient Safety Agency. Its initial activities on the reporting of errors are described by Dimond (2002).

Feinstein, Grunden and Harrison (2002) have described a regional initiative to improve patient safety. It involves 35 hospitals, 4 major insurers, more than 30 major and small-business health care purchasers, dozens of corporate and civic leaders, and organized labour.

The Coalition identified patient safety (nosocomial infections and medication errors) and 5 clinical areas (obstetrics, orthopaedic surgery, cardiac surgery, depression, and diabetes) as

ideal starting points. In each area, multi-facility and multidisciplinary groups have defined perfection (the desired goal), established region-wide reporting systems, and designed and implemented improvement strategies. Many design and conceptual elements of the strategy were adapted from the Toyota Production System and its Pittsburgh derivative, the Alcoa Business System.

Piotrowski, Saint and Hinshaw (2002) described the establishment of a Safety Case Management Committee within a hospital group in the USA. The committee was expected to develop ideas for improving patient safety. Its members included senior and mid-level managers, but mainly comprised practising clinicians. It also included a consumer representative. Critical issues are addressed through rigorous case discussion, literature review, and expert consultation. In a 3-year period, it has made recommendations on topics such as reducing medication errors during emergency procedures, enhancing palliative care services, minimizing the risk of missed x-ray findings, optimising anticoagulation management, reducing the risk of vascular catheter-related infection, and improving pain management.

Etchells and Bernstein (2001) argued that hospitals need to establish Patient Safety Consultation Teams – groups with specific responsibility for patient safety. The teams need to be well trained and supported.

Frankel, Gandhi and Bates (2003) described the establishment of patient safety infrastructure across a large, integrated, non-profit health care delivery group in the United States. The group first appointed a central Patient Safety Officer, who then formed a Patient Safety Advisory Group with local expert members, as well as a Patient Safety Leaders Group composed of personnel responsible for patient safety at each member institution. The latter group meets monthly to help determine future projects and to share the results of piloting and implementation.

There was broad consensus that interventions should include the areas of culture change, process change, and process measurement. There were many difficulties because many projects aimed at different components of patient safety must occur at the same time, culture and care-related beliefs vary substantially within the system, and measurement is especially challenging.

Gandhi, Graydon-Baker, Barnes, Neppl, Stapinski, Silverman, Churchill, Johnson and Gustafson (2003) described the establishment of an integrated Patient Safety Team at a large US hospital. The main goal was to create the safest possible environment for patients and staff by creating a culture of safety, increasing the capacity to measure and evaluate processes, committing to change unsafe processes, and adopting new technologies. The Patient Safety Team was integrated into existing committees and departments, and this helped to reinforce the multidisciplinary nature of safety efforts. It is critical that pre-existing groups feel that patient safety represents ‘value added’ and is not a threat to their current roles.

3.3.4 Error reporting systems

The IOM study argues that much can be learned from the analysis of errors. All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

The emphasis is on the situation in the USA. The IOM study recommends that a national reporting system be established, that will require all state governments to collect standardized information about adverse medical events that result in death and serious harm. Hospitals

should be required to begin reporting first, and eventually all health care organizations should be required to report. This system will ensure a response to specific reports of serious injury, hold health care organizations and providers accountable for maintaining safety, provide incentives to organizations to implement internal safety systems that reduce the likelihood of errors occurring, and respond to the public's right to know about patient safety.

The authors noted that about a third of the states in the USA have mandatory reporting requirements. Voluntary reporting systems will provide an important complement to the mandatory system. Such systems can focus on a much broader set of errors, mainly those that do no or minimal harm, and help detect system weaknesses that can be fixed before the occurrence of serious harm, thereby providing rich information to health care organizations in support of their quality improvement efforts.

Finally, the IOM study argued that, to ensure there is wide participation in voluntary systems, Congress should enact laws to protect the confidentiality of certain information collected. Without such legislation, health care organizations and providers may be discouraged from participating in voluntary reporting systems out of worry that the information they provide might ultimately be subpoenaed and used in lawsuits.

Some responses to this IOM recommendation have already occurred. For example, in 2002 the National Academy for State Health Policy (NASHP) convened leaders from both the executive and legislative branches of the states to discuss how states with mandatory hospital error-reporting requirements administer and enforce their programs (www.nashp.org). The Agency for Healthcare Research and Quality has contracted with the National Quality Forum to produce a list of so-called "never events" that states might use as the basis of a mandatory reporting system.

Bagian, Lee, Gosbee, DeRosier, Stalhandske, Eldridge, Williams and Burkhardt described an events monitoring system developed by the Veterans Administration in the USA. It included a prioritisation scoring method, the Safety Assessment Code (SAC) Matrix, for close calls and adverse events, which requires assessing the event's actual or potential severity and the probability of occurrence. The SAC Matrix specifies actions that must be taken for given scores. Use of the SAC score permits a consistent handling of reports throughout the VA system and a rational selection of cases to be considered.

VA also developed a system for performing a root cause analysis (RCA) to guide caregivers at the frontline. It includes a computer-aided tool, a flipbook containing a series of six questions, and reporting of the findings back to the reporter. The final step requires that the facility's chief executive officer formally to agree or disagree with each recommended corrective action. The RCA team outlines how the effectiveness of the corrective action will be evaluated to verify that the action has had the intended effect, and it ascertains that there were no unintended negative consequences.

The tools were implemented nationally in 2000, supported by a 3-day training course. The training included didactic components, an introduction to human factors engineering concepts, and small- and large-group simulation exercises. Facility leaders were reminded of the necessity to reinforce the point that assignment to an RCA team was considered an important duty.

The authors emphasised that tools must take account of the concerns of practising clinicians, and must be seen as tools for learning and not accountability. The focus must be on the dissemination of positive actions that reduce or eliminate vulnerabilities that have been identified, not a counting exercise of the number of reports.

Schenkel (2000) described processes of improving patient safety in hospital emergency departments. Error detection has focused on subjects of high liability: missed myocardial infarctions, missed appendicitis, and misreading of radiographs. Some system-level efforts in error prevention have focused on teamwork, on strengthening communication between pharmacists and emergency physicians, on automating drug dosing and distribution, and on rationalizing shifts.

Romano, Geppert, Davies, Miller, Elixhauser and McDonald (2003) argued that a national profile of patient safety would be extremely useful. They focused on describing a methods of counting and classifying problems of safety by use of 20 patient safety indicators, and described the results when it was applied to national hospital discharge data in the USA. Care providers could use them to screen for preventable complications, target opportunities for improvement, and benchmark performance.

Runciman (2002) described the experiences of the Australian Patient Safety Foundation in establishing a national patient safety surveillance system. He defined the attributes of an ideal system: agreed frameworks for patient safety and surveillance systems; common, agreed standards and terminology; a single, clinically useful classification for things that go wrong in health care; a national repository for information covering all of health care from all available sources; mechanisms for setting priorities at local, national and international levels; a just system which caters for the rights of patients, society, and healthcare practitioners and facilities; separate processes for accountability and "systems learnings"; the right to anonymity and legal privilege for reporters; systems for rapid feedback and evidence of action; mechanisms for involving and informing all stakeholders. Runciman argued that there are powerful reasons for establishing national systems, for aligning terminology, tools and classification systems internationally, and for rapid dissemination of successful strategies.

Scheckler (2002) argued in favour of establishing and refining ideas for national studies of healthcare epidemiology. They sought a focus on the study of iatrogenic illness.

Silver and Lusk (2002) described and compared two approaches to managing patient safety: the traditional quality management approaches and another that built on an existing electronic medical record system. They argued that the latter approach has efficiencies because of its use of largely by-product data at marginal cost.

Kliger and Diamond (2001) argued that an effective problem-reporting system must have two components, one for public accountability for errors that result in serious injury and another for confidential reporting of mistakes that have the potential for serious injury. Regulatory protection from discovery must be established for voluntary error and near-miss reporting systems.

3.3.5 Research and analytical techniques

By research, we mean investigation of the magnitude and types of patient safety problems, the causes, and potential solutions. Analytical techniques in this context mean methods of extracting and interpreting potentially relevant information.

Young (2001) reported that some pharmacists believe there is a need for more research with regard to safe prescribing and use of medications. Meyer and Rall (2002) reported that the US Agency for Health Care Research and Quality (AHRQ) is committed to the sponsoring of further research. The Agency believes the research results "… will provide an evidentiary base for system improvements that, when implemented, will greatly enhance the safety of the nation’s health care system."

Gosbee (2002) explained human factors engineering and discussed its relevance to improving processes in health care. HFE is a framework for efficient and constructive thinking that includes methods and tools to help healthcare teams perform patient safety analyses, such as root cause analyses.

Vicente (2003) discussed the implications of taking a human factors engineering approach to patient safety. This implies a radical behavioural shift from "blame and shame," which emphasizes further training, to systems thinking, which also emphasizes improved system design. He presented a case study of a medical device manufacturer. Radical behavioural change was preceded by a critical 9-month period with three characteristics: new corporate leadership, perceived poor corporate performance, and aligned disruptions occurring within a relatively short time at almost every level in the external environment in which the company operated. The author concluded his findings were consistent with punctuated equilibrium theory, according to which organizations can experience long periods of resistance to change followed by fast revolutionary change (approximately two years).

Weinger and Slagle (2001) described the conduct of human factors research in anaesthesia. The focus was on identifying factors that affect job performance and consequently put patient safety at risk. The authors presented results from a case study involving task analysis and workload assessment during actual patient care and the use of cognitive task analysis to study clinical decision making. They developed a novel idea related to ‘non-routine events’.

Neily, Ogrinc, Mills, Williams, Stalhandske, Bagian and Weeks (2003) explained how research results could be better understood by use of aggregate root cause analysis "… which provides a systematic process for analysing high-priority, frequent events." Root cause analysis has also been discussed by Gerberding (2002).

Mawji, Stillman, Laskowski, Lawrence, Karoly, Capuano and Sussman (2002) described the use of root cause analysis as a component of a quality improvement program at a US hospital. They illustrated its application to wrong-site surgery. In response to errors, the hospital introduced a process of marking "yes" on the surgical site and "no" on the other side. However, several near misses occurred, and a root cause analysis indicated that the policy was not always followed for some very specific reasons. For example, the operative record included no prompt to address laterality, and the procedures in which laterality should be addressed were never specified. Interventions to address these issues were quickly developed that were in keeping with the recommendations outlined in a second alert warning on the issue in December 2001. A year after these stepwise changes, compliance with the policy is almost 100%, and there have been no further near misses.

Spath (2003) defined failure mode and effects analysis and illustrated its use to improve patient safety. Failure mode and effects analysis is mainly a technique for prospective risk analysis. It involves close examination of high-risk processes to identify needed improvements that will reduce the chance of unintended adverse events, and is used in other industries including manufacturing and aviation. The author illustrated its use in a high-risk perioperative process.

3.3.6 Education, training, and learning

A wide variety of ideas is presented in the literature with regard to education. Several articles emphasise the need for training at all levels in the system. For example, Elkin and Gorman (2002) argued that it was necessary to design and implement training in patient safety that covered all levels and types of formal, informal, and continuing medical education programs.

Some articles emphasise the need to change formal education programs for clinical professionals. For example, Holmes, Balas and Boren (2002) described the needs, and presented and discussed a guide for developing patient safety curricula for undergraduate medical education.

Martin, Scalabrini, Rioux and Xhignesse (2003) noted that complications after surgical procedures performed by residents are thought to occur most often early in the first postgraduate year. They evaluated the number of pneumothoraces (PTXs) caused by central venous line insertion (CVLI) by two groups of PGY-1 residents in both the first 3 months of residency and the entire year from 1996 through 2000 to determine the impact of CVLI training on PTX. From 1996 through 1998 there was no specific training in medical school and residents therefore learned on the job. They introduced a structured training program in CVLI that included didactic sessions detailing anatomy and technique followed by skill performance in a fresh cadaver model. Students performed skills initially under the direct supervision of a faculty member, who provided immediate feedback. Videotapes of this performance were reviewed with the students by both surgeons and kinesiologists to correct deficits before repeat sessions. Skills were repeated until competence was attained. They found that, after the introduction of the teaching program the number of pneumothoraces decreased significantly. They concluded that the structured teaching program of CVLI skills had led to improved patient safety.

Martin, Vashisht, Frezza, Ferone, Lopez, Pahuja and Spence (1998) described the development and testing of a new approach to training in invasive surgery that was structured around the goal of 100% success in a battery of competencies. They concluded that trainee surgeons' skills rapidly improve with competency-based instruction, skills learned in the laboratory can be translated to and sustained in the clinical setting, and competency-based instruction produces competent surgeons who perform skills rapidly and with minimal complications.

Messenger, Rumsfeld, Carroll, Combes and Chen (2002) argued that new technologies for training were badly needed. They described an effective approach to improved patient safety during cardiac catheterisation that used simulation-based training.

Many authors emphasised on-the-job training. For example, Manning, Palmer and Yonekura (2003) described the introduction of new processes whereby staff nurses provided coaching (that is, on-the-job supervision and advice) to the more junior nursing staff with the emphasis on improving patient safety. Nolan (2000) argued that it was important to improve the way that debate takes place in the context of providing care.

Barrett, Gifford, Morey, Risser and Salisbury (2001) emphasised the need to provide training in working as a team. They described a study of teamwork training in an Emergency Department in a US hospital. The training process included assessment of weaknesses and error patterns in Emergency Department teamwork, and prospective evaluation of a formal teamwork training intervention. Improvements were obtained in five key teamwork measures, and most importantly, clinical errors were significantly reduced.

Sokol and Cummins (2002) discussed the development of a web-based safety education module for nurses. The contents were defined using ideas from a focus group of professional nurses that raised issues such as the culture of tolerance, barriers to reporting and resolving errors. Cosby and Croskerry (2003) have described a curriculum for teaching patient safety in emergency medicine.

Eisenberg (2000) presented a continuing education program for care providers that focuses on use of a systems approach to patient safety. The themes of the program are informatics for

information, guidelines as learning tools, learning from opinion leaders, learning from the patient, decision support systems, the team learning together, learning organizations, and just-in-time and point-of-care delivery.

Mustard (2002) outlined a process whereby an advanced practice nurse acts as a daily teacher and facilitator for hospital nurses based on a curriculum of day-to-day examples of good patient care through training and observation of patient care as it is being given.

Finally, Landry and Sibbald (2002) described the work of the US Agency for Healthcare Research and Quality in formulating a program for improvement in patient safety that includes five educational-based strategies directed at changing doctor behaviour: Academic Detailing, Audit and Feedback, Local Opinion Leaders, Reminder Systems, and Printed Material. The authors discussed ways of implementing these kinds of activities in the context of critical care medicine.

3.3.7 Reference sources for clinical practice information

The majority of authors believe that more should be done to make information about good clinical practice more easily available. For example, Williams and Zipperer (2003) suggested that nurses should make more use of library services, including seeking the advice of medical librarians.

Zipperer, Gluck and Anderson (2002) suggested that health care professionals should make more use of knowledge maps (indexes to people and organizational resources) with the assistance of librarians. In this way, a blend will be created of the knowledge of the practitioner and the administrator with regard to managing problems of patient safety. Zablocki (2003) and others argued that more use should be made of the Internet for the purpose of finding and sharing information.

Many references are made to the need to create and disseminate clinical practice guidelines. For example, O'Grady, Gerberding, Weinstein and Masur (2003) argued that there was an urgent need to make more easily available guidelines for the prevention of intravascular catheter-related infections.

Verheecke and Himpe (2001) were equally enthusiastic. However, they reported experiences with the dissemination of guidelines for safety in anaesthesia in Belgium where they found that 65% of responders did not fully comply with some aspects of the guidelines.

Simpson and Knox (2003) discussed the risks of litigation related to care during labour and birth. They argued that the risks can be reduced if all members of the perinatal care team (nurses, nurse-midwives, and physicians) agree to follow two basic rules: use applicable evidence and published standards and guidelines as the foundation for care and, whenever a clinical choice is presented, choose patient safety rather than production.

An increasing quantity of guidelines is being generated that refer specifically to ways of increasing patient safety. Processes for the development and dissemination of policies, procedures, standards and systems are discussed by Rollins (2001a; 2001b; 2003).

Goldstein, Hoffman, Coleman, Tu, Shankar, O'Connor, Martins, Advani and Musen (2002) described a software package that helps store, access, and analyse guidelines on drugs prescribing. It provides additional functionality including easy review and updating by clinician experts.

Greengold (2002) described a web-based program for implementing evidence-based patient safety recommendations. It comprises 7 modules. The Literature Module features detailed

synopses that are graded and organized into summary statements to provide recommendations for improving patient safety. The Implementation/Tracking Module includes numerous risk-reduction strategies. The Incident Reporting Module enables the collection of data at the point of care on a variety of incidents, using either paper-based or on-line forms. Other modules offer opportunities to assess adherence to JCAHO patient safety standards, forecast the benefits of certain evidence-based guidelines, evaluate staff competency, and obtain information from a variety of key safety Web sites.

3.3.8 The purchasing of health care

The IOM study advocated a change in the actions of purchasers of health care – both government and private. They must make safety a prime concern in their contracting decisions. Doing so will create financial incentives for health care organizations and providers to make needed changes to ensure patient safety.

In response to the IOM study, the Leapfrog Group was created. Delbanco (2001) explained that the Group is a consortium of Fortune 500 companies and other large private and public health care purchasers. The group is working to mobilize employer purchasing power to affect big "leaps" in patient safety by educating consumers and rewarding health care providers who meet defined safety standards.

Eikel and Delbanco (2003) described the main goal of the Leapfrog Group: to mobilise consumers to seek out higher-quality providers, and to reward higher-quality providers. The first phase concentrated on three patient safety practices: computer physician order entry, evidence-based hospital referral, and intensive care unit physician staffing. Care providers are being audited against standards in these areas, and the results being placed in the public domain.

Miller and Bovbjerg (2002) emphasised that there are two important determinants of success in improving patient safety: a demand for safety from external factors (legal, market, and professional), and appropriate organizational responses that depend on internal factors such as leadership and governance, professional culture, information-system assets, and financial and intellectual capital. The greatest improvement would come from boosting the demand for quality and safety from both private and public larger group purchasers. Current policy relies too much on litigation and discipline, which have sometimes helped, but not solved, problems because they are inefficient, tend to drive needed information underground, and complicate needed cultural change. Patients' safety demand is also weak for want of information and market power. Big purchasers' demands, however, quickly influence the internal environment of medical groups, helping managers advance patient safety toward the top of groups' congested decision-making "queues."

Romano (2001) described recent changes in the way that hospitals are being contracted in the USA by two major insurers, with the deliberate intention of stimulating improved patient safety. Several articles argue that there is a financial case for improving patient safety without the need for changes in payment methods. For example, Massaro (2003) claimed that hospital boards in the USA could appreciate the financial benefits of investing in patient safety if they reviewed the evidence. Shulkin (2003) proposed a model for analysing the financial aspects of investing in patient safety. Turnbull and Mortimer (2002) and Weeks and Bagian (2003) also presented a financial justification for investing in patient safety.

3.3.9 Consumerism and empowering patients

It has long been argued that consumers must have the right to be involved in designing, monitoring, and evaluating the services they receive, relatively little progress has been made in

most health systems. Vicente and Coulter (2002) reported that the need for involvement has been increased by the recent emergence of concern about patient safety. They argued that care providers must do more to ensure that patients play a major role in helping to reach an accurate diagnosis, deciding about appropriate treatment, choosing an experienced and safe provider, ensuring that treatment is appropriately administered, monitored and adhered to, and identifying adverse events and taking appropriate action. "They may experience considerable psychological trauma both as a result of an adverse outcome and through the way the incident is managed. If a medical injury occurs it is important to listen to the patient and the family, acknowledge the damage, give an honest and open explanation and an apology, ask about emotional trauma and anxieties about future treatment, and provide practical and financial help quickly."

Morath (2003) pointed out that consumers will play an increasingly important role by way of their insurers. Through their purchasers of health care, consumers "… are demanding new methods, new metrics, and a higher standard of accountability for all parties. Purchasers themselves are turning up the heat on providers to act with the consumer perspective in mind and are advocating continuous, consumer-driven healthcare delivery."

Sanford (2002) argued that there must be more encouragement and support for consumers, so they will be empowered to ask about the care they receive. Robinson and Nash (2000) covered similar ideas.

The IOM study suggested that patients themselves could provide a major safety check in most health care settings. For example, they should know which medications they are taking, their appearance, and their side effects, and they should notify their doctors of medication discrepancies and the occurrence of side effects.

The Agency for Healthcare Research and Quality (AHRQ) has produced a booklet of practical tips on what individual consumers can do to improve the quality of health-care services they receive. The booklet focuses on key choices that individuals and their families face, such as choosing doctors, hospitals, and treatments, and it stresses the importance of individuals taking an active role in selecting and evaluating their care (AHRQ at www.ahrq.gov).

Anthony, Miranda, Mawji, Cerimele, Davis and Lawrence (2003) developed a video for patients to support their empowerment and involvement. The video, intended to be shown during pre-admission care, covered six topics relevant to patient safety: treatment plan, medication safety, falls, surgical site identification, hand washing, and discharge planning. Each segment outlines strategies that patients may employ or observations they should make to improve patient safety. Subsequent analysis indicated that patients felt more comfortable talking with their health care workers about questions or concerns after viewing the video and that they rated their knowledge of patient safety higher.

Cranfill (2003) argued that the key to patient safety is a willingness to disclose and discuss problems. This includes disclosure to patients and families, as partners in the process. Many healthcare providers are worried about disclosure. The Lexington VA Medical Centre in the USA has been disclosing errors for approximately 10 years, and has found this to be practical and beneficial.

Kraman, Cranfill, Hamm and Woodard (2002) also described experiences at the Lexington VA Medical Centre. They reported a case study where an informal risk management team learned that a medication error had caused a patient’s death. Although the family would probably never have found out, the team decided to honestly inform the family of exactly what had happened and assist in filing for any financial settlement that might be appropriate. This decision evolved

into an organization wide full disclosure policy and procedure. The authors argued that full disclosure is the right thing to do and the moral and ethical thing to do. Moreover, doing the right thing actually seems to have mitigated the financial repercussions of inevitable adverse events that result in injury to patients. In 1999, Lexington VAMC was in the top quarter of medical centres for number of tort claims filed but was in the lowest quarter for malpractice payouts resulting from these torts.

Meyer and Arnheim (2002) noted the evidence that poor communications between patients and doctors leads to avoidable harm. They argued that "… helping patients become more informed and involved in their care could be your best strategy for reducing medical errors."

3.3.10 Regulation, certification, licensing, and accreditation

The IOM study advocated the regulation of explicit performance standards for patient safety through such processes as licensing, certification, and accreditation. The standards should cover minimum performance levels for health professionals and the organizations in which they work, and the tools (drugs and devices) they use to care for patients. The process of developing and adopting standards also helps to form expectations for safety among providers and consumers.

There are several articles that describe recent legislative changes directed at improving patient safety. For example, Ferris (1998) described new legislation in Ontario that is intended to protect care providers as well as patients. Ondeck (2001) described new legislation in the USA (The Patient Safety Act 2001) that emphasises improved credentialing. Other articles cover such matters as regulation of office-based surgery (Sutton, 2001), and tort reform and the role that can be played by state medical boards (Rohrich, 2003).

There have been many calls for the refinement of accreditation processes so they might encourage improvements in patient safety. A focus of attention has been recent changes in accreditation standards of the JCAHO in the USA, which incorporate many that are designed specifically to address patient safety (McLaughlin, 2001; Sarudi, 2001a, 2001c, 2001b; Saufl, 2002). Schyve (2003) discussed the potential impact of the new standards on the responsibilities of members of hospital boards and other senior staff.

There has been much discussion of the new JCHAO standards on requirements for hospitals to inform patients of outcomes of care, including unanticipated outcomes. For example, LeGros and Pinkall (2002) argued that the standards were appropriate in principle but presented many practical problems, both legal and ethical. An example concerned confusion over what hospitals are required to do when members of the medical staff refuse to inform patients of medical error.

Berman (2000) noted that the American Medical Association intends to conduct further reviews of accreditation standards. Particular attention will be paid to the way that care providers respond to indications of problems with patient safety.

The IOM study argued that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. The health professional associations have a role to play in redefining standards and expectations, with the aim of influencing training and practice. Professional societies should become leaders in encouraging and demanding improvements in patient safety by setting their own performance standards, convening and communicating with members about safety, incorporating attention to patient safety in training programs, and collaborating across disciplines.

Following the IOM study, several professional groups responded positively. For example, the Council on Graduate Medical Education (COGME) and the National Advisory Council on Nurse

Education and Practice (NACNEP) have been considering the effect of the relationships between physicians and nurses on patient safety, the impact of physician-nurse collaboration on systems designed to protect patient safety, and educational programs to ensure interdisciplinary collaboration in the interests of improved patient safety (www.cogme.org).

3.3.11 Facility design

The IOM study argued that many mistakes can best be prevented by designing the health system at all levels to make it safer – to make it harder for people to do something wrong and easier for them to do it right. This does not mean that individuals can be careless – they must still be vigilant and held responsible for their actions. However, when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Reiling, Breckbill, Murphy, McCullough and Chernos (2003) also argued that safety could be built into any redesign. They emphasised the opportunities created by the redesign of a facility with nursing practice in mind. They noted it is much more common to blame the caregivers than to look for design flaws when errors occur. They gave the example of redesign of a community hospital. Safety-driven design principles were developed including designs to minimize the most prominent serious, and precarious events. The design changes reduced the extent to which errors were made in the provision of nursing. Reiling and Neal (2003) make similar points in the context of major construction or reconstruction of care provider facilities.

Larson (2003) described a process of design of a new hospital, where patient safety dominated the entire process. An important early stage was that of consulting with leading experts on patient safety. This was followed by involving all staff in identifying where errors occur, how work flow and processes can change to enhance safety and how a building can be designed to incorporate those improvements.

3.3.12 Technological solutions

The IOM study argued that more use should be made of new technologies that could reduce the risk of errors. The authors gave the example of the medication process where there were many opportunities for implementing better systems that would yield better human performance. Medication errors now occurred frequently in hospitals, yet many hospitals were not making use of known systems for improving safety, such as automated medication order entry systems, nor were they actively exploring new safety systems.

Nobel (1996) discussed the significant number of patient injuries and deaths that are associated with the use of medical devices. He argued that many of these adverse effects could not be predicted, even with the most sophisticated design validation techniques. It was therefore necessary to have effective reporting networks with investigational capability that identify problem devices and provide feedback about adverse effects to manufacturers and medical device users.

Harvey and Alpert (1997) discussed the challenge of managing the pre-market review process for medical devices. They argued that it was necessary to re-establish the government-academia industry partnership, and thereby more efficiently obtain clinical trial data necessary for a medical device to enter the market.

Eskew, Geisler, O'Connor, Saunders and Vinci (2002) discussed the potential and the problems associated with clinician order entry with a pharmacy interface. They described a system in a US hospital that electronically transmits clinicians' orders to the laboratory, radiology, and pharmacy.

By careful testing and progressive refinement, they were able to establish an information system used by clinicians that provides for efficiency, standardization, documentation compliance, and improved patient safety.

Lanser (2001) described the significant potential for new medical technology and information technology to improve patient safety. Kuperman, Teich, Gandhi and Bates (2001) described experiences with computerized ordering of medications and other services at a US hospital. Physicians entered 85% of orders, with the remainder entered electronically by other clinicians. The system included several features designed to improve medication safety: structural features (for example, required fields, use of 'pick lists'), enhanced workflow features (order sets, standard scales for insulin and potassium), alerts and reminders (drug-drug and drug-allergy interaction checking), and adjunct features (the pharmacy system, access to online reference information). They measured the rates of serious medication error and preventable adverse drug events, the impact of computer guidelines on the use of vancomycin, the impact of guidelines on the use of heparin in patients at bed rest, and the impact of dosing suggestions on excessive dosing. They concluded that the order entry system and associated clinical decision support modules substantially decreased the frequency of serious medication errors and had an even bigger impact on the overall medication error rate.

Nadzam and Macklis (2001) presented a summary of a conference on technology in patient safety. Examples included an evaluation of a computerized clinician order-entry system used to provide decision support, reduce excess test ordering, introduce cost savings, and meet regulations for inpatient radiology and cardiology tests. Another example was the use of bar coding technology for point-of-care validation of medication administration, which has resulted in improvements in response time, the efficiency of the dispensing, delivery, and administration process, and patient care. The potential was also discussed for using predictive modelling to identify the risks of therapeutic intervention.

Newell and Christensen (2003) discussed the estimation of return on investment in patient safety information technology (IT). They argued that a traditional return on investment (ROI) must evolve to focus beyond the financial benefit, encompassing overall patient safety, patient satisfaction, and employee and physician satisfaction benefit categories. Computerized physician order entry and bar code medication administration systems are two particular clinical point-of-care products that will play a key role in addressing patient safety objectives. Integrating the two technologies can bring both financial and clinical benefits.

Tribble explained how bar coding can improve patient safety in several contexts. Other articles discussed the potential of IT to improve nursing practice (Abrahamsen, 2003), the risks associated with computerized physician order entry (Gunasekaran, Knecht, & Garets, 2003), recent refinements in computerized physician order entry (May 2002), and constraints to the introduction of new technologies including high costs, and gaps in infrastructure and standards (Wahls, Chatterjee, Ting, & Clancy, 2002). They also argued that reporting systems will be resisted: changes will continue incrementally until the cost of enabling information technology falls and medical groups compete on the basis of quality.

McMullin, Reichley, Watson, Steib, Frisse and Bailey (1999) noted that most commercially available drug-interaction screening systems have important limitations that fail to protect patients from dangerous drug combinations. They attempted to overcome the limitations of their commercial program by developing a Web-based clinical information system to serve as a safety net. This system identifies drug interactions with newly marketed medications not screened by the commercial program, and generates a second alert on dangerous interactions that were

overridden during order processing. The Web-based system uses patient-specific pharmacy, laboratory, and demographic data to generate detailed alerts on patients receiving potentially dangerous drug combinations. The system's impact on the use of dangerous drug combinations and related adverse events was evaluated by a retrospective analysis of patients receiving cisapride with contraindicated medications in the two years before and after implementation. They found the system was efficient in controlling and reducing the errors.

Meadows and Chaiken (2002) emphasised the importance of clinician involvement from the start, when computerized physician order entry systems are being designed. Ortiz, Meyer and Burstin (2001; 2002) emphasised the central role of clinical informatics in patient safety, within the research plan of the US Agency for Healthcare Research and Quality. Simpson (2001) described the role of the private sector Leapfrog Group in the USA, and stressed the need for collaboration between payers, providers, and IT vendors.

Valusek (2002) was concerned about overestimation of the ease with which patient safety might be improved through IT solutions. He argued for the need to take account of the 'decision intensity' of healthcare and the consequent importance of addressing all aspects of information, from how it is delivered to how it is managed. The current emphasis on efficient transaction systems needs to be augmented with work on establishing safe and effective clinical decision environments, which cannot be achieved with transaction mentalities and processes.

Battles and Keyes (2002) emphasised that, while the automation of repetitive, time-consuming, and error-prone tasks is necessary, there are dangers. New technologies must be tested in actual operational settings to determine what, if any, unanticipated failures exist. Field-based research is essential to generate the evidence as to which technologies actually improve patient safety and those that may well increase the potential for harm.

Kaushal, Barker and Bates (2001) reviewed information technologies relevant to patient safety in children's health care, and particularly to drug prescribing. They identified the most useful, although they noted that evidence of success was limited. They were computerized medication administration records, robots, automated pharmacy systems, bar coding, "smart" intravenous devices, and computerized discharge prescriptions and instructions. In the outpatient setting, where adherence is especially important, personalized Web pages and World Wide Web-based information have substantial potential.

3.3.13 Leadership

The importance of leadership is a common theme in the literature. Some articles discuss its general features. For example, Mohr, Abelson and Barach (2002) discussed the attributes of good leadership and how it might be developed. Winokur (2002) covers similar ground. Braithwaite and colleagues (2004) assessed the role of clinician-managers, pointing out that they were often under pressure, conducting multiple tasks simultaneously, and did not focus sufficiently on safety and quality issues.

Mycek (2001) argued that leadership responsibilities in patient safety rest with the board of management of the health care facility. Reinbold (2001) explained how board leadership is expected under revised accreditation standards from the JCAHO.

Spath (1999) discussed ways of ensuring that governing boards accept their responsibilities for patient safety. White and Ketring (2001) gave an example of the way that senior staff have accepted responsibility for leadership in a care provider organisation in the USA.

Classen (2000) discussed the role that must be played by trustees of health care providers agencies in communicating the importance of an organization-wide quality program. Patient safety is a natural outgrowth of an aggressive and non-punitive approach to quality.

Ebright, Patterson and Render (2002) described the "New Look" approach to patient safety, which involves senior nurses in a leadership role. It focuses on understanding and managing the complexity of clinicians' decision making environment.

Frankel, Graydon-Baker, Neppl, Simmonds, Gustafson and Gandhi (2003) described patient safety 'Leadership Walkrounds'. These involve a core group of senior executives and clinicians conducting weekly visits to different areas of the hospital. The group, joined by one or two nurses in the area and other available staff, asks specific questions about adverse events or near misses and about the factors or systems issues that led to these events. Events in the Walkrounds are entered into a database and classified according to the contributing factors. The data are aggregated by contributing factors and priority scores to highlight the root issues. The priority scores are used to determine QI pilots and make best use of limited resources. Executives are surveyed quarterly about actions they have taken as a direct result of Walkrounds and are asked what they have learned from the rounds. Wachter, Shojania, Saint, Markowitz and Smith (2002) described the idea of 'quality grand rounds', whereby senior medical staff focus on issue of quality of care and patient safety.

3.3.14 Improving teamwork

The need to improve teamwork is a component of most patient safety programs that have been described in the literature. Particular emphasis is given to clinical teamwork, but articles also address teamwork involving clinical and administrative staff, cross-setting teamwork, and teamwork involving purchasers and providers.

Sherwood, Thomas, Bennett and Lewis (2002) described a teamwork model for intensive care clinicians. They emphasised the extent to which ideas could be taken from experiences in the aviation industry. Emphasis was given to the need to have explicit instruction in communication and teamwork rather than learning by trial and error – which can instil unintended values, attitudes, and behaviours.

Sprenger (2001) emphasised the importance of teamwork as a way of ensuring there is shared responsibility for patient safety. Thomas, Sherwood and Helmreich (2003) described how ideas about teamwork can be borrowed from the aviation industry.

Turnball (2001) discussed how teamwork is required that includes all components of the health care system. He emphasised the importance of a teamwork view that includes care providers (physicians, nurses and pharmacists) and consumers (patients and their families). Consumers can be empowered through programs that raise awareness, prevent error and mitigate its effect when error does happen.

Uhlig, Brown, Nason, Camelio and Kendall (2002) described the patient safety activities in the cardiac surgery department of a major hospital in the USA. Design of the program took account of human factors science, aviation safety, and high-reliability organization theory. An important component of the Program was the use of a structured communications protocol was conducted daily at each patient's bedside. The entire care team met at the same time each day to share information and develop a plan of care for each patient, with patient and family members as active participants. A biweekly system rounds process was established to provide a forum for discussion of team goals and progress and to address system-level concerns. Following

implementation, mortality of cardiac surgery patients declined significantly, patients were more satisfied, and care providers were also more satisfied.

Mohr, Barach, Cravero, Blike, Godfrey, Batalden and Nelson (2003) emphasised the importance of designing teamwork at the level of interaction with individual patients. They developed the concept of ‘microsystems management’ and illustrated how attention to the detail of specific cases can generate rules for larger systems.

Barrett, Gifford, Morey, Risser and Salisbury (2001) described a formal training program directed at improving teamwork in an Emergency Department. Improvements were obtained in five key teamwork measures, and clinical errors were significantly reduced.

Firth-Cozens (2001) described how learning in teamwork can take place, and the cultural change necessary to encourage it. Teams and team leaders are claimed to be potentially powerful forces for bringing about the management of patient safety. Kaissi, Johnson and Kirschbaum (2003) developed an instrument for measuring teamwork and patient safety attitudes of high-risk areas of hospitals. It can be used to diagnose problems and define appropriate training in teamwork.

3.3.15 Managing cultures

The IOM study argued that it was necessary to "… break down legal and cultural barriers that impede safety improvement." It did not address either in detail, and was particularly reticent to address cultural change.

It did, however, state that health care organizations must develop a “culture of safety” such that their workforce and processes are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal that is demonstrated by strong leadership on the part of clinicians, executives, and governing bodies. This will mean incorporating a variety of well-understood safety principles, such as designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and enabling care providers to avoid reliance on memory. Systems for continuously monitoring patient safety also must be created and adequately funded.

Many authors suggest that it is necessary for each health care provider agency to take an organisation-wide view of patient safety. Larson (2001) argued that the goal must be to create a ‘patient safety mindset’. This could be achieved only through making patient safety an organization-wide priority.

Ketring and White (2002) described such a process in a US hospital group that started with a patient safety framework built on the foundation of a culture of patient safety. Essential elements were ensuring there was a high-level management commitment, increasing the number of forums in which it was a sign of strength to admit errors, and prospectively identifying risky processes and taking action to improve them. Challenges includes maintaining interest, demonstrating progress, developing effective mechanisms for communicating safety solutions and ensuring that they were implemented in all the facilities, and figuring out how to measure success in a meaningful way.

Kliger and Diamond (2001) explored possibilities for improving patient safety in end-stage renal disease. They argued that the main ideas were acknowledging medical errors, encouraging the reporting of errors, improving systems to reduce the likelihood of future errors, and ensuring there was a recognition that most of the problems arise from poor systems rather than

individuals. In total, a ‘culture of safety’ had to be created. Other important elements included the identification and resolution of problems at the human-machine interface.

Spath (2001) argued that there is a need for a revolution in patient safety culture. This can only be accomplished by "… winning the hearts as well as the minds of clinicians." They must be convinced of the importance of the improvement process.

Stalhandske, Bagian and Gosbee (2002) reported the experiences of the Department of Veterans Affairs in the USA, which has played a leading role in improving patient safety. It established a separate entity in 1998, called the National Centre for Patient Safety. The Centre takes a non-punitive approach, to building a culture of safety whereby clinicians report unsafe situations and close calls without fear of reprisals. The program stresses that iatrogenic injury is best managed through an examination of system and process vulnerabilities, with a focus on why something occurred rather than who is at fault.

Weinberg (2002) described ways in which it appears that the cultures of health care must change in order to meet the challenge of patient safety. First, the clinician-centred system, in which decision making is one-sided, must be replaced by a shared system of negotiated care between clinician and patient, and between administrator and payer. Second, the nature of quality in health care must change through the use of technological and pharmaceutical enhancements to patient care. Third, there must be improved methods of conflict resolution. Finally, the regulatory structure of health system must be changed. It was largely set in place to control fee-for-service care when few external technologies were available. In the current health care culture, that structure seems inadequate and diffuse, with multiple and overlapping federal and state regulatory structures that make implementation of patient safety systems difficult.

Wong, Helsinger and Petry (2002) described experiences in a US hospital after it made patient safety a strategic priority in 2000, and devoted resources to incorporate safety as a part of the hospital’s culture and care processes. The vice president of clinical effectiveness and performance improvement, as a champion for safety, led a consensus-building effort to enlist the support of key physician and hospital leaders to a safety program. A ‘Safety Board’ was created to manage the safety program and to produce policies and procedures associated with safety. The main aims were to demonstrate patient safety as a top leadership priority, promote a non-punitive culture for sharing information and lessons learned, and implement an integrated patient safety program throughout the organization. The Safety Board evaluates performance bimonthly, using a 5-point-scaled self-assessment tool. The Safety Board established three subcommittees, which were to test ideas and achieve improvements in medication, clinical care, and environmental factors. The new structures have stimulated a cultural change in the way that patient safety issues are perceived and acted on throughout the organization.

Classen and Kilbridge (2002) argue that it is essential directly to address aspects of medical culture that militate against improvements in patient safety. This should be directed at ensuring there are shared objectives and values between doctors and other parts of the care provider organisation.The authors present a model for change that has seven essential components. First, there must be shared responsibility and accountability. Second, there must be shared values and beliefs throughout the care provider agency that include a commitment to improve patient safety. Third, there must be a learning organisation – one that allows the organisation to openly report, discuss, learn from, and seek solutions to safety problems.

Fourth, there should be concrete and auditable objectives for a safety program. Fifth, there should be safe processes that are based on knowledge gained from other industries, local experiences, and monitoring activities, and that will reduce the probability of error. Sixth, the processes should be defined in a standard way across the organisation, but with allowance for customisation. Finally, there should be a continuous process of measurement and improvement – a process of continuous learning.

3.3.16 Learning from other industries

Runciman and Moller (2001) examined the available information about patient safety in Australia. They noted high rates of errors and suggested it was necessary to recognise that healthcare is a complex system, and also to apply the approaches to system failure and human error which have been proven effective in other complex human endeavours (such as nuclear power stations, off-shore drilling rigs, and aviation). The Australian health care sector should learn about the considerable expertise that has been accumulated in these other disciplines, and apply it to the business of health care.

3.3.17 Publicity and shaming

Millenson (2002) noted that, although the problem of patient safety had been repeatedly identified in the medical literature since the mid-1950s, there had been little improvement in clinical practice until recently. He argued that a major cause of the diffusion of innovation in medical error reduction has been the public shaming of the profession that occurred as a result of stories that appeared in the news media. The focus is on the USA, but news stories about patient safety are sparking a similar process throughout the western world.

3.3.18 Patient documentation and coding

There are many articles that emphasise the need to improve the quality of patient documentation. For example, Tessier (2003) summarised the basic principles and emphasised the importance of documentation being shared among all members of the clinical team.

Health information managers have described ways in which they can promote patient safety during the course of abstraction and coding of clinical information (Romano, Elixhauser, McDonald, & Miller, 2002; Servais, 2003; Spath, 2002a).

Beyea (2003a) emphasised the importance of patient identification in the context of patient safety and summarised some elementary techniques.

3.3.19 Medical litigation

Brennan and Mello (2003) reviewed the medical malpractice literature from the point of view of patient safety. They concluded that the tensions between the system and patient safety initiatives suggest a need to re-consider the process of adversarial dispute resolution in health care. They proposed targeted reforms that could improve the functioning of the system and create incentives to improve safety and quality.

3.3.20 Nursing and patient safety

The distinctive roles of nurses in patient safety are discussed in many articles. For example, Beyea (2003b) discussed patient safety issues for perioperative nurses. Stetler, Morsi and Burns (2000) discussed patient safety from the point of view of both physical and emotional wellbeing.

Maddox, Wakefield and Bull (2001) emphasised the importance of recognising that nurses are the largest component of the health care workforce, and consequently have the opportunity to make the largest contribution to patient safety.

Mrayyan and Huber (2003) argued that nurses need to play a much more active role in shaping health policy. At present, the dominant inputs are from doctors. Hemman (2002) argued that nurses need to have a better understanding of patient safety and strategies for change, so they may be more active in shaping the changes.

Luther, Maguire, Mazabob, Sexton, Helmreich and Thomas (2002) described experiences in encouraging intensive care nurses to play a major role in developing and implementing changes to improve patient safety. Encouragement of nurses' involvement depended on leaders at all levels of the organization consistently demonstrating their enthusiasm and support for every aspect of the initiative. Nurses' ideas were generated through formal surveys, informal focus groups, clinical practice groups, and root cause analyses. Topics addressed included clarification of orders, establishing care protocols, strengthening chain of command, improving staff levels and staff education, and eliminating the overflow of non-specialty patients to specialty units. Progress is measured, and feedback is frequent. The culture remains one of collaboration and continuous problem solving with nurses viewed as central to the process.

3.3.21 Details of clinical practice

There are many articles that deal with minor changes in clinical practice. For example,

Gunnarsson, Theodorsson, Karlsson, Fridriksson, Bostrom, Persliden, Johansson and Hillman (2000) recommended that use should be made of mobile computerized tomography scanning in the neurosurgery intensive care unit, in order to reduce risks associated with transportation of unstable patients.

Stafrace (1998) proposed changes in the processes of assessment of patients when undergoing endoscopic procedures. Teichman and Caffee (2002) recommended changes in the ways that drugs prescriptions are written, and Thompson and Scheckelhoff (2002) suggested improvements in unit dose packaging that would increase patient safety.

Meaney (2003) recommended increased use of case management. Slonim and Ognibene (2001) discussed safety in paediatric bronchoscopy, including alternatives to conscious sedation. Ulmer (1996) discussed patient safety during electrosurgical minimally invasive procedures, and Valentine and Behara (2001) focussed on using a sociotechnical approach to patient safety in hospital laboratories. West, Golden and Sanchez (2001) discussed patient safety in preoperative antibiotic prophylaxis.

4 Discussion

The literature on patient safety is extensive but not always informative. One factor is that patient safety has become a popular topic, and this has led many authors to produce manuscripts that mention it merely to impress editors who wish to be seen to be up to date.

However, there is a small set of articles that have been written with great care and skill – and which are mostly consistent in their views. Examples are Ferlie and Shortell , Small and Barach (2002), Weinberg (2002), Runciman and Moller (2001) and Affonso and Doran (2002). To these may be added reports on the major enquiries into patient safety at Bristol Royal Infirmary in the UK and the King Edward Memorial Hospital in Australia. We have relied heavily on these few sources in drawing seven conclusions, as follows.

4.1 Patient safety is a major problem

One might reasonably argue that health care is a fundamentally difficult enterprise. It is certainly more difficult in many ways than most other industries – if not all of them. We mention this because it may mean that comparisons with safety in other industries might not necessarily be valid.

Take the simple example of the commercial air transport industry. It has a similar number of customers, but the large majority require the same services. In contrast, almost every customer of the health care industry requires a significant degree of specialised attention. Airlines need only record a small number of data elements about their customers, whereas there are hundreds (if not thousands) of potentially relevant data elements for many hospitalised patients. Most of the data elements relating to airline passengers can be self-reported by the customer, whereas the majority of relevant data for patients must be deduced by the service providers – often by use of sophisticated equipment. And so on.

Another important difference is the nature of the risk. The airline industry is often cited as a model when it comes to customer safety. In some senses, this is true: it injures or kills a much smaller proportion of its customers than does the health care industry. However, the nature of the risks is radically different. A simple example is that the airline industry can harm its customers in only one significant way (through a plane crash), and the consequential harm is impossible to hide. Moreover, unlike the surgeon, the airline pilot usually suffers the same fate as the customer. There may be techniques used in the airline industry that can be adapted for use in health care, but that is a different matter.

A more useful basis for judging seriousness is required: one cannot reasonably benchmark against the airline industry, the car industry, and so on. The most obvious bases are the health care sector's own performance over time, and the relative performance of its constituent parts. Another, perhaps less obvious benchmark is what informed people believe should be possible with existing resources.

On each of these dimensions, patient safety appears to be a major problem. We have seen that most authors believe there has been little progress (with a few exceptions), and that most doctors in Australia and similar countries believe quality of care has declined or remained unchanged at best. This is in spite of large investments in patient safety and related topics. There are some obvious data problems: many errors probably go unreported, but the level of reporting has improved – and the pessimism might be based on little more than upward trends

that reflect improved reporting. Nevertheless, the statistics would be a cause for disappointment even if they were twice as good in reality.

There is also a widespread sense that it is possible to do much better. Few authors we reviewed were satisfied that significant numbers of avoidable errors were actually being avoided. Where progress was reported, it mainly concerned particular components of patient care episodes (such as anaesthesia or drugs prescribing) where improvement depends on a single profession. According to the literature, most problems occur at interfaces (between clinical professions, between care settings, and so on), and the indicators of improvement are rare in these circumstances.

4.2 There are some obviously unimportant causes and one dominant cause

Some authors believe there are problems that would be reduced if there were more resources, better trained staff, and more information about the nature of errors and their causes. However, no-one has presented evidence to show that, by themselves, they are able to resolve more than a fraction of the weaknesses.

In contrast, many authors refer to culture, either directly or indirectly, as the primary constraint to improvement. The common view is that we perform in an unsatisfactory way because the patterns of thinking and acting are rarely conducive to fixing problems that are obvious for the most part. The articles on the Bristol Royal Infirmary and the King Edward Memorial Hospital provide powerful evidence of this. Incidentally, the problems at the King Edward Memorial Hospital were occurring at a time when concern about patient safety was growing at a rapid rate, and when large amounts of money were being spent under the Australian Health Care Agreements specifically to improve quality of care.

In short, the importance of culture is overwhelmingly supported by the evidence. If the harmful aspects of the culture of care providers are not addressed, most problems will remain regardless of the extent to which we complete research, improve the accuracy of measurement of errors, increase health care resources, and improve the knowledge and skills of clinical staff.

There is a variety of views about culture. However, most authors agree on two points. First, there are several cultures (organisational, professional, and so on) within the same care setting, and most are deficient in terms of the attributes that would encourage the right kinds of steps to improve patient safety. Second, differences between the cultures are large and contribute to poor patient safety. For example, it is obvious that the idea of team is perceived quite differently by doctors and nurses.

4.3 Solutions must take account of the causes

If the main constraints to improved patient safety are cultural, then the preferred solutions must surely be those that encourage cultural change. The literature suggests this has to involve pressure from the outside that encourages and rewards changes, as well as commitment by each care provider organisation to change itself regardless of what the outsiders might choose to do. It must also cause individuals to understand why they think and act the way they do, and to understand the thoughts and actions of people from other clinical cultures.

4.4 Systems problems require systems solutions

This is a basic idea from systems thinking. If, as is clearly the case for patient safety, the problem is defined by large numbers of elements and interactions that span a large and complicated production system then no single intervention at one point will be effective. Indeed, a sensible intervention in one part of the system might lead to unintended losses of performance elsewhere.

It is therefore necessary to apply systems solutions: those that are founded on an understanding of the links, and which involve a set of interventions. This is the single most important theme presented by the most carefully prepared articles in the literature.

4.5 The irrelevancies must be put aside

There appear to be several weaknesses in the literature that derive from a mix of underlying factors. One is that there are vested interests: it is wise, for example, to be cautious of any article that originates in IT consultants, especially if it begins by pointing out that IT investments are lower in health care than (say) banking. This is true but one would need to avoid the assumption that banking is better managed, rather than merely different in terms of the complexity of production processes and information structures. Other vested interests may be less obvious but they exist.

Another disruptive view is presentation of patient safety as a new problem that requires new kinds of solutions. There has always been (and will always continue to be) good reason for concern about patient safety. Spath (2002b) is surely correct in arguing that there is relatively little that is new about the present work on patient safety, and suggesting it might involve little more than the re-naming of activities that have always been needed (and often undertaken, albeit with moderate success at best).

4.6 More of the same, but with more commitment and intelligence

Patient safety is not a new concern. Indeed, it is founded in some of the most basic ideas of health care: it is regularly noted that the Hippocratic Oath says "First do no harm". In fact, it states that doctors should "… help, or at least do no harm". The intent is the same.

Moreover, as is obvious from our review of the literature, many of the ideas and methods relevant to improving patient safety have long been present under other headings like quality assurance, quality improvement, total quality management, and learning organisations. So it is reasonable to ask whether there is any reason to change what health professionals have been trying to do for some time (if not for ever).

In fact, there are several differences of emphasis. The most important is the reminder to health professionals that patients are members of the community who do not deserve to die or to suffer injury as a consequence of mistakes that could have been avoided. The reminder is worth issuing, especially after more than a decade during which the dominant themes in health policy have been matters like reducing government funding in favour of private insurance, reducing the overhead costs of industries that must compete in the global marketplace, fair payment for hospitals, protection of the patents of pharmaceutical companies, privatisation, protection of care providers from unreasonable litigation and excessive insurance fees, and user pay (with its implication that patients and citizens at large must themselves be more responsible and prudent). None of these is a solution to the patient safety problem.

The second aspect that is being emphasised by the patient safety movement is accountability at all levels, from the boardroom to the ward. This reflects many factors, of which perhaps the most important is the recognition that the overwhelming majority of health professionals are never sued if only because most mistakes are concealed and there are ample opportunities to transfer the blame when necessary for self-protection. In a decade where senior managers and board members in most sectors are becoming increasingly likely to be dismissed and publicly shamed for their mistakes, we have yet to experience any significant increase in personal risk in health care boardrooms. We also note that, in some minds, accountability means retribution – thus promoting or perpetuating a culture of blame. There is no evidence to indicate that this leads to sustainable solutions.

For these and other reasons, it is worth supporting the patient safety movement. As Spath (2002c) puts it, all health care professionals must accept their personal responsibility for patient suffering as a consequence of correctable weaknesses in the care process. The movement adds little if anything in a technical sense but it provides additional reasons for the health sector to do what it should have done long ago, and to do it better.

This said, there are some technical themes that have been given additional impetus. They might have become more prominent anyway, even without the surge of interest in avoidable harm, but it is impossible (and not necessary) to know. The enhanced themes are almost all worthy of the additional attention. Among them, it is encouraging to see an increased emphasis on addressing the litigation processes to the extent that they discourage open discussion of errors, on the importance of ‘human factors engineering’ in the sense of recognising the large store of science regarding environmental factors that affect individuals’ error rates, and on the importance of organisational and professional cultures.

Therefore the main message is more of the same or better in terms of clinical practice improvement. This means taking the matter seriously at every level in the health system. All health professionals have a personal responsibility to avoid poor practice that directly or indirectly harms the community at large.

4.7 Three levels of intervention

At the most basic level, it should be easy to design (say) improved methods of patient identification or labelling of the side of the body on which surgery is to take place. It is hardly more complicated to deal with (say) the need for information on each patient to be easily accessible to all clinicians at all times.

At the second level of problem-solving, it is not difficult to see that a stronger sense of team would help resolve most of the first-order problems. The main reason why (say) doctors and nurses tend not to share information very well is that they believe they are different, that they have different interests and responsibilities, and so on: their concept of team is weak. It is also easy to see that (say) there should be routine processes within each clinical team that identify and resolve problems as they are noticed, or that there should be shared responsibility and accountability.

That leads to the third level of problem-solving, where we need the interventions that will address problems like poor teamwork or unclear accountabilities. At this level, the literature suggests we must address culture: attitudes, beliefs, and so on. This applies to all kinds of health professionals, and to patients and their families.

If the cultural constraints are tackled, it seems to us that everything else becomes relatively easier to accomplish. For example, if the senior managers in a large hospital have the right attitudes, they would think of the idea of 'Leadership Walkrounds' as described by Frankel et al (2003) and other authors without having to read about them. If health insurers and other purchasers have the right attitudes, it would not be necessary to tell them that some purchasers are already purchasing patient safety (Delbanco, 2001). Similarly, the lack of consumer involvement is more a consequence of their attitudes to clinicians than of their lack of interest in asking what is happening or why there is no clinical pathway.

We have used the term 'attitudes' here for simplicity. The correct term is culture, which is a more complicated idea. Thus patients need to understand why they behave the way they do, and why doctors and nurses are the way they are.

Fortunately, there is growing evidence that changes in the cultures of concerned parties can be brought about. The evidence is, however, mostly in the literature on clinical pathways, clinical teambuilding, and consumer empowerment.

Finally, it might be expected that the causes of poor patient safety might also be a cause of less than optimal writing about it. This is in fact very obvious: for example, nurses mostly talk about nursing, and anaesthetists about anaesthesiology. Thus it follows that we agree with Woolf (2004) when he says that the patient safety movement can do harm as well as good. His main concern is that there is too little recognition of the fact that patient safety is just one aspect of health system error – which also includes failing to invest adequately in health promotion and chronic disease management. By implication, he is suggesting that articles about patient safety within a single clinical area may divert our attention from the main game.

5 Making a new start

The literature suggests that there are attributes of care provider agencies that are associated with the ability to address problems of patient safety. It would be extremely useful to define these attributes, and develop a way that they might be measured. In the ideal world, one would then have a diagnostic tool that could be applied to indicate those parts of the care provider sector (at facility, department, or clinical team level) that most need attention.

In this section, we will begin by proposing a list of attributes that might serve as indicators. We will then present a template for developing a plan of action for a care provider agency that makes use of that list. Finally, we will suggest how a care provider agency might establish an ongoing process of continual refinement of measures to improve patient safety.

5.1 Attributes of care providers associated with patient safety

The literature on patient safety has many weaknesses, including a significant lack of evidence of cause and effect that was derived from controlled experiments. However, there are many ideas that are supported by strong logic, anecdote, and informed opinion.

We have used the available evidence, with all its weaknesses, as the basis for defining attributes of health care provider agencies that seem to be associated with an ability to recognise and address problems of patient safety. They are arranged in ten domains below, but it should be understood that there are strong relationships – and that some ideas could be listed in more than one domain.

The reader will note that the emphasis is on how care provider staff feel, think, and act rather than on specific actions that are conducive to patient safety. For example, we do not mention ways of identifying patients or writing prescriptions. Even if techniques and technologies are sensible today, they will not remain so for ever.

We believe the literature suggests the underlying strategy underpinning improved patient safety is the establishment of a purposeful system: that is, one that is able to improve itself on a continual basis without outside pressure. Purposeful systems only exist where the attributes listed below are present to a significant extent.

While we have synthesised the literature to develop what follows, there is often no direct 1:1 correspondence between the literature and the domain. Where we have drawn on particular references, or where it would be useful to do some follow up reading, we identify those references.

Domain 1: generating ideas ***(key references and further readings: Institute of Medicine 2001; Small and Barach 2002; Douglas et al 2001)***

Health care is a fundamentally complicated activity, and it can never be free of weaknesses. It follows that there must be a continual search for opportunities to improve. Ways of ensuring this is the case include the following.

Universal responsibility for generating ideas.

Everyone should believe they have a responsibility to suggest improvements. Attitudes that (say) promote the view that ideas are best if introduced by senior staff need to be overcome. Similarly, no-one should be allowed to take the position that they ‘just follow orders’.

Much depends on helping people to understand that most of the weaknesses that result in poor patient safety are not difficult to see or to resolve. The goal is to ensure that everyone in the care provider agency believes he or she is able to design better systems. Assuming it is necessary to obtain expert outside help is a major constraint to improvement.

- Ideas are welcomed.

All ideas should receive positive feedback. They should never generate negative responses, such as 'We tried that before and it didn't work' or 'You don't have enough experience to understand'.

- New or junior staff are given particular encouragement.

Ideas from new or junior staff should be especially encouraged and welcomed. It should be universally accepted that they have different perspectives which are more likely to lead to questioning of long-established approaches.

- It is easy to obtain agreement to make changes.

If someone (or a team) has a good idea, it is should not be necessary to wait a long time while approvals are sought. It should be possible to give rapid approval for action to occur almost immediately.

- Confidential methods of proposing new ideas.

Some staff will always be concerned about openly expressing their ideas. Confidential methods (such as the use of a suggestions box) need to supplement more open approaches. Ideas through confidential sources must be discussed in regular team meetings.

- Public recognition of new ideas and their sources.

It is useful to give public acknowledgment to new ideas, to reward their generation and ensure ideas are widely shared. One method that can be used for this purpose is a regular newsletter that contains summaries of ideas.

- Meetings are structured to ensure the sharing of ideas.

For example, a part of each regular team meeting can be set aside exclusively for the purpose of inviting and briefly discussing ideas for improvement. Clear rules should exist that ensure ideas are given positive responses, along the lines of the rules for brainstorming.

Domain 2: good communication between junior and senior staff *(key references and further readings: Douglas et al 2001; Department of Health 2001)*

Individuals need to receive encouragement and support from their supervisors, if they are to feel free to give and seek advice, discuss problems and opportunities, and so on. This mean junior staff need to be able to have regular, spontaneous, open, and non-threatening communications with senior staff.

Moreover, there needs to be a balanced relationship – for example, a recognition that learning goes both ways. Conversations between senior and junior staff should be based on an acceptance that benefits accrue on all sides, rather than being seen to be the granting of a favour to the junior staff.

- Easy accessibility to senior staff.

Junior staff must believe that they are always welcome to initiate discussions with senior staff. This might mean, for example, that senior staff always have their doors open, and it is not

necessary always to make an appointment – or to explain the purpose to the senior staff's personal assistant.

- Senior staff welcome discussion of problems with junior staff.

Talking about problems should be taken as a positive sign – that the junior staff are thinking about how to change, and how to improve performance.

- Senior staff voluntarily share information.

It is destructive to openness if senior staff act as if there is much information that junior staff should not know or would not understand. Senior staff can overcome this in several ways, such as by routinely volunteering information.

- Effective mentoring.

Mentoring can be an effective way of building teamwork, encouraging and informing junior staff, and so on. However, the process needs to be well designed and operated. For example, it should be multidisciplinary, be subjected to regular evaluation, and there should be formal training in the process.

- Discussions initiated by senior staff.

It is important that senior staff take the initiative in having informal discussions with junior staff. For example, senior staff should regularly go to visit junior staff where they work, to ask for their views. This is not only a good way to generate ideas and build a sense of belonging: it also gives an important cultural message about valuing the contributions of junior staff.

Domain 3: good communication between clinicians in different professions *(key references and further readings: Sherwood et al 2002; Turnball 2001; Mohr et al 2003)*

Patient care is almost always a task that requires teamwork among clinicians of different professions. Effective communication is therefore essential if processes are to be safe, and clinical work is to be less stressful.

- Patient documentation is shared.

If documentation is not shared, there are likely to be risky misunderstandings. The processes of documentation will be less than efficient, and there are likely to be omissions and duplications. Moreover, mutual understanding and respect are difficult to achieve unless all information about a patient is easily available to all clinical staff.

- The best way to share information is on a patient care plan.

The details can be variable, but it is hard to see how good communication can be achieved unless there is a single document that contains all the important notes about care to be provided, by whom and when, and where actual care can be documented. Care pathways are essential to good communication among the clinical staff.

- Meetings are usually multidisciplinary.

Meetings to make plans and review progress regarding each patient's episode of care should normally be multidisciplinary. As a minimum, there should be a clearly understood schedule of meetings for planning and review, and all clinicians should be encouraged to attend.

There should also be clear rules for the conduct of meetings. They should include, for example, a requirement to ensure everyone feels free to participate regardless of seniority.

Domain 4: shared management of information systems *(key references and further readings: Lanser 2001; Nadzam and Macklis 2001; Abrahamsen 2003)*

Health care is an information-intensive industry. It is important that there is shared management of all aspects including design, operation, and evaluation. All clinical staff should view clinical documentation as an essential definition of what they need to know.

- Recording of information is determined by the multidisciplinary team.

No information should be routinely compiled unless the reasons for doing so have been discussed by all members of the care team, and agreement has been reached on its usefulness.

There should never be an unchallenged opinion that there are too many routine statistics. No-one should be expected to collect data if they are not convinced as to its usefulness.

- Information about patients is owned by the patient.

With rare exceptions, all clinical staff should believe that information is never theirs, but always the patient's. Each clinician is merely an agent of the patient in this regard.

- Information is easily available for all the care team.

There should be no secrets, unless it is clearly in the patient's interests. All information should be designed to maximise ease of access by all members of the care team.

Confidentiality of that information is a matter for the patient to decide. Failure of clinicians to share that information with other clinicians should only be allowed when the patient has formally indicated this is to be done.

- All information is patient information.

No clinical profession should claim exclusive rights to define and manage subsets of patient information. Clinicians of one profession should be encouraged to ask questions and give opinions about the information generated by clinicians of other professions.

- Reporting is by exception to the maximum extent possible.

One common cause of errors is that there is too much information to be easily absorbed, and consequently important elements (or relationships between them) are overlooked. This risk should be reduced by specifying what is normal (and which therefore only need to be briefly noted) and giving emphasis to what is not normal.

This is, of course, the idea underlying variance reporting on a care pathway. The pathway itself defines what is normal, thus leaving staff with more time to identify and document what is abnormal (or for other reasons places the patient's safety at risk).

Domain 5: shared responsibility and accountability *(key references and further readings: Classen and Kilbridge 2002; Deming 1993; Weinberg 2002)*

There should be a willingness to share responsibility for all aspects of patient care. This includes sharing of responsibilities for identifying problems, defining solutions, and taking action to resolve problems of all kinds.

There must also be shared accountability – that is, for ensuring that performance is accurately reported to all parties who have a right to know.

- All staff should take the initiative in fixing problems.

All problems are shared problems, and everyone should have the attitude that it is appropriate for them to fix it. No-one should have the view that it is somebody else's problem.

- Blame is the last option for fixing mistakes.

No-one should be blamed for making mistakes, unless it is the last option available. Rather, everyone should accept that they are a part of a complicated system in which errors are unavoidable.

- Admission of errors is a sign of strength and deserves praise.

Taking responsibility and accountability means that everyone must be willing and able to declare their own mistakes. Those who do so should be regarded by all staff as being brave and sensible.

- Passing the blame is indefensible and needs to be criticised.

It is always desirable for staff to admit they made mistakes, and never useful to point out that someone else was to blame. The correct approach is for everyone to agree there is a problem for which there is collective responsibility, and for everyone to focus on solving it.

Domain 6: continuous learning ***(key references and further readings: Eisenberg 2000; Elkin and Gorman 2002; Ferlie and Shortell 2001)***

There should be attitudes and behaviours that ensure there is a continuous desire to identify opportunities for improvement through acquisition of knowledge. Learning should be driven by self-motivation – all staff should have a personal desire to improve. It should also be driven by an organisation-wide respect for learning together with clear rewards for doing so.

- Processes are always subjected to monitoring and evaluation.

There should be a universal attitude that processes need to be checked, no matter who designed them or how long they have been in use.

- Monitoring and evaluation are ongoing and informal.

It is always appropriate to ask questions about the suitability of care processes. It is not necessary to wait for a formal plan or protocol.

- Finding and announcing mistakes are signs of strength.

There should be an all-pervasive attitude that it is helpful to discover mistakes, and that patients will suffer in future unless the mistakes are openly declared and subjected to discussion. Every mistake found and discussed creates opportunities to make improvements.

- Asking for advice is a sign of strength.

There should be a willingness in all staff continually to seek advice. If they are embarrassed to admit they do not know or they do not understand, they will be missing opportunities for self-improvement and enhancement of patient safety.

- Organisational honesty.

By this, we mean a continuous process of declaring the truth as far as it is understood. This should encompass open acceptance of both strengths and weaknesses. It is not present if the official face of the care provider organisation is characterised by claims of excellence, or that most of its problems are caused by outsiders (such as the government or the insurer).

Domain 7: team work *(key references and further readings: Firth-Cozens 2001; Bender 2000; Barrett et al 2001)*

Team work means there is a recognition that good patient care requires the skills of many people. It means there is an understanding and respect for the contributions of everyone, and that there is a commitment to share ideas, information, responsibilities, and accountability.

- Patient care is a team task unless otherwise agreed.

There are some tasks that are better done by individuals, but the default is that all tasks are team tasks. An attitude should exist whereby individuals are happy to work in a team, and understand that this is beneficial both to care providers and to patients and their families.

- If someone asks for help, people are happy to give it.

Asking for help should usually be seen as an opportunity to make a contribution to the patient care process, and consequently to improved patient safety. It is also an invaluable way of building teamwork and mutual respect.

- Everyone talks about ‘our’ patients rather than ‘my’ patients.

This is one simple illustration of the importance of language in creating and maintaining the sense of team. The use of ‘my patient’ is known to lead to a sense among the listeners that comments and suggestions would not be welcomed.

- People are often praised for their work.

Most clinicians work better if there are open signs of appreciation. The degree to which good work is praised is largely a reflection of habit (rather than the extent to which work performance is praiseworthy). Changing the habit is possible with a little persistence at the level of individuals and the team as a whole.

- Patients are also part of the team.

The health system exists for patients, not to do things to them. Patients should be an integral part of the process, and also need to share responsibility for what happens.

Domain 8: consumer involvement *(key references and further readings: Sanford 2002; Vicente and Coulter 2002; Sage 2002)*

The effective involvement of patients and families is not only a matter of right. It is also a cost-effective way of finding problems and solutions.

- Well-written materials for patients and families.

Patients and families should be given well-written materials to read, without having to ask. The materials should describe every aspect of the care patients are likely to receive, and should be based on frequent testing that involves asking recent patients and their families.

- Questions from patients and families are welcomed.

Questions from patients and families should be welcomed by all care provider staff. They should be seen to be an opportunity to provide better care, rather than an annoyance. Questioning by patients and families should be accepted as normal and desirable, and answers should be thoughtful, useful, and respectful.

Domain 9: effective meetings ***(key references and further readings: Piotrowski et al 2002; Frankel et al 2003; Gandhi et al 2003)***

We have already made passing mention of meetings, but they are sufficiently important to merit separate reference to them. Meetings create excellent opportunities to meet patient safety goals – to share ideas, to build team spirit, to motivate, to make collective decisions, and so on. However, meetings are often poorly managed in many care provider agencies.

- There are agreed rules of conduct that are regularly evaluated.

There have to be agreed rules if constructive behaviour is to become the norm. The rules should cover many aspects including chairing, avoidance of destructive behaviour such as ponceing, and logistical matters such as starting and finishing on schedule.

- Meetings should be routinely evaluated.

This is a simple but important point. One reason why meetings are seldom evaluated is that there are fears of giving offence, and another is that it takes time to do so.

- Different kinds of meetings are needed for different purposes.

This is an obvious point, but it is often overlooked. For example, a meeting that aims to generate ideas needs different rules to one where the aim is to make decisions.

Domain 10: a useful definition of leadership ***(key references and further readings: Cohen et al 2003; Mycek 2001; Wachter et al 2002)***

- What leadership means.

By leadership, we mean the act of encouraging others to take a particular course of action. It typically involves choosing to be first to suggest a new course of action, and volunteering to make sure agreed actions are implemented.

This said, there are many ways in which leadership can be shown and some can be counter-productive. Of particular importance, it can result in a diminution of shared responsibility and accountability, and it can reduce the extent to which other staff (and particularly junior or new staff) are willing and able to identify errors and propose practice improvements.

- Leadership is a shared task.

All staff should consider themselves to be responsible for showing leadership on occasions. Furthermore, all staff should recognise that leadership can be shared: groups can and should work together to take the initiative, make sure decisions are made, and so on.

- No leadership can be effective unless it occurs at all levels in the organisation.

It is often said that Boards of Management should show leadership, and this is true to some extent. However, they cannot by themselves effectively encourage practising clinicians to take particular courses of action on a daily basis in all parts of the organisation. Indeed, the Board's most useful function with regard to leadership is to encourage and reward large numbers of staff to exercise it.

5.2 An action plan for improving patient safety

All health care organisations have distinctive features, and are at different stages in terms of improving their patient safety. Consequently, no single course of action is suitable for everyone.

The following is therefore presented as a checklist against which each organisation might review its own programs. Many of the ideas might not be relevant, and others might have already been

applied in other ways. In general, they emerge from this review and our own research experience as a set of sensible, well-grounded actions.

Step 1: appoint an ad hoc group to initiate the process

Responsibility for implementing the process outlined here needs to be assigned to a group within the care provider agency. It may well be that a suitable group already exists, such as a high-level clinical council or even a patient safety committee. If so, that group might need only appoint a subset of its members to manage the work.

If a suitable group does not exist, we suggest that one be created for a short period of time (and probably not more than six months) to manage these tasks. There seem to be few rules that need to be followed when appointing the group, of which the most important is ensuring that the members are committed to the ideas and are influential among clinical staff.

Given the nature of most care provider agencies, we suspect that at least one practising clinician from each of medicine, nursing, and allied health is required. The main challenge will be to engage practising clinicians, and this is usually better done by using opinion leaders from each of the groups.

Finally, we believe that at least one consumer representative should always be present in any group that is being asked to stimulate change in clinical practice. This may be especially important in the context of patient safety. It will, however, be important to make sure that the consumer representative is well-informed, and willing and able to take a strong position on key ideas.

Step 2: form a shared view of the importance of the problem

It is highly unlikely that much progress will be made if the issue of patient safety is not considered to be important, or if only some staff think it is important. We have noted above that problems of patient safety mainly arise as a consequence of attitudes and behaviours that tend to be system-wide. In other words, if the dominant organisational and clinical professional cultures are unsuitable to achieving a satisfactory level of patient safety.

A consequence is that, if change is to occur, it will require many staff to believe it is necessary. The modification of dominant cultures depends on a collective commitment.

There are several ways of establishing a shared view of the importance of improving patient safety. We recommend you consider distributing the questionnaire shown as Appendix B to a representative sample of staff, and collating the results.

You should aim to produce a simple report that summarises the main results. This might consist of little more than the average rating of each item separated by profession. The main categories should be as follows:

- Medical managers (doctors with supervisory responsibilities over other doctors)
- Medical clinicians (practising doctors without significant supervisory responsibilities)
- Nursing managers (nurses with supervisory responsibilities over other nurses)
- Nursing clinicians (practising nurses without significant supervisory responsibilities)
- Allied health managers (allied health staff with supervisory responsibilities over other allied health staff)

- Allied health clinicians (practising allied health staff without significant supervisory responsibilities)
- Lay managers (management staff with no direct clinical responsibilities such as managers of accounts, personnel, and supplies)
- Senior executives and Board members.

You need to achieve a level of at least 85% of staff believing that patient safety is ‘high priority’ or ‘very high priority’. Moreover, there should be at least 65% in each of the five professional categories. Unless these levels are achieved, you might have insufficient momentum to ensure progress is made.

Step 3: take corrective action if the level of concern is below thresholds

You can choose to proceed even though fewer than 85% of staff overall (or fewer than 65% in any professional category) believe that patient safety is ‘high priority’ or ‘very high priority’. However, we believe this would be unwise.

Rather, you should consider taking action to change the views of some staff who do not yet believe the issue is important. We suggest you use a combination of the following measures:

- Distribution of this document to all senior staff with an invitation to comment.
- Distribution of copies of some of the key papers listed in Appendix C, again with an invitation to comment.
- Conduct of lunchtime seminars by opinion leaders in each of the professional categories, who themselves believe the issue is of ‘high priority’ or ‘very high priority’. You can target the professional group(s) where there is the least support.
- Organisation of an open debate, to which you should invite a mix of strong proponents of both views.
- The conduct of informal meetings with those staff who have the least concern for patient safety, together with strong proponents of action
- The conduct of informal workshops for clinical teams where there seems to be a significant degree of conflicting opinion.

By the end of this step, you should have achieved some degree of improvement in attitudes towards treating patient safety as a high-priority issue. If not, you may need to continue to repeat the steps listed above (together with others that you think might help) until there is no sign of any further movement.

Step 4: organisation-wide statement of commitment

Here, we are envisaging a document signed by all senior staff and opinion leaders in the care provider agency that states why there is concern about patient safety and what, in general terms, needs to be done. Here, we will call this the Patient Safety Policy Statement (or simply the Policy Statement) for convenience.

Much of the content of the Policy Statement can be based on materials from this paper, together with the results of administering the questionnaire described in Step #2. In general, it should have at least the following elements:

- A summary of the evidence worldwide regarding the significance of problems of patient safety
- What seem to be the factors that are conducive to improvements in patient safety
- The views of staff in the care provider agency regarding problem areas
- How the care provider agency intends to address the problem areas on an ongoing basis (and in particular what is intended to be done in Steps #5 and #6 as described below).
- How the Policy Statement relates to existing activities that are related to patient safety (such as the reporting of adverse events, or participation in accreditation).

The Policy Statement should be widely distributed for comment, and the comments received carefully reviewed. Serious responses should be prepared and returned to those who provided the comments, and account taken of those comments in finalising the Policy Statement.

Step 5: a one-year workplan for every clinical team

We suggest that every clinical team be asked to outline a one-year workplan to improve its own patient safety, of which an essential element would be the conduct of a review of patient safety for one of its high-volume case types. The review would involve an initial assessment, a set of activities, and a final assessment to indicate the extent to which there had been improvements during the period.

It would probably be unwise to over-specify the required actions, since this might result in a degree of resentment about 'top-down management', clinical ignorance, and so on. However, a general template should be provided as a guide, together with appropriate comments on the freedom of care teams to take a different approach towards the same general objectives. Such a template is illustrated in Appendix D, which includes the use of a survey instrument that is presented in Appendix E.

Step 6: workshop for presentation and discussion of results

The reports generated in Step #5 should be distributed across the care provider agency in advance of a workshop at which the results are presented. Depending on the number of teams, it might be necessary to hold two or more sessions. It should be an expectation that all teams will present their results.

Presentations should be largely unnecessary (perhaps five minutes at most) given that the reports have been distributed in advance. Most of the time should be allocated to asking questions and discussing the results.

Step 7: iterate from Step #4

The results of the workshop might require the Policy Statement to be updated. The main requirement, however, is likely to be that each clinical team established another one-year workplan leading to reports of the type described above.

We see no need to be prescriptive here: if sufficient numbers of clinicians have taken the above process seriously, there will be enough local knowledge and commitment for the teams to set their own agendas for the future.

5.3 Summary: Attributes to aim for

- **Generating ideas:** everyone should believe they have a responsibility to suggest improvements, openly as well as confidentially.
- **Good communication** between junior and senior staff, as well as between clinicians in different professions.
- **Shared management of information systems:** all information is patient information (not exclusively clinical staff information), and should be easily available for the entire care team.
- **Shared responsibility and accountability**: all staff should take the initiative in fixing problems; blame is the last option for fixing mistakes.
- **Continuous learning:** processes are always subjected to informal, ongoing evaluation; finding and announcing mistakes, and asking for advice, are signs of strength.
- **Team work** means that good patient care requires the skills of many people; team members should be regularly praised for their work; patients are also part of the team.
- **Consumer involvement:** providing well-written materials to, and welcoming questions from, patients and their families.
- **Effective meetings:** meetings are excellent opportunities to share ideas, to build team spirit, to make collective decisions, etc. To be effective, they need agreed rules and benefit from routine evaluation.
- **A useful definition of leadership:** all staff, at all levels in the organisation, should consider themselves responsible for showing leadership on occasion.

5.4 Summary: Action plan for improving patient safety

- ☐ **Step 1: appoint an ad hoc group to initiate the process** which includes at least one practicing clinician from each of medicine, nursing and allied health professions.
- ☐ **Step 2: form a shared view of the importance of the problem:** unless at least 85% of staff believe that patient safety is ‘high priority’ or greater, progress may be hard to achieve.
- ☐ **Step 3: take corrective action if the level of concern is below thresholds:** distribute documents, organise formal and informal meetings as required to raise awareness.
- ☐ **Step 4: write an organisation-wide statement of commitment** that has sign-off from all senior staff and opinion leaders.
- ☐ **Step 5: create a one-year workplan for every clinical team.**
- ☐ **Step 6: present and discuss results** to consolidate the aims of each workplan across the entire care provider agency.
- ☐ **Step 7: update statement of commitment** if feedback from Step#6 warrants it.

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Appendices

Appendix A: references and bibliography

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Appendix B: diagnostic questionnaire

This questionnaire is intended to provide a basis for care provider agencies to survey the views of their staff regarding factors associated with patient safety. It is for illustration only, and each agency should feel free to adapt it as considered appropriate. It can also be used by individual services or units to develop a workplan for their own patient safety initiatives (see Appendix E).

Overview of your opinions about patient safety

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Health care is more complicated than most other industries, and some errors are unavoidable.	☐	☐	☐	☐	☐
We could do much better, even within the limited available resources.	☐	☐	☐	☐	☐
We need to make a more concerted effort to improve patient safety across our agency.	☐	☐	☐	☐	☐
We need to begin immediately to find ways of improving patient safety.	☐	☐	☐	☐	☐

Domain 1: generating ideas

Health care is a fundamentally complicated activity, and it can never be free of weaknesses. It follows that there must be a continual search for opportunities to improve.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Nearly everyone accepts responsibility for suggesting improvements, and they do in fact generate good ideas at frequent intervals.	☐	☐	☐	☐	☐
Most people believe they must wait for ideas to be introduced by senior staff. They believe they should just follow orders.	☐	☐	☐	☐	☐
All ideas for change are welcomed, and they always receive positive feedback.	☐	☐	☐	☐	☐
Ideas from new or junior staff are especially encouraged and welcomed. It is good that they bring different perspectives.	☐	☐	☐	☐	☐
If someone has a good idea, it is usually given rapid approval.	☐	☐	☐	☐	☐
We make use of confidential methods (such as a suggestions box) for ideas generation, in case some people are concerned about openly expressing their ideas.	☐	☐	☐	☐	☐

If staff have a good idea, we give them public acknowledgment as a reward (for example, in our Newsletter).	☐	☐	☐	☐	☐
We set aside a part of each regular team meeting for the purpose of inviting and briefly discussing ideas for improvement.	☐	☐	☐	☐	☐
We have clear rules, to ensure that ideas are always given positive responses.	☐	☐	☐	☐	☐

Domain 2: good communication between junior and senior staff

Individuals need to receive encouragement and support from their supervisors, if they are to feel free to give and seek advice, discuss problems and opportunities, and so on. This mean junior staff need to be able to have regular, spontaneous, open, and non-threatening communications with senior staff.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
Junior staff are always able easily to initiate discussions with senior staff. For example, some senior staff always have their doors open, to reduce the barriers.	☐	☐	☐	☐	☐
Senior staff encourage junior staff to talk about problems. Senior staff believe this is a positive sign – that the junior staff are thinking about how to change, and how to improve performance.	☐	☐	☐	☐	☐
Senior staff voluntarily share information with junior staff, to show they are respected.	☐	☐	☐	☐	☐
We use mentoring as a way of building teamwork.	☐	☐	☐	☐	☐
Our mentoring is well-designed and is multidisciplinary. In other words, mentors can be from a different clinical profession than the person being mentored.	☐	☐	☐	☐	☐
Senior staff often take the initiative in having informal discussions with junior staff. They often go to visit junior staff where they work, to ask for their views.	☐	☐	☐	☐	☐

Domain 3: good communication between clinicians in different professions

Patient care is almost always a task that requires teamwork among clinicians of different professions. Effective communication is therefore essential if processes are to be safe, and clinical work is to be less stressful.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Almost all patient documentation is shared among all clinical professions. For example, we have largely abandoned the idea of separate medical and nursing notes.	☐	☐	☐	☐	☐
Multidisciplinary care plans (care pathways, clinical pathways) are widely used, and are becoming the normal approach.	☐	☐	☐	☐	☐
Our meetings to review progress regarding each patient's episode of care are almost all multidisciplinary.	☐	☐	☐	☐	☐
We have clear rules about the conduct of our clinical team meetings.	☐	☐	☐	☐	☐
In our clinical team meetings, we make sure that everyone feels free to participate regardless of seniority or clinical profession.	☐	☐	☐	☐	☐

Domain 4: shared management of information systems

Health care is an information-intensive industry. It is important that there is shared management of all aspects including design, operation, and evaluation. All clinical staff should view clinical documentation as an essential definition of what they need to know.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
All patient care documents are subject to review by the entire multidisciplinary team.	☐	☐	☐	☐	☐
There are too many routine statistics to collect. For some of them, most people don't know the purpose of collecting them.	☐	☐	☐	☐	☐
With rare exceptions, all clinical staff believe that information is never theirs, but always the patient's. Each clinician is merely an agent of the patient in this regard.	☐	☐	☐	☐	☐
All patient information is easily available for all the care team, regardless of whether it concerns medical, nursing, or any other component of care.	☐	☐	☐	☐	☐
Recording of patient data is largely by exception. For example, the care pathway defines what is normal, and then we can focus on abnormal (the variances from the pathway).	☐	☐	☐	☐	☐

For complicated patients, our records are not well structured. This means there is always a risk that important elements (or relationships between them) are overlooked.	☐	☐	☐	☐	☐

Domain 5: shared responsibility and accountability

There should be a willingness to share responsibility for all aspects of patient care. This includes sharing of responsibilities for identifying problems, defining solutions, and taking action to resolve problems of all kinds. There must also be shared accountability – that is, for ensuring that performance is accurately reported to all parties who have a right to know.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
Every problem is a shared problem, and everyone is willing to have a go at fixing it. We don't just leave it for someone else.	☐	☐	☐	☐	☐
We don't spend time trying to find someone to blame. We just accept it that we are a part of a complicated system in which errors are unavoidable.	☐	☐	☐	☐	☐
We believe that we should openly admit our mistakes. Being able to do so is a sign of strength rather than weakness.	☐	☐	☐	☐	☐

Domain 6: continuous learning

There should be attitudes and behaviours that ensure there is a continuous desire to identify opportunities for improvement through acquisition of knowledge. Learning should be driven by self-motivation – all staff should have a personal desire to improve. It should also be driven by an organisation-wide respect for learning together with clear rewards for doing so.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
We believe all processes should be reviewed from time to time, no matter who designed them or how long they have been in use.	☐	☐	☐	☐	☐
We are always monitoring and evaluating. It is part of good clinical practice, and does not need to wait for a formal plan or protocol.	☐	☐	☐	☐	☐
We believe every mistake, once found and discussed openly, becomes an opportunity to make improvements.	☐	☐	☐	☐	☐
We regularly ask each other for advice. We are not embarrassed to admit we do not know or understand.	☐	☐	☐	☐	☐
We make very few mistakes. Most of our problems are caused by outsiders (such as the government or the insurer).	☐	☐	☐	☐	☐

Domain 7: team work

Team work means there is a recognition that good patient care requires the skills of many people. It means there is an understanding and respect for the contributions of everyone, and that there is a commitment to share ideas, information, responsibilities, and accountability.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
We like to define as many tasks as possible to be team tasks.	☐	☐	☐	☐	☐
If someone asks for help, people are happy to give it.	☐	☐	☐	☐	☐
Everyone talks about 'our' patients rather than 'my' patients.	☐	☐	☐	☐	☐
People are often praised for their work. This builds trust, respect, and self-confidence.	☐	☐	☐	☐	☐
Patients are considered part of the team.	☐	☐	☐	☐	☐

Domain 8: consumer involvement

The effective involvement of patients and families is not only a matter of right. It is also a cost-effective way of finding problems and solutions.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Patients and families are normally given well-written materials to read, without having to ask.	☐	☐	☐	☐	☐
Materials prepared for patients and families usually describe every aspect of the care patients are likely to receive, and are continually refined through asking recent patients and their families for suggestions.	☐	☐	☐	☐	☐
Questions from patients and families are welcomed by most of our staff. Answers are usually thoughtful, useful, and respectful.	☐	☐	☐	☐	☐

Domain 9: effective meetings

We have already made passing mention of meetings, but they are sufficiently important to merit separate reference to them. Meetings create excellent opportunities to meet patient safety goals – to share ideas, to build team spirit, to motivate, to make collective decisions, and so on. However, meetings are often poorly managed in many care provider agencies.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
We have well-designed rules of conduct for our meetings, and we make sure there is compliance with those rules.	☐	☐	☐	☐	☐
We formally evaluate our meetings from time to time.	☐	☐	☐	☐	☐

Domain 10: leadership

By leadership, we mean the act of encouraging others to take a particular course of action. It typically involves choosing to be first to suggest a new course of action, and volunteering to make sure agreed actions are implemented. Leadership must be shared, and must exist at all levels of the organisation.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
We believe all staff should consider themselves to be responsible for showing leadership on occasions.	☐	☐	☐	☐	☐
We regularly try to ensure that leadership is shared.	☐	☐	☐	☐	☐
We have good leadership at all levels in our organisation, from the clinical team to the boardroom.	☐	☐	☐	☐	☐

Appendix C: important references

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Appendix D: a template for the workplan

In section 5, we suggested that a health care provider organisation might consider undertaking a plan of work directed at reviewing and possibly improving patient safety. Step #5 of the proposed approach referred to the conduct of a one-year workplan by each clinical team in the organisation. This Appendix outlines the form that such a workplan might take.

Foreword

Each clinical team is invited to undertake an analysis of aspects of its work in accordance with the underlying ideas illustrated below. Any structured activity is acceptable as long as it meets the broad objectives of this work.

By clinical team, we mean all clinicians who are normally involved in the care of a category of patient during an episode of care. Thus it will normally comprise doctors, nurses, diagnostic services staff, and allied health professionals in areas such as physiotherapy, dietetics, and social work. An episode of care will usually comprise a complete inpatient episode, and might also include pre-admission and post-discharge services.

D.1 Objective

The objective is to provide each clinical team with the opportunity to review factors of its work that are related to patient safety, to undertake some interventions to improve the situation, and to asses the extent that there have been improvements as a consequence of those interventions.

D.2 Method of study

1 Select one of more case types

Each clinical team should select one or more high-volume case types to be the focus of attention. The choice is largely a matter for each team's discretion, but account might be take of other factors – such as the degree to which there seems to be a higher than average risk to patient safety, or whether there is an intention of making changes in normal methods of care during the study period.

2 Undertake a baseline survey of views of members of the team

We recommend that the core method of study should be recording and analysis of the subjective views of all members of the clinical team, by use of a questionnaire of the kind shown in Appendix E.

The questionnaire should be administered as soon as possible in the study period. Assistance with compilation of the results should be provided (and this might involve the use of a simple computer package for survey data analysis).

3 Identify and implement one or more changes in clinical practice

The changes should be those that are likely to have the most significant effect in terms of improvement in patient safety. However, the dominant principle is that the changes are generally considered to be advisable in the interests of improving clinical practice. It is likely that the changes had already been considered necessary by at least some members of the clinical team (and possibly for reasons that had not been explicitly associated with patient safety).

The questionnaire in Appendix E provides a format for recording the views of each team member regarding possible interventions to improve patient safety. However, the clinical team should not feel constrained to define its interventions in that way.

Implementation should be well designed, of course. However, it is preferable to avoid any unnecessary delays in implementation because this will reduce the interval between the baseline and the post-intervention surveys.

4 Identify any data elements that may be useful for evaluation

Before implementation, the team should decide whether it wishes to collect additional information of relevance to evaluation of the impact of the changes. For example, if it does not have this already, the team might wish to establish a process of recording of adverse events, or to modify the classification of variances within a clinical pathway system.

This is a matter left to the discretion of the team itself. The only required data are results of the initial and post-intervention surveys of opinion by use of the instrument shown in Appendix E, plus a brief description of the interventions themselves.

5 Undertake the post-intervention survey of views of members of the team

This simply involves repeating administration of the opinions questionnaire shown in Appendix E. Again, all team members should be asked to participate. It is advisable to be able to match questionnaire results across the two applications, so that changes in opinions can be analysed by type of respondent (such as whether doctors or nurses changed their assessments to the greater degree).

D.3 Report the results

The format, content and length of the report may be adjusted according each team's interests and judgement. However, as a minimum, there should be sections on the following matters:

- Baseline views about problems of patient safety, categorised by type of team member
- Descriptions of the interventions, how they were introduced, and lessons learned
- Post-intervention views about problems of patient safety, categorised by type of team member, and compared with baseline views.

Finally, there should be a brief summary of the experiences in terms of what has been learned about patient safety, and ideas that might be of interest to other care teams. We envisage a report of no more than five to ten pages. The key factors are honesty, shared views across members of the team, and educational value.

Appendix E: a questionnaire for use in a patient safety workplan

In Appendix D, we suggested the conduct of an annual workplan to review and possibly refine patient safety. A core element of the workplan would be the recording and analysis of subjective views of all members of the clinical team, by use of a questionnaire of the kind shown below. The questionnaire would be administered at the start and near the end of the workplan period.

Note that it is almost identical to that shown in Appendix B. This is deliberate: a common structure of enquiry will facilitate comparisons. Note also that the questionnaire provides a format for recording the views of each team member regarding possible interventions to improve patient safety.

Domain 1: generating ideas

Health care is a fundamentally complicated activity, and it can never be free of weaknesses. It follows that there must be a continual search for opportunities to improve.

Overall assessment of your team's performance for this category of patient care episode:

Put 'X' in one box on each row to show extent to which you agree with each statement about your team.	***Yes, true*** ↓	2	3	4	***No, not true at all*** ↓
Nearly everyone accepts responsibility for suggesting improvements, and they do in fact generate good ideas at frequent intervals.	☐	☐	☐	☐	☐
All ideas for change are welcomed, and they always receive positive feedback.	☐	☐	☐	☐	☐
Ideas from new or junior staff are especially encouraged and welcomed.	☐	☐	☐	☐	☐
If someone has a good idea, it is usually given rapid approval.	☐	☐	☐	☐	☐

Possible actions that might be needed to correct deficiencies in your team:

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Very useful*** ↓	2	3	4	***Not needed*** ↓
A suggestions box or other method of allowing team members to make suggestions in confidence.	☐	☐	☐	☐	☐
Public acknowledgement of good ideas, through a Newsletter or in other ways.	☐	☐	☐	☐	☐
Changing our regular team meetings for the purpose of inviting and briefly discussing ideas for improvement.	☐	☐	☐	☐	☐
Changing attitudes, to ensure that ideas are always given positive responses.	☐	☐	☐	☐	☐
Other (write in): _____	☐	☐	☐	☐	☐
Other (write in): _____	☐	☐	☐	☐	☐

Domain 2: good communication between junior and senior staff

Individuals need to receive encouragement and support from their supervisors, if they are to feel free to give and seek advice, discuss problems and opportunities, and so on. This mean junior staff need to be able to have regular, spontaneous, open, and non-threatening communications with senior staff.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
Junior staff are always able easily to initiate discussions with senior staff. For example, some senior staff always have their doors open, to reduce the barriers.	☐	☐	☐	☐	☐
Senior staff encourage junior staff to talk about problems. Senior staff believe this is a positive sign – that the junior staff are thinking about how to change, and how to improve performance.	☐	☐	☐	☐	☐
Senior staff voluntarily share information with junior staff, to show they are respected.	☐	☐	☐	☐	☐
We use mentoring as a way of building teamwork.	☐	☐	☐	☐	☐
Our mentoring is well-designed and is multidisciplinary. In other words, mentors can be from a different clinical profession than the person being mentored.	☐	☐	☐	☐	☐
Senior staff often take the initiative in having informal discussions with junior staff. They often go to visit junior staff where they work, to ask for their views.	☐	☐	☐	☐	☐
Other (write in): _____	☐	☐	☐	☐	☐
Other (write in): _____	☐	☐	☐	☐	☐

Domain 3: good communication between clinicians in different professions

Patient care is almost always a task that requires teamwork among clinicians of different professions. Effective communication is therefore essential if processes are to be safe, and clinical work is to be less stressful.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree***				***Strongly disagree***
	↓	2	3	4	↓
Almost all patient documentation is shared among all clinical professions. For example, we have largely abandoned the idea of separate medical and nursing notes.	☐	☐	☐	☐	☐
Multidisciplinary care plans (care pathways, clinical pathways) are widely used, and are becoming the normal approach.	☐	☐	☐	☐	☐
Our meetings to review progress regarding each patient's episode of care are almost all multidisciplinary.	☐	☐	☐	☐	☐

We have clear rules about the conduct of our clinical team meetings.	☐	☐	☐	☐	☐
In our clinical team meetings, we make sure that everyone feels free to participate regardless of seniority or clinical profession.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 4: shared management of information systems

Health care is an information-intensive industry. It is important that there is shared management of all aspects including design, operation, and evaluation. All clinical staff should view clinical documentation as an essential definition of what they need to know.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
All patient care documents are subject to review by the entire multidisciplinary team.	☐	☐	☐	☐	☐
There are too many routine statistics to collect. For some of them, most people don't know the purpose of collecting them.	☐	☐	☐	☐	☐
With rare exceptions, all clinical staff believe that information is never theirs, but always the patient's. Each clinician is merely an agent of the patient in this regard.	☐	☐	☐	☐	☐
All patient information is easily available for all the care team, regardless of whether it concerns medical, nursing, or any other component of care.	☐	☐	☐	☐	☐
Recording of patient data is largely by exception. For example, the care pathway defines what is normal, and then we can focus on abnormal (the variances from the pathway).	☐	☐	☐	☐	☐
For complicated patients, our records are not well structured. This means there is always a risk that important elements (or relationships between them) are overlooked.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 5: shared responsibility and accountability

There should be a willingness to share responsibility for all aspects of patient care. This includes sharing of responsibilities for identifying problems, defining solutions, and taking action to resolve problems of all kinds. There must also be shared accountability – that is, for ensuring that performance is accurately reported to all parties who have a right to know.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Every problem is a shared problem, and everyone is willing to have a go at fixing it. We don't just leave it for someone else.	☐	☐	☐	☐	☐
We don't spend time trying to find someone to blame. We just accept it that we are a part of a complicated system in which errors are unavoidable.	☐	☐	☐	☐	☐
We believe that we should openly admit our mistakes. Being able to do so is a sign of strength rather than weakness.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 6: continuous learning

There should be attitudes and behaviours that ensure there is a continuous desire to identify opportunities for improvement through acquisition of knowledge. Learning should be driven by self-motivation – all staff should have a personal desire to improve. It should also be driven by an organisation-wide respect for learning together with clear rewards for doing so.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
We believe all processes should be reviewed from time to time, no matter who designed them or how long they have been in use.	☐	☐	☐	☐	☐
We are always monitoring and evaluating. It is part of good clinical practice, and does not need to wait for a formal plan or protocol.	☐	☐	☐	☐	☐
We believe every mistake, once found and discussed openly, becomes an opportunity to make improvements.	☐	☐	☐	☐	☐
We regularly ask each other for advice. We are not embarrassed to admit we do not know or understand.	☐	☐	☐	☐	☐
We make very few mistakes. Most of our problems are caused by outsiders (such as the government or the insurer).	☐	☐	☐	☐	☐

Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 7: team work

Team work means there is a recognition that good patient care requires the skills of many people. It means there is an understanding and respect for the contributions of everyone, and that there is a commitment to share ideas, information, responsibilities, and accountability.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
We like to define as many tasks as possible to be team tasks.	☐	☐	☐	☐	☐
If someone asks for help, people are happy to give it.	☐	☐	☐	☐	☐
Everyone talks about 'our' patients rather than 'my' patients.	☐	☐	☐	☐	☐
People are often praised for their work. This builds trust, respect, and self-confidence.	☐	☐	☐	☐	☐
Patients are considered part of the team.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 8: consumer involvement

The effective involvement of patients and families is not only a matter of right. It is also a cost-effective way of finding problems and solutions.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
Patients and families are normally given well-written materials to read, without having to ask.	☐	☐	☐	☐	☐
Materials prepared for patients and families usually describe every aspect of the care patients are likely to receive, and are continually refined through asking recent patients and their families for suggestions.	☐	☐	☐	☐	☐
Questions from patients and families are welcomed by most of our staff. Answers are usually thoughtful, useful, and respectful.	☐	☐	☐	☐	☐

Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 9: effective meetings

We have already made passing mention of meetings, but they are sufficiently important to merit separate reference to them. Meetings create excellent opportunities to meet patient safety goals – to share ideas, to build team spirit, to motivate, to make collective decisions, and so on. However, meetings are often poorly managed in many care provider agencies.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
We have well-designed rules of conduct for our meetings, and we make sure there is compliance with those rules.	☐	☐	☐	☐	☐
We formally evaluate our meetings from time to time.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐

Domain 10: leadership

By leadership, we mean the act of encouraging others to take a particular course of action. It typically involves choosing to be first to suggest a new course of action, and volunteering to make sure agreed actions are implemented. Leadership must be shared, and must exist at all levels of the organisation.

Put 'X' in one box on each row to show extent to which you agree with each statement about your agency.	***Strongly agree*** ↓	2	3	4	***Strongly disagree*** ↓
We believe all staff should consider themselves to be responsible for showing leadership on occasions.	☐	☐	☐	☐	☐
We regularly try to ensure that leadership is shared.	☐	☐	☐	☐	☐
We have good leadership at all levels in our organisation, from the clinical team to the boardroom.	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐
Other (write in):	☐	☐	☐	☐	☐