

Strategies for Hospitals to Improve Patient Safety: A Review of the Research

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PREFACE

The Patient Safety project was a joint initiative by The Change Foundation and the Ontario Hospital Association. This report is a research synthesis intended to help hospital managers and front-line workers prevent the mistakes and accidents that can endanger patient safety. The injuries caused by treatment rather than the underlying condition are known as adverse events and affect thousands of people every year by prolonging hospitalization, and causing lasting disability or death.

This study focuses on preventable adverse events — the wrong dose of a medication, for example, rather than unanticipated events, such as allergic reactions to a drug. If an event was preventable in one instance, it can be learned from and strategies can be developed to keep it from happening again. This is not a subject that has been widely studied in Canada so international research, arising from Canada, the U.S., Britain and Australia was used to produce this synthesis.

An expert panel was brought together to provide guidance in carrying out this review. This group helped to develop a set of comprehensive recommendations for action. Because patient safety is multi-faceted, change will require participation by policy makers, educators, governments, professional associations and the public. The recommendations put special emphasis on:

- The role of hospital leadership in making patient safety a priority;
- The need to improve reporting to capture the extent and causes of adverse events;
- The role of a “just” organizational culture in learning from mistakes;
- The need for training and education for professionals, patients and families; and
- Next steps in research on what causes adverse events and how to prevent them.

The Change Foundation and the Ontario Hospital Association would like to thank the members of the Steering Committee for their time, guidance, and valuable input in the project.

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EXECUTIVE SUMMARY AND RECOMMENDATIONS

Over the past decade, mismanaged health care that actually makes patients sicker has increasingly drawn the attention of the public, the media, and those involved in health care. Studies in the United States, the United Kingdom, Australia, and New Zealand have begun to reveal the magnitude of the problem of these adverse events, as they're called, and raise concern among consumers, health-care professionals and policy makers. Fewer studies have been done in Canada, but that is changing as the extent of the problem is recognized elsewhere.

This research synthesis is a joint initiative by The Change Foundation and the Ontario Hospital Association. It is a review of an extensive body of literature on adverse events, both international and Canadian. We looked at adverse events in acute-care hospitals, because they are the sites of a variety of risky medical procedures and extensive drug treatment — all with a high potential for mistakes and accidents. The synthesis focuses on preventable adverse events, those where methods for averting a given injury are known, but the knowledge is not used and an injury occurs. The scope of the review is further narrowed to include only latent conditions, those where the system (rather than an individual) failed to detect and intercept adverse events before they caused harm.

Acute-care hospitals are complex environments and many factors contribute to patient safety within them. Studies show that improving patient safety is a multi-faceted task that requires involvement of all the players in a health care system. This synthesis identified five major causes of adverse events in hospitals: 1) Errors caused by flaws in equipment design; 2) Failure in communication among staff or among different departments and hospitals; 3) Staff shortages resulting in stress and fatigue and leading to lapses in performance; 4) Complexity of health care organizations making them error-prone environments; 5) Punitive organizational cultures that discourage people from reporting adverse events and learning from experience. Preventing adverse events requires understanding how they happen and making improvements in the above-mentioned areas.

An expert panel was brought together to provide guidance in carrying out this review. Following are recommendations developed as a result of the literature synthesis, and input from the expert panel.

Providing Leadership for Patient Safety Initiatives

1. Hospitals must launch patient-safety initiatives and monitor their success, perhaps by including safety in hospitals' measures of performance, including balanced scorecards.
2. Investments — of staff and money — must be made, including spending for new technology. Spending priorities must include information transfer such as clear labelling of medications and computerised physician orders. Organizational investment is needed to develop a workforce of people with advanced training in occupational health and safety and patient safety. Additional funds are required from sources such as Provincial governments.
3. Hospital Administrators must initiate change management programs to build support for patient safety and get leaders across the organization committed to a prevention program.

Creating a Culture of Safety

1. Hospitals need to stop assigning fault to individuals and foster the attitude that mistakes are a chance to learn and improve care.
2. Processes to improve quality should be established among hospitals.
3. Patient safety should become part of performance assessment and accountability.
4. Hospitals should clearly communicate patient-safety requirements and enforce those standards.

Providing Training and Continuous Education

1. Hospitals must maintain up-to-date patient-safety standards and protocols.
2. Universities should train health sciences students in the prevention of adverse events.
3. Professional associations, colleges and hospital associations should promote improved patient safety by disseminating information on best practices and giving professionals training in risk management.
4. Provincial governments must finance training and development programs supporting safety in hospitals.

Improving Reporting Systems

1. Hospitals should use international documentation and reporting as a basis for developing a Canadian reporting system.
2. Provinces should standardize reporting systems and share information on adverse events in hospitals to support national efforts and performance accountability.
3. “Near misses” — adverse events averted at the last minute — can be complicated to report, but should be noted by hospitals because they may offer valuable safety lessons.
4. Hospitals should expand their Internet capabilities to include patient-safety systems to assist patients and their families in reporting adverse events and near misses without fear of potential reprisals.

Establishing A National Patient Safety Strategy

1. The federal government and the newly formed Canadian Patient Safety Institute should support hospital-based demonstration projects and evaluation exercises to promote improved patient safety. Programs are needed that focus on patients and their role in improving the accountability of the acute care system.
2. Accreditation bodies, such as the Canadian Council on Health Services Accreditation should include whether there are protocols for patient safety and adherence to standards of practice for it in their assessments.
3. Professional and accreditation bodies should also identify best practices and specific strategies that would make hospitals safer for patients.

Next Steps in Research

1. Patient safety requires continuous monitoring and search for new strategies. Research on establishing national and international benchmarks is needed.
2. Public and private sector research should focus on developing technology to prevent or intercept adverse events. Ongoing evaluation should be done to assess long-term effectiveness of new technology.
3. Research into best practices and strategies needs to be translated into tools and templates for use by health care managers.
4. Patient safety research should focus on approaches, return on investment and cost-effectiveness, to show where hospitals resources can best be allocated.

INTRODUCTION

The issue of human errors in complex systems has been a topic of debate for decades. In the aviation industry system failures cause great publicity and are addressed quickly for a very simple reason: aviation accidents attract great attention because they involve a large number of people and resources. Accidents and complications are common in health care as well, and can be deadly. However, they happen one or two at a time and are far less dramatic. Only in the 1990s did errors in health-care settings begin to draw public attention.

Adverse medical events, as injuries to patients that arise from mistakes and accidents during medical treatment are called, can be result of human errors, technological errors, or a system that failed to detect these mishaps and prevent them (Bernstein, et al., 2003). Two landmark studies, one in New York and the other in Utah and Colorado (Brennan et al., 1991; Thomas et al, 2000), estimated that 44,000 to 98,000 Americans die every year as a result of adverse medical events. The Washington, D.C. based Institute of Medicine came out with a study in 1999 designed to raise awareness among the public and key stakeholders of the scope of the problem; it was followed with studies by the United Kingdom and Australia, which tried to get a complete picture of the inconvenience, morbidity, extended stays, or death resulting from adverse events in hospitals (NHS, 2000; Weingart et al., 2000).

The per capita rate of adverse events in Canada is probably similar to the U.S., so researchers estimate adverse events claim 5,000 to 10,000 lives every year in this country. A review of hospital data compiled by the Canadian Institute for Health Information shows that 3.3 to 5 per cent of patients admitted to Ontario hospitals from 1992 to 1997 experienced adverse events related to their treatments (Hunter et al., 1999; Wanzel et al., 2000).

Recently, the Canadian Institute for Health Information and the Canadian Institutes of Health Research sponsored a study on adverse events that undertook a chart review. As part of this work, a group of nurses is screening patient records looking for adverse events in British Columbia, Alberta, Ontario, Quebec and Nova Scotia. After cases are identified, physicians will re-examine them to confirm the occurrence of adverse events. The findings of this study are expected in 2004 (Sibbald, 2003).

Accidents are inevitable in any complex system. Outside of health care, however, there are organizations that have fewer hazardous events than would be expected, given their high complexity. These organizations, such as nuclear aircraft carriers, nuclear power plants, and air traffic control centres, are referred to as 'high reliability organizations.' All continuously look into the deeper causes of adverse events to build safety records that are fundamental to the survival of their industries. Their success stories should serve as benchmarks for health care services seeking to improve safety (Reason, 2000).

FOCUS OF THIS SYNTHESIS

Making mistakes is human nature and cannot be eradicated. What can be changed, however, are the conditions under which humans work (Reason, 2000). This synthesis briefly reviews the literature on the impact and cost of adverse events, and then focuses on strategies directed at improving patient safety.

Only adverse events in hospitals are included in this synthesis, because hospitals have a high concentration of patient injuries associated with potentially risky medical procedures and high rates of drug administration. Special attention is focused on intensive care and emergency departments, which are particularly error-prone environments (Donchin et al., 1995). Studies suggest that the majority of the adverse events in emergency department (70 to 82 per cent) are preventable. It is thought that overcrowding and a shortage of medical staff underlie the compromised quality of care in Canadian emergency departments (Croskerry et al., 2001, Brennan, 1991).

Not all adverse events are caused by errors — some, such as previously unsuspected drug reactions, cannot be avoided. Those patient injuries where a method to avert the injury is known, but it occurs anyway because of a failure to apply that knowledge, are called preventable adverse events (Leape et al., 1993). They may be caused by human error, or by defective systems that allow mistakes to happen and go undetected (Bernstein, et al., 2003).

Literature on adverse medical events and patient safety refers to ‘active’ and ‘latent’ failures. Active failures are unsafe acts committed by people who are in direct contact with the patient or the system, and thus these failures present immediate risk to patients. They include mechanical failures such as picking up the wrong syringe, cognitive failures such as memory lapses or misreading instructions and violations — deviations from standards and protocols (Vincent et al., 1998). Latent conditions are failures of a system to detect and intercept adverse events before they cause harm, or error-provoking conditions in the workplace that create long-lasting weaknesses in the system (Reason, 2000). Examples of latent failures include heavy workloads, inadequate supervision, stressful environments, rapid change within an organization, and inadequate communication.

This synthesis focuses on the literature that discusses latent failures and the “system approach” to preventing them. In a system approach, conditions under which people work are studied and defenses are designed to intercept adverse events and mitigate their effects (Reason, 2000). Such defences require individuals and teams to be alert to error-prone conditions and maintain accountability for their actions, but system design should provide a safety net above and beyond human awareness (Shapiro et al., 2002).

ADVERSE EVENTS IN HEALTH CARE SETTINGS

Defining Key Terms

An *Adverse Event* is an injury to a patient caused by medical management rather than the underlying disease, which prolongs the hospitalization and/or produces disability at the time of discharge (Brennan et al., 1991). A U.S. study showed that of the 3.7 per cent of hospitalized patients who experienced adverse events, 70.5 per cent suffered disability lasting fewer than six months, 2.6 per cent suffered permanent disability, and 13.6 per cent died as a result (Brennan et al., 1991).

An *Adverse Drug Event* (ADE), the most common type of adverse event, (Leape et al., 1993) is an injury resulting from medical intervention related to a drug (Bates et al., 1995). Examples of adverse drug events include wrong dose, wrong choice, wrong drug, wrong technique, equipment failure, etc. The Harvard Medical Practice Study documented that ADE accounted for 19.4 per cent of all disabling adverse events in hospital settings (Leape, et al, 1995). With the advancement of technology and increased number of prescription drugs, the risk of adverse drug events is likely to increase (Classen et al., 1997). Another U.S. study shows that the largest share of preventable adverse drug events happen with analgesics (29 per cent), followed by sedatives (10 per cent), antibiotics (9 per cent) and anti-psychotics (7 per cent) (Bates et al., 1997). U.S. studies have also found a relationship between the area of medical specialty and rate of preventable adverse drug events: 21 per cent of adverse events occur in cardiovascular patients, 19 per cent in central nervous system patients, and 9 per cent in respiratory cases (Bates et al., 1997). The majority of adverse drug events were either of minor consequence (35.4 per cent), or no clinical importance (57.5 per cent). Only 1.4 per cent resulted in major morbidity, and less than 0.4 per cent resulted in death (Orser et al., 2000).

A Canadian study found that 85 per cent of participating anesthesiologists (N=687) had experienced at least one adverse drug event or *near miss* — that is the error was detected and intercepted before harm was done (Orser et al., 2000). Near misses often go underreported. A U.S. study showed that there are approximately seven times as many near misses as adverse events (Bates et al., 1995).

Patient Safety encompasses the processes that protect patients from injury caused by medical mismanagement. Ensuring patient safety requires operational systems and processes that will maximize the likelihood of preventing adverse medical events (Institute of Medicine, 1999).

Two other terms frequently found in literature on patient safety and adverse events are *nosocomial* (originated in hospital) and *iatrogenic* (unintended and unwanted, as a result of treatment).

Causes of Preventable Adverse Events

Health care is often delivered in a dynamic environment with complex interactions among patients, medical staff, infrastructure, equipment, and policies and procedures (Institute of Medicine, 1999; Nolan, 2000). Challenging procedures must be undertaken, sometimes under circumstances that are not controlled by those at the front line. While care is mostly successful, errors do occur (Vincent, 2003). Understanding how hospitals function is imperative in identifying causes of preventable adverse events, especially as a variety of factors may contribute to these mishaps. There are many factors related to the increased risk of preventable adverse events. Understanding risk factors will help healthcare organizations develop strategies targeted at reducing the risk and improving patient safety.

This synthesis focuses on literature relating to latent failures and strategies to prevent them. In this light, underlying causes that have been identified include: a lack of safeguard on automation; failure in communication; shortage of staff; an error-prone environment; and a punitive organizational culture.

Errors caused by a lack of safeguard on automation: Many complex medical procedures are currently performed by automated systems using programmable machines. The importance of automating repetitive, time-consuming, and error-prone tasks through the use of technology is widely recognized. While automation holds substantial promise for improved safety, it should be kept in mind that all technology introduces the potential for new adverse events. It is critical that any new automated system be tested in operational settings (Battles et al, 2002). An example of automation error is an infusion pump free-flow that causes an overdose (Nolan, 2000). However, such incidents can be significantly reduced when safety controls, such as regular monitoring by workers, are put in place.

Failure in communication is an underlying cause of many adverse events. Complex organizations need information systems that provide smooth communication within and among medical teams. Lack of communication may arise from insufficient discussion of cases at shift change, or a failure of staff in different departments to coordinate clinical care (Baker et al., 2001).

Shortage of staff is a pressing issue in health care. In understaffed hospitals, medical personnel are overworked. Stress, sleeplessness, and fatigue impair thinking and cause lapses in performance. Many hospitals and nursing homes in the U.S. require nurses to work more than 12 hours a day (IOM 2004). A U.S. national survey of residents' work hours revealed that 50 per cent of first-year residents and 30 per cent of second-year residents work 30 hours per shift and over 80 hours per week (Baldwin et al., 2003). Undoubtedly, this affects their performance and the quality of health care.

Error-Prone Environment The sheer complexity of modern medical care is one of the factors that cause adverse events (Leape et al., 1993). A hospital, stocked with dangerous substances and operated by people with high stress levels doing complex technical procedures, is a risky environment. Studies show that intensive care, a very complex environment, has an even greater concentration of adverse events. Heavy workloads, inadequate staffing, and limited access to vital equipment are also work-environment factors that can lead to mishaps.

Punitive Organizational Culture When workers feel threatened by a ‘blame and shame’ culture, problems are less likely to be identified and addressed. Improvement of patient safety relies on the analysis of, and learning from reported adverse events, but blame and punishment discourage professionals from reporting them. A punitive organizational culture is a disincentive to the recognition of system flaws and efforts to improve the quality of care. Legal liability tends to discourage a safety culture; the fear of lawsuits is a disincentive for healthcare workers to come forward. A just organizational culture, where employees believe the focus is on improving care and not finding scapegoats, is essential in encouraging people to report adverse events and learn from their mistakes.

Costs and Impacts of Adverse Events

Adverse events can have serious consequences to patients and to society as a whole. A number of studies have tried to calculate the total economic and social impact of adverse events.

Direct Costs. The direct health care cost of preventable adverse events in the United States was estimated to be \$10.1 billion in 1984 (Leape et al., 1993). It has likely increased since. Another study using a representative sample of 28 hospitals in Utah and Colorado suggested that the total health care cost of preventable adverse events in hospitals could be as high as \$159,245,000 U.S. (Thomas et al., 1999). Forty six percent of the cost was attributed to outpatient medical care (Thomas et al., 1999). Inpatient care cost was also significant. Bates (1997) indicated that on average, preventable drug events resulted in an additional 4.6 days in length of stay or \$5,857. For a 700-bed teaching hospital, it costs could increase by \$2.8 million. There is no data on costs of adverse events in Canada.

Malpractice litigation is a source of additional direct costs to the health care system. The average settlement award between 1989 and 1999 in Ontario was \$172,000 CDN, in Canada \$131,000 CDN (CMPA, 2000).

Indirect costs. The issue of indirect costs has not been studied as extensively, but they can include lost productivity and wages, disability costs, and emotional trauma. It can be difficult to attach a dollar value to these outcomes, which makes it harder for researchers and policy makers to judge the total economic burden of iatrogenic injury (Thomas et al., 1999). A U.S. study of patients who experienced adverse events during surgery indicated that the experiences had a considerable effect on the quality of their lives. Increased pain, disability and psychological trauma affected their work and social lives. In cases of avoidable death, the psychological trauma to the family was even more devastating (Vincent et al., 2002).

Lost household wages account for a large proportion of the indirect costs associated with adverse events. A U.S. study shows losses may average \$63,309 per household per year (Thomas et al., 1999). *Lost household productivity*, the third-largest cost of medical mishaps, is estimated at \$85,828 per household annually (Thomas et al., 1999). *Disability costs* are associated with a person’s inability to perform regular activities such as childcare, cooking, cleaning, etc. In the case of serious disability or death, costs shift from the health care to the social welfare system. *Costs of personal care* include rehabilitation, outpatient care, and informal care provided by the family.

Impact on health-care workers An adverse event can have profound consequences on health-care workers, particularly if one individual is seen as primarily responsible for the mishap. After making a mistake, caregivers may experience shame, guilt, and depression; litigation and complaints impose an additional burden. Workers may become very anxious about carrying out their clinical activities, seek out a specialty with less direct patient contact, or abandon clinical work entirely (Wu, 1991; Fonseca, 1996). The impact of adverse events can go beyond health care workers to their families, such as in cases of failed infection control.

Clearly, we must improve the quality of health care and reduce the burden of mistakes and accidents on patients, families and workers. Effective strategies for reducing adverse events are urgently needed.

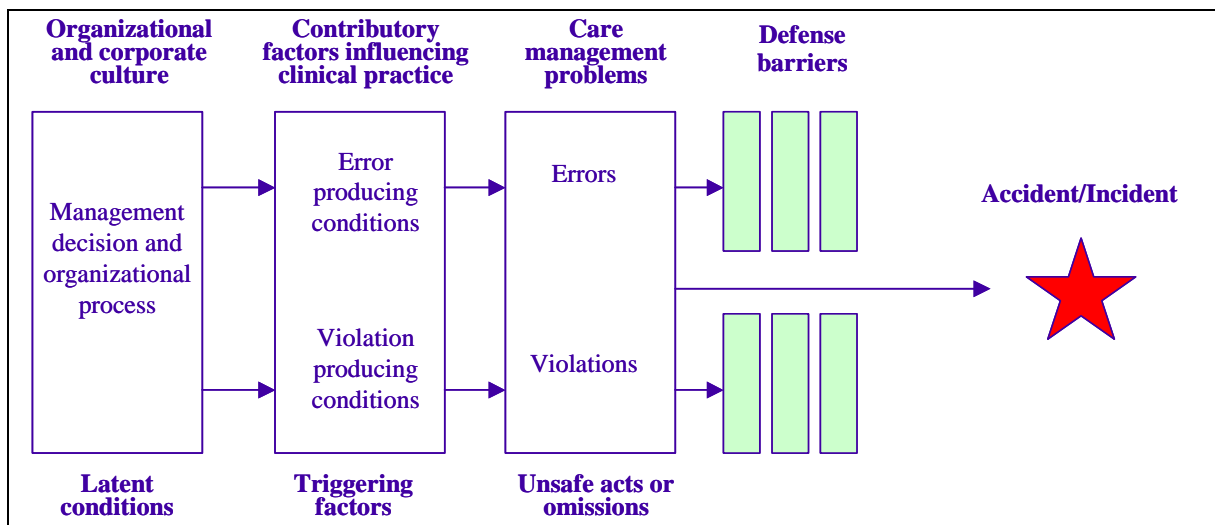
STRATEGIES TO IMPROVE PATIENT SAFETY

To prevent or reduce the impact of latent adverse events (those caused by flawed systems) a system approach is required, one which not only tries to create defences against adverse events, but also addresses the flaws in the organization that can cause them.

One such approach is called the *Root Cause Analysis*, a retrospective approach to error analysis, adapted by the Veterans Affairs National Center for Patient Safety in the U.S.A. Root cause analysis has been used to investigate major industrial accidents, through industrial psychology and human factors engineering where the focus is on the relationship between the person and the machine (Classen et al., 1997). It provides a structured and process-focused framework identifying system and organizational flaws that lead to adverse events (AHRQ, 2001). In 1997, the Joint Commission on the Accreditation of Healthcare Organizations in USA starting requiring accredited U.S. hospitals to use root cause analysis to investigate adverse events (AHRQ, 2001) and it has been implemented in some of the healthcare organizations in Canada as well. According to Joint Commission requirements, RCA should be thorough and credible including human and other factors closely associated with the events. It should include participation from the organization's leaders. All findings should be explained (Boyer, 2001). Figure 1 represents a schematic diagram of some of the issues revealed by root cause analysis.

Root Cause Analysis has invaluable advantages. It provides an opportunity to build cooperative relationships among physicians, nurses, and other team members. It also provides an excellent learning opportunity for health care professionals. Most importantly, though, it has the potential to help correct system flaws to prevent the recurrence of similar events (Boyer, 2001).

Figure 1. Model of Organizational Causes of Adverse Events



Source: Vincent C., et al, 2000

The disadvantage of this strategy is that it requires the time and expertise of multiple specialists and may be viewed as an expensive process; however, it is seen as worth the investment when effectively performed (Boyer, 2001).

Another safety strategy borrowed from high-risk industries is the *Failure Mode and Effects Analysis*. This technique examines the individual components of a system to determine the ways in which each component could fail and the effect of that failure on the stability of the entire system. It is a risk-assessment guideline, done in advance to estimate the potential for mishaps. A multidisciplinary team comes together to implement the steps, which include: 1) setting up a process flow diagram; 2) re-tracking the process and simulating what can go wrong; 3) deciding how failures can affect the system, 4) ranking the possibility of an adverse event; 5) ranking the severity of adverse events; 6) ranking the likelihood of intercepting the adverse event; and 7) taking action (Fletcher, 1997).

In 2001, the Joint Commission on Accreditation of Healthcare Organizations in the U.S. selected Failure Mode and Effects Analysis as the basis for patient-safety risk assessments. Since 2003, the Commission has required health-care organizations to engage in at least one risk-assessment initiative per year, although they can choose any risk assessment model that complies with commission standards. Some health care organizations, such as the Veterans Health Administration, have adapted failure mode and effect analysis to create their own models (Spath, 2003) and it is also recommended by the Canadian Institute for Safe Medication Practices because it ensures that plans are made for safe medication use, preventing adverse drug events that can lead to fatalities and debilitating situations (Fletcher, 1997).

Despite its utility, the Failure Mode and Effects Analysis is a challenging process. It is resource intensive and often difficult to incorporate into already overcrowded workdays. As well, risk assessment terms, such as 'failure mode' and 'hazard analysis,' can be intimidating. To successfully build these into existing processes requires changes in priorities and attitudes in health care organizations and calls for implementation skills and active leadership.

Many people question the difference between RCA and FMEA. Root cause analysis is reactive because it is conducted after an incident has occurred. On the other hand, a FMEA is proactive because it is designed to prevent an incident from happening. Initiating a RCA after an incident has occurred may result in hindsight bias, but FMEA remains unbiased because no one is being or feeling blamed for an incident. Actual or theoretical blame that often occurs with an RCA results in fear and resistance by some participants. A FMEA ultimately involves openness. Additionally, the RCA concentrates on an event, while the FMEA focuses on the entire process. Most important is that the RCA asks the questions "Why?" or "Who?" while the FMEA poses the question "What if...?" (Spath 2003)

The RCA and FMEA processes, however, are similar. Both processes are nonstatistical methods of analysis aimed at reducing patient harm, and both involve identifying situations that lead to harm via a team approach.

In summary, Root Cause Analysis and Failure Mode and Effects Analysis help to identify fundamental system flaws, and assess each component of a system to determine the impact of a

particular component failure on the entire system. These processes make it possible to create buffers to stop accidents from happening, and eventually remove error-producing conditions.

Clinical Level Strategies to Improve Patient Safety

i) Improving Communication Within the Clinical Team.

Communication problems are one of the main causes of adverse events and should be the focus of improvement efforts. The Institute for Safe Medical Practices Canada reports that approximately 10 per cent of serious adverse drug events occur as a result of flawed communication. Pronunciation, dialects, background noises, and fatigue can contribute to failures in verbal communication. Illegible handwriting and abbreviations are potential causes for failure in written communication (McKerrow et al., 2001). Proper communication between the members of clinical teams (nurses, physicians, and pharmacists) is an important step towards reducing adverse events. Clearly defining roles for each member of the health-care team is another important step towards safeguarding effective information exchange.

Health care professionals work in groups and the overall performance of the team is highly dependent on individuals' abilities to work in a team and learn from mistakes. Experience shows that effective teamwork is not a spontaneous occurrence; it requires the development of specific skills (Sexton et al, 2000). Effective teamwork gives caregivers increased control over complex and constantly changing environments, particularly in emergency departments and intensive care units and creates safety nets for patients and caregivers when inevitable human errors occur (Risser et al, 1999). The management and accessibility of patient information is crucial in stressful and complex hospital environments. A U.S. study showed that 48 per cent of nurses surveyed felt they did not have sufficient information to carry out their duties, and that there was lack of supervision and professional updating (Meurier et al., 1997).

Courses are now available on how to build teams, modeled on aircrew crisis resource management training (Howard, 1992), which include training in communication, leadership, delegation, monitoring, use of information and other resources needed in a crisis. Routine team debriefing sessions, especially after a problem, are used as a strategy to reduce adverse events in the future. Debriefing provides an opportunity to probe team members' attitudes, to clarify roles and responsibilities and to serve as a forum for finding local solutions (Felton, 1998). Debriefing reinforces team membership and is an effective method for consistent quality improvement.

In addition to the core strategy of team building, technology can help overcome communication barriers.

Information technology can improve communication on all levels. For example, *Clinical Decision Support Systems* are designed to assist physicians in applying new information to patient care through the analysis of patient specific variables (Payne, 2000). Among the simplest clinical support systems are drug-dosing calculators that help prevent errors in dosages. They are most effective when used with *computerized physician order entry* — a tool that lets physicians order drugs on-line to prevent adverse drug events caused by misinterpretation (Bates et al., 1994; Bates et al., 1997). Physician order entry is a fast, legible tool that contains a decision support system. Bates and colleagues observed that even when not equipped with the decision-

support component, computerized order entry could decrease the number of near misses by 84 per cent. By adding decision support, adverse events decreased from 2.9 to 1.1 per 1,000 patient days (Bates et al., 1999). The 2001 Canadian Hospital Pharmacy Survey found that only nine out of fifty-two teaching hospitals in Canada had operational computerized order entry, but the same survey indicated that at least 17 more teaching hospitals were planning to implement it (McKerrow, 2001).

Effective implementation of CPOE depends on the organizational culture. In 2002 a project was initiated at the Cambridge Memorial Hospital to introduce CPOE to reduce the incidence of medication errors. The project met with barriers including unexpected implementation costs and physician dissatisfaction, and was discontinued. Project leaders maintain that collaboration between medical staff, hospital administration and information services is essential for such a change in practice. Community hospitals successful who have had success with CPOE have physicians leading the initiative (Metzger, Fortin, 2003). The findings from the Ontario project are mirrored in a recent Cochrane review (AHRQ, 2001).

Another computerized device that could improve communication is the *Personal Digital Assistant*, which gives professional's access real-time patient information and evidence-based resources at the point of care. A Canadian study showed that it provided useful and accurate clinical practice guidelines and an alert system, and was believed to be more efficient than its paper-based counterparts (Van Den Kerkhoff, 2003). Again, understanding local context is key for effective use of such technology.

ii) Reporting Adverse Events

Successfully preventing adverse events relies on comprehensive and systematic data collection and analysis so broad participation is essential. Mandatory reporting systems focus on serious and fatal incidents while voluntary systems are often used for less severe events. Both require support and cooperation of health care workers. A questionnaire distributed to more than 100 health-care facilities across Canada revealed that 88 per cent of them have critical incident reporting systems; 76 per cent have adverse drug event reporting systems; and 72 percent have routinely monitored selected indicators (Baker & Norton, 2002).

Adverse event reporting is not always comprehensive or consistent. Although many surgical departments have weekly morbidity and mortality conferences, they are usually a form of voluntary reporting of adverse events and generally detect only a small portion of complications. A Canadian study showed that in one hospital setting five out of 10 life-threatening complications and half of all fatal ones were not reported. Only 13 out of 26 complications attributable to error were discussed at the weekly rounds (Wanzel et al., 2000). Perhaps morbidity and mortality rounds could be expanded to other departments on a more routine basis to encourage regular reporting of adverse events.

Another Canadian study in anesthesiology revealed that among surveyed anesthesiologists (N=469), none of the adverse events described in the survey were reported to a national or a provincial body because 68.3 per cent of participants considered those events inconsequential. Health-care workers were uncertain whether and how to report near misses or intercepted potential errors. They had legal concerns (6 per cent) as well (Orser et al., 2001).

Existing programs for reporting adverse drug events collect and sort data for statistical analysis but are often not equipped to make improvement recommendations. The Institute for Safe Medication Practices Canada and that of the United States have developed *Analyse-ERR* software, which is a system-error and root-cause-analysis tool. It is currently being examined to assess the impact of error prevention efforts in 30 hospitals across Ontario (U, 2001).

There is some disagreement about the value of mandatory versus voluntary reporting systems. Those opposed to voluntary reporting systems believe that fear of blame and legal liability will make health-care professionals choose not to disclose medical mishaps, and that only mandatory reporting can capture adverse events reliably. Others argue that mandatory systems do not solve the issue of fear, i.e. fear of blame or fear of legal liability. There is a sense that reliable reporting is only possible when a positive organizational culture is put in place, which recognizes the value of capturing adverse events as a way to remove error-producing conditions and to improve patient safety.

There is also some debate around the merit of reporting near misses. Some say that hospitals need full reporting including near misses because medical personnel are more likely to discuss near misses with their peers, having fewer worries about liability. Knowing about the occurrences of near misses can also provide learning opportunities as they are successfully intercepted (Bernstein et al., 2003). Some hospitals, such as the Sunnybrook and Women's College Health Sciences Centre in Toronto, have focused on close calls and other techniques to reduce medical errors (Wilson, 2002).

Those who argue against the focus on reporting near misses believe that near misses are difficult to identify and could complicate the standardization of reporting systems. They feel that focusing on actual adverse events should be a first step in improving patient safety. This strategy deals with high profile cases, is more focused and a more effective use of currently limited healthcare resources.

Despite the debate, one of the success stories arises from the University of Missouri Health Care (www.muhealth.org). This organization developed a secure, web-based system that allows staff, physicians, patients, families, and visitors to report comments, adverse events, and near misses from any computer in the hospital and from home, using the Internet. Reports are immediately available to department managers responsible for resolution and managers are alerted to the presence of a report by e-mail. A pilot study performed in two intensive care units of this hospital showed that the system can dramatically reduce resolution time. The study also demonstrated increased reporting rates by physicians and respiratory therapists (Vincent et al., 2002).

iii) Increasing Patient Involvement

As demonstrated in the Missouri example, patients can play a key role in ensuring that health care is safe (Vincent et al., 2002). Increasing patient awareness of safety issues is a powerful but underused strategy toward improving the quality of health care. With emerging consumerism, patients are better aware of problems that occur in hospitals; they become active players in the system.

Increased patient awareness can be a crucial part of risk-prevention. When sufficiently informed about prescription medications, patients can help recognize and intercept mistakes related to dosage of their medication and interactions between drugs. A U.S. study showed that 60 per cent of patients were not given sufficient information about danger signals to look for after discharge from hospital (Vincent et al., 2002). The level of patients' involvement and participation, however, varies according to the complexity of medical treatment and degree of educational background necessary to understand the treatment process. Facilitating an active partnership between consumers and health care providers should be an important component of patient safety strategy (Vincent et al., 2002).

iv) Developing Protocols and Guidelines

One of the ways to avoid human error is to reduce reliance on short-term memory. This limited cognition should be used to perform only essential tasks (Nolan, 2000). Checklists, protocols, guidelines, and reminders are successful tools for workers to ensure better patient communication. Simple examples such identification by colour coding or eliminating drugs that sound or look alike have proved to be effective (Nolan, 2000). Changing a brand or having a look-alike in the same storage unit is often the cause of irreversible mistakes. For high-risk medications, written and computerized guidelines, checklists, pre-printed orders, double-checking, special packaging, and labeling should be used to avoid human mistakes (Baker et al., 2001; Institute of Medicine, 1999). A Canadian study shows that the most common error in anesthesiology is the misidentification of the syringe or "syringe swap" (Orser et al., 2001). As a part of a national medication safety initiative, Canadian Standards Association International has published a new standard on the labeling of ampoules, pre-filled syringes, and vials aimed at defining a minimal performance level and consistency across the pharmaceutical industry (Orser et al., 2001). U.S. and Canadian studies show that anesthesia has taken exceptionally effective actions to reduce preventable adverse events.

There are hundreds of health care protocols and guidelines. Designed originally to help health-care professionals, they are increasingly being used by patients and their families to learn about health care processes and avoid undesirable outcomes. When patients are more educated about risk factors for disease, they are more likely to participate in a dialogue with their physician regarding preventive treatments as well as drug interactions (Pazirandeh, 2002).

The Clinical Guideline Clearinghouse in U.S., the Ontario Medical Association and the Cochrane Collaboration, based in the U.K., have all posted guidelines on their websites designed to increase patient safety and improve the quality of health care. The Guideline Advisory Committee of the OMA, in collaboration with The Change Foundation, is developing a physician/consumer website that will allow Ontario physicians and consumers quick access to

recommended guidelines for common medical conditions, summaries of guidelines, and tools to assist diagnosis, delivery and management of care. Ontario consumers will have quick access to the same recommended clinical information as physicians have. It will help to align physician and consumer knowledge of the best available information, with the intention of improving their relationship. A consumer-oriented guideline website may also help to improve physician guideline adherence, which ranges from an estimated 20 per cent to nearly 100 per cent, depending on the guideline (Halm et al., 2000).

Organizational Level Strategies to Improve Patient Safety

Infection control is an important issue in hospitals, because of the need to protect patients and health care workers. U.S. studies show that nosocomial infections occur in about 7 to 10 per cent of hospitalized patients and result in approximately 8,000 deaths each year (Haley et al., 1985; Jarvis, 1996). Lack of leadership, lax enforcement of protocols and procedures, and the belief that infectious diseases are under control all contribute to the spread of preventable infectious disease from one patient to another, from patients to workers and to workers' families. The recent SARS outbreak drew attention to how prepared hospitals are to deal with infectious diseases; there has been much debate over whether proper protocols and procedures to isolate suspected cases were followed¹.

i) Managing Human Resources

In an understaffed facility employees are overworked and fatigued, which increases the danger of adverse events caused by human errors and system deficiencies, so the availability of personnel is a major concern for many hospitals. Staff shortages increase stress in the workplace, and stress increases the chance of cognitive failures (Reason, 1988). Managing human resources is key to decreasing adverse medical events. One study shows a higher ratio of staff to patients increases patient safety (Robertson et al., 1999) and there is strong evidence that a shortage of nursing staff is associated with increased rates of nosocomial infection and increased length of hospital stays (Lichtig et al., 1999). A California study showed that in hospitals with high patient-to-nurse ratios, surgical patients experience higher risk-adjusted 30-day mortality and failure-to-rescue rates, and nurses are more likely to experience burnout and job dissatisfaction (Aiken et al., 2002).

Nursing shortages have long been a challenge in Canada. The Canadian Institute for Health Information (CIHI) reports that Ontario lost nearly 10 per cent of its nursing workforce between 1992 and 1997. Nurses in the age group 50 and up comprise 30% of the nursing workforce. If retirement age is set at 65, 16% of the nursing force will retire by 2006. If retirement age is set 55, 28% of nursing workforce will retire by 2006 (CIHI, 2003), which creates a significant challenge to human resources planning for the industry.

Human resource management is critical to improving patient safety in a hospital setting and needs to be given most serious consideration (University of Toronto and CIHI 2004). A report sponsored by the Canadian Health Services Research Foundation and The Change Foundation re-emphasised the importance of organizational team support on the recruitment and retention of nurses and the impact of nursing work life on the quality of care (Bauman, 2001).

¹ The Change Foundation has launched a project on better protection for health-care workers to determine how to set priorities for infection control in Ontario. This project places a special emphasis on making infection control a top priority for management, improving communication between management, the infection control committee and staff and providing education and training on how to choose appropriate protection equipment. The goal is to assist managers and workers to be more prepared for the next wave of infectious disease.

Efforts are currently underway to introduce human-resources management strategies into health-care organizations. This is being done, for example, through workshops that introduce research on healthy workplaces to senior managers and board trustees, who are then encouraged to identify issues faced by their organizations and develop strategies to address human resources issues at their core (The Change Foundation, 2003).

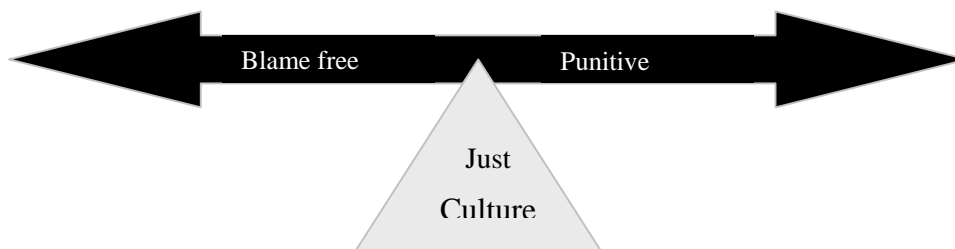
ii) Leadership Commitment to Safety Culture

Given the complex nature of hospitals and their susceptibility to errors, experts believe that more attention should be focused on organizational structure and strategy. Complex systems involving a high risk of adverse events need to create a workplace that addresses and rises above mistakes. There is an ample body of literature arguing that punitive and blaming cultures create disincentives for professionals to report adverse events and learn from their mistakes. However, the health-care system cannot afford a totally blame-free approach, because society does expect accountability. The key is to balance the need to learn from mistakes with discipline. Marx emphasizes the benefits of a well balanced, “just” culture, where the inevitability of human error is recognized, but reckless acts are not tolerated (see Figure 2). In this culture, workers are encouraged to report adverse events and seek solutions (Marx et al., 2001).

Leaders of health-care organizations need to become patient safety champions and encourage an organizational culture where disclosing adverse events and investigating root causes is not only non-threatening but also an organic part of the organizational process. Every organization should maintain a continuous focus on redesigning and improving safety systems, especially in the ICU, ER, and OR. Training on safety issues for medical personnel is also recommended.

Health-care managers have a potentially large role in creating and supporting a culture of safety (Baker et al., 2001). Safety needs to be an integral part of an organization’s culture; it has been shown that health-care workers’ compliance with safety protocols is more likely where safety is on the management priority list. A Canadian survey showed that 96 per cent of surveyed health-care professionals rated senior leadership commitment to identifying adverse events and improving patients safety as “very important” (Baker & Norton, 2002).

Figure 2. Finding the balance between Blame-Free and Punitive Cultures



Source: Stevens, P & Matlow, A, 2003

Another survey found that understanding safety culture and directing resources in ways that will most improve outcomes could reduce adverse events (Harris et al., 2000). Health-care managers are recognizing that adverse events cannot be reduced until more attention is given to human solutions, such as improving teamwork and communication in health care teams (Kaissi et al, 2003). One Ontario hospital has adopted a policy that encourages practitioners to disclose adverse events to patients (Herbert et al., 2001).

iii) Public Disclosure

Public disclosure has practical, legal, and ethical dimensions. Fear of legal liability is part of the reason why people avoid reporting adverse medical events (Donchin et al., 1995). Over the past two decades there has been a steady increase in the number of malpractice claims against health care providers in the United States and in Canada (Brennan et al., 1991) (CMPA 2000). The threat of malpractice litigation presents financial and non-financial incentives for health care providers to work towards improving substandard care (Brennan et al., 1990).

The ethics of health care imply that patients have the right to know if there are any significant deviations from the norm during medical treatment (Bernstein et al., 2003). The public expects health-care organizations to be accountable and disclose problems related to patient safety, and that the entire system will be committed to optimizing patient safety. The media play an important role in shaping public opinion and raising awareness. The publication of the 1999 Institute of Medicine report got a tremendous response from the public, the media and policy makers. As a result, government agencies were forced to direct resources to improve safety standards. One of the greatest challenges of the patient safety issue is changing societal attitudes by promoting a clear understanding that, when it comes to impact, errors by individuals are secondary to system and process problems (Croskerry et al., 2001).

Professional bodies such as the College of Physicians and Surgeons of Ontario do not have specific policies that require physicians to disclose adverse events, except in some cases of incompetence and incapacity. However, the Canadian Medical Protective Association (which provides malpractice insurance to physicians) encourages physicians to disclose adverse events and offers assistance in talking to patients and their families about them. It is argued that disclosing adverse events may be less traumatic if medical personnel follow standard guidelines (Herbert et al., 2001).

Saskatchewan is the first province in Canada to require mandatory reporting of all adverse events to the province's Department of Health (Ehman, 2003). Currently, adverse event reports are submitted voluntarily. The regulations, which will take effect in the spring of 2004, are expected to lead to the distribution of advisories to health workers. To respond to this provincial legislation, the College of Physicians and Surgeons of Saskatchewan has become the first in Canada to require physicians to report mistakes, in the form of full disclosure of adverse events to patients who might not otherwise have suspected one. The province now also requires the disclosure of near misses that were caught and corrected. The policy also applies to incidents that occurred in the past and were never disclosed. In this new system there will be no sanctions or penalties. The focus is on learning and on improving the system.

Disclosure, Blame and the Law. Blame is a deeply rooted human response to harm. Inappropriate attribution of blame inhibits open disclosure to both victims and those in a position to rectify antecedent causes. Blame may also harm health care professionals, seriously impede patient safety initiatives, and damage physician-patient relationships. A New Zealand study found that patients are more likely to blame and desire to punish the health-care professional under the following circumstances: if they were not properly informed about material risks; if they could not fully participate in the decision to proceed; or if the physician seemed not to care and did not express regret or if the problem was not acknowledged and there seemed to be no attempt to prevent the problem from recurring (Vincent 2001; Merry 2001).

Understanding the true causes of adverse events requires looking into the root causes beyond the human errors. It is the responsibility of health-care organizations to set standards and ensure that the line between safe and unsafe care is not crossed. The process for ensuring accountability must be separate from that for obtaining information for system improvement. Organizations need to articulate the difference between behavior that is culpable and unacceptable and will not be tolerated, and behavior that, although erroneous, is more understandable and can be addressed within a system of self-reporting and detailed analysis.

The provision of an appropriate system of anonymous or confidential and legally privileged reporting takes nothing away from the rights of patients but adds a powerful tool for making health care safer (Runciman, 2003). In 2003 the U.S. Senate Health, Education, Labor and Pension Committee voted unanimously to pass a bill that would establish a certification system for patient safety organizations that collect information on medical errors. The legislation would conditionally shield adverse event data from use in lawsuits against physicians and institutions creating a privilege for data on medical errors, near misses and health care quality practices that are voluntarily reported to patient safety organizations. That privilege would ensure that the information was not used in civil, criminal or administrative proceedings (Patient Safety and Quality Improvement Act, 108 U.S.C. 2003). Such legislation also exists in Australia at both federal and state levels and there are moves to unify and strengthen it (Runciman, 2001). However, protection is patchy in the United States, limited in New Zealand and nonexistent in the United Kingdom or Canada. The health-care system could be fundamentally improved if the need to find blame in order to award compensation were removed and combined with clear responsibility for making effective procedural changes to prevent recurrence.

Scandinavian countries deal with the victims of medical mistakes through the social security system, which picks up the bulk of care costs and compensation for lost earnings; a no-fault scheme tops up with a lump sum for full compensation and the right to sue is retained. However, very few patients opt to sue because the compensation payable under the statutory scheme uses common-law damage assessment principles without the need to show fault.

To balance this, patients must be fully informed at all stages, and there must be robust mechanisms for dealing with practitioners or units whose performance is unacceptable. The attribution of blame could then be limited to those individuals

“Advances in patient safety, especially when involving the management of human error, depend upon our collective ability to learn from our mistakes...”

David Marx, 2001

or corporations responsible for unequivocally egregious acts. This will require fundamental reforms toward mediation and transparency which will lead to a system that is fair to both patients and professionals (Studdert, 2001).

iv) Educating Health-Care Providers on Safety Culture

Current research suggests that the old, passive methods of changing the behaviour of health-care providers, such as lectures, notes and guidelines do not work as well as setting up a system of personal interaction with people such as peer leaders. These approaches appear to be the most effective way to create a culture of safety and accountability as well. Medical schools are a prime place to introduce safety culture. “Safety sciences” are a combination of knowledge such as cognitive psychology, engineering and work-group sociology and organizational development that address how technology can be used to ensure a safe environment. Root-cause analysis has already been introduced into the curriculum of some medical programs (AHRQ, 2001). A Cochrane review indicated that 62 per cent of education interventions had a beneficial effect on changing provider behavior (Davis et al., 1995). In 1999 a medical-error course, Applied Cognitive Training in Acute-Care Medicine, was introduced into the medical undergraduate program of the Dalhousie University in Halifax, Nova Scotia. Taught by an emergency physician, this course places considerable emphasis on cognitive errors in clinical practice (Croskerry et al., 2001).

Hospitals play an important role in educating and training; on-site experience and continuing education for staff help establish positive attitudes towards preventing adverse events. Teaching hospitals have a responsibility to instruct residents in the importance of patient safety and demonstrate how to scan for potential problems and intercept adverse events.

CONCLUSIONS

The growing number of medical services, complex procedures, medications and patients significantly increase the potential number of adverse events, which lead to human loss and suffering and are costly for the health-care system and to society in general.

Acute-care hospitals are complex environments where many factors contribute to patient safety. Studies show that improving patient safety is a multi-faceted task that requires involvement of all the players in a health care organization. Change management strategies, well documented in management literature can be adopted for improving and promoting a culture of safety.

The role of leaders in hospitals is pivotal in developing a patient-safety agenda. They are well positioned, along with professional associations, to identify, establish and support safe practices. Patient safety must be identified as an organizational priority and sufficient resources allocated to it, including money for technology and procedures that improve the safety of patients. It must also be identified as a national and/or provincial priority to allow more funds to be made available.

When employees experience work-related stress they are more likely to make mistakes that can endanger the safety of patients. As well, staff shortages limit the options for addressing patient safety, so human-resource decisions should take into account the need to create a culture of safety.

Raising awareness of the problem is fundamental to improving patient safety. The release of a landmark report on the issue by the Institute of Medicine triggered wide-spread discussion of adverse events by the public and caregivers, but universities must also educate health-care professionals and managers about the scope of the problem and potential strategies for dealing with it. Professional associations can support their members and hospitals by providing on-the-job training and disseminating information.

When health care workers are faced with punitive economic, emotional, or professional consequences arising from a reported patient safety incident, it is less likely that they will disclose an incident or learn from it. Finding a balance between a blameless culture and accountability to the public is critical for an effective and safe health care environment. It is widely held that hospitals should disclose adverse events and work towards system improvements. Health care workers are more comfortable in revealing adverse events and near misses in the context of a 'just culture', where hospitals exhibit fairness in their dealings with employees. Just Culture implements two complementary ideas. First, it is a system within which health professionals can report injuries and near misses "safe from blame, humiliation and retaliation". Second, such open and complete reporting is key in creating an environment that reliably avoids injury and near misses (Marx 2001). Patient safety depends on the system's ability to learn from experience and mistakes.

Information on the mistakes and accidents that hurt patients must be collected, analyzed and shared among providers to further understanding the scope of the problem and help set safety standards. Hospitals, the scene of many adverse events, are a natural location for developing tools to identify problems and strategies for improvement. We must also develop our

understanding of how health-care systems work in order to identify the root cause of events. The U.S., U.K. and Australia have well-developed strategies for documenting adverse events. In 2001, the Royal College of Physicians and Surgeons of Canada began looking at how to create a national strategy on patient safety and the federal government recently announced the establishment of the Canadian Patient Safety Institute. Its goal is to reduce the risk of system failures and ensure that patients receive the best care possible. A series of demonstration projects involving clinicians and teams from organizations across Canada is underway to evaluate the effectiveness of strategies aimed at improving patient safety.

To paraphrase an old adage, to err will always be human, but patient safety systems put mechanisms in place to predict and prevent different aspects of human fallibility. Patient safety requires continuous searching for and identification of potentially error-prone situations and action to prevent them. Research on the prevention of adverse events at a system level is urgently needed and will assist managers in their efforts to provide high-quality and safe patient care.

Our recommendations for improving patient safety in hospitals, as well as advice for professional organizations and governments and next steps in research are summarized below.

RECOMMENDATIONS

Based on the existing literature on patient safety and adverse events this synthesis outlines several recommendations. Most are geared toward hospitals but some address professional organizations and governments as well.

Providing Leadership for Patient Safety Initiatives

1. Hospitals must launch patient-safety initiatives and monitor their success, perhaps by including safety in hospitals' measures of performance, including balanced scorecards (Herbert et al, 2001).
2. Investments — of staff and money — must be made, including spending for new technology. Spending priorities must include information transfer such as clear labelling of medications and computerised physician orders (Orser et al, 2001; Harris et al, 2000). Organizational investment is needed to develop a workforce of people with advanced training in occupational health and safety and patient safety. Additional funds are required from sources such as Provincial governments.
3. Hospital administrators must initiate change management programs to build support for patient safety and get leaders across the organization committed to a prevention program (Levin, 2004; Kotter, 1996).

Creating a Culture of Safety

1. Hospitals should refrain from assigning fault to individuals and foster the attitude that mistakes are a chance to learn and improve care (Reason, 2000; Marx et al, 2001; Vincent, 2001; Merry et al, 2001).
2. Processes to improve quality should be established among hospitals (Institute of Medicine, 1999).
3. Patient safety should become part of performance assessment and accountability (Ohlhauser, Schurman, 2001).
4. Hospitals should clearly communicate patient-safety requirements and enforce those standards (Felton, 1998).

Providing Training and Continuous Education

1. Hospitals must maintain up-to-date patient-safety standards and protocols (Howard, 1992).
2. Universities should train health sciences students in the prevention of adverse events (Croskerry et al, 2001; AHRQ, 2001).
3. Professional associations, colleges and hospital associations should promote improved patient safety by disseminating information on best practices and giving professionals training in risk management (Baker, Norton, 2001).
4. Provincial governments must finance training and development programs supporting safety in hospitals (Baker, Norton, 2001).

Improving Reporting Systems

1. Hospitals should use international documentation and reporting as a basis for developing a Canadian reporting system (Esmail, 2001; U, 2001).
2. Provinces should standardize reporting systems and share information on adverse events in hospitals to support national efforts and performance accountability (Orser, 2001; Croskerry, 2001).
3. “Near misses” — adverse events averted at the last minute — can be complicated to report, but should be noted by hospitals because they may offer valuable safety lessons.
4. Hospitals should expand their Internet capabilities to include patient-safety systems to assist patients and their families in reporting adverse events and near misses without fear of potential reprisals (Vincent et al, 2002).

Establishing A National Patient Safety Strategy

1. The federal government and the newly formed Canadian Patient Safety Institute should support hospital-based demonstration projects and evaluation exercises to promote improved patient safety (Baker and Norton, 2001). Programs are needed that focus on patients and their role in improving the accountability of the acute care system.
2. Accreditation bodies, such as the Canadian Council on Health Services Accreditation should include whether there are protocols for patient safety and adherence to standards of practice for it in their assessments (Murphy et al, 1998; Baker, Norton, 2001).
3. Professional and accreditation bodies should also identify best practices and specific strategies that would make hospitals safer for patients (Wade, 2003; Baker, Norton, 2001).

Next Steps in Research

1. Patient safety requires continuous monitoring and search for new strategies. Research on establishing national and international benchmarks is needed (Davis et al, 2001).
2. Public and private sector research should focus on developing technology to prevent or intercept adverse events. Ongoing evaluation should be done to assess long-term effectiveness of new technology (AHRQ, 2001; Bates et al, 2001).
3. Research into best practices and strategies needs to be translated into tools and templates for use by health care managers (Newell et al, 2003).
4. Patient safety research should focus on approaches, return on investment and cost-effectiveness, to show where hospitals resources can best be allocated (Smith, 2000).

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APPENDIX A. SEARCH STRATEGIES

This literature search used Medline, Current Content, Cochrane Library, administrative databases, search engines and Internet resources such as the websites for Health Canada, Statistics Canada, the Canadian Institutes of Health Research, the Canadian Institute for Health Information, the Government of Ontario, and the U.S. National Institute of Health. Attention was focused on articles containing numeric data and statistical analysis. Both peer-reviewed and grey literatures were included. The search was limited to English language articles from 1980 to the present. The following key words were used in the search:

- Adverse events +/- medical, drug
- Patient safety +/- nursing, physicians, technologies
- Patient safety +/- workload, process, staff mix

Key word search for outcome measures included:

- Death
- Disability
- Near misses
- Preventability
- Failure-to-rescue
- Staff shortage
- Burnout, fatigue, dissatisfaction
- Just culture
- Malpractice
- Root-cause Analysis
- Failure Mode and Effects Analysis

The literature was evaluated for the strength of evidence according to the rigours of study and the measures. It included *type of study, sample size, level of data collection*. For review papers, *integration criteria, and track record of investigators* were highlighted. The ranking of evidence will be provided in a future draft. The quality of the grey literature will be evaluated on the basis of *face validity (whether expert panel was involved)*.

APPENDIX B. STRATEGIES FOR IMPROVING PATIENT SAFETY: THE EVIDENCE

CLINICAL LEVEL STRATEGIES

Improving Communication within the Clinical Team

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome measures	
Classen, D.C., Pestotnik, S.L., et al, 1997	Peer -reviewed Journal article	Matched case-control study	N=1580 cases N=2197 controls	Chart review	^a Increased length of stay associated with ADE ^b Increase risk of death associated with ADE ^c Excess cost attributable to ADE	^a P<0.001 ^b P<0.001 ^c P<0.001
AHRQ 2001	Report	Evidence based review	Varying among 11 patient safety strategies	Literature review of existing publications	Ranking on implementation costs, and complexity of each of the 11 strategies	Consensus of experts
Bates, D.W., O'Neil A.C., et al, 1994	Peer-reviewed Journal article	Case-control trial	N=3,138	Chart review	^a Easy identifiability of serious and preventable AEs by using IS ^b Identifiability of non-preventable AEs by using IS	^a P<0.001 ^b P<0.05

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome measures	
Bates, D.W., Spell, N., et al, 1997	Peer-reviewed Journal article	Nested case-control study within a prospective cohort study	N=4,108	Self report and chart review	^a Increased length of hospital stay associated with ADE ^b Excess cost due to ADE associated with hospital stay	^a P<0.04; ^b P<0.07
Bates, D.W., Teich J.M., et al, 1999	Peer-reviewed Journal article	Prospective Time Series Analysis (4 periods)	N=52,568	Review of CPOE	^a Decrease of dose error ADE ^b Decrease of serious incident ADE	^a P<0.0001, ^b P<0.0003
Boyer, M.M.	Peer-reviewed Journal article	Article on Root Cause Analysis Process	N.A	Detailing sequential steps in Root Cause Analysis	Concept in Risk Reduction Strategies	N.A
Fletcher, C.E.	Peer-reviewed Journal article	Review and Case Study using Failure Mode and Effect Analysis	One hospital	Process Flow evaluation	Ranking the possibility of KCL overdose	N.A.
Spath, P.	Peer-reviewed Journal article	Description of FMEA processes for The Association of Perioperative Registered Nurses	N.A.	Continuing Nursing Education	Description with tools and templates	N.A.
Sexton	Peer-reviewed Journal article	Cross Sectional survey of operation theater and ICU staff	N=1033	Questionnaire Observer rating	Rating of team work in attitude, perspectives among surgeons and nurses by participants and observers.	Frequency distribution

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size	Data level (type of tool)	Outcome measures	
Risser	Peer-reviewed Journal article	Review article on the rate of team work failure in ER	8 hospitals in MA	Retrospective review of claim files and Team work failure check list by physician nurse pair	54 preventable adverse events from 1985-1996 occurred in ER	None
Howard SK	Peer-reviewed Journal article	Course description	Sample size non specific Course for anesthesiolo gists	Course feedback	2-h simulation session followed by a debriefing session which used a videotape of the simulator performance. Participants rated the course intensive, helpful	None
Felton JS	Peer-reviewed Journal article	Review paper	Sample size non specific Health professional s at risk for burn out	Literature review	A wide range of the health professionals are at risk, Prevention, early identification and treatment of burn outs are important	None
Payne SJ	Peer-reviewed Journal article	Review paper	Not specified	Designing and implementing computer decision support system	Example of HIV Guidelines at Boston Beth Israel, Antimicrobial Use in the ICU, The Veterans Affairs Computerized Patient Record System	None

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size	Data level (type of tool)	Outcome measures	
VanDenKerkhof, E.G., Goldstein, D.H., et al, 2003	Peer-reviewed Journal article	Before/after study with historical control, non-randomized	Unknown	Record review	Shorter median “total encounter” using PDA vs. paper	P<0.00
Meurier, C.E., Vincent, C.A., et al, 1997	Peer-reviewed journal article	One-time Survey	N=175	Questionnaire	Communication as a perceived cause of AEs	P<0.01
McKerrow, R., Johnson, N. (eds.)	Annual Report	One-time survey Hospital Pharmacy in Canada – Annual Report	N=123 pharmacy	On-line survey	ADE rate	Prevalence of ADE at the time of survey

Reporting Adverse Events and Increasing Patient Involvement

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size	Data level (type of tool)	Outcome measures	
Wanzel, K.R. Jamison C.G., et al, 2000	Peer-reviewed Journal article	Chart Review and Interview	N=192	Chart reviews, attendance of rounds, and interviews	Rate of reporting complications attributable to AEs	P<0.0001
Orser, B.A., Chen R.J., et al , 2000	Peer-reviewed Journal article	Mail survey	N=687 (mailed to 2,266 members, response rate 30%)	Self-reporting survey (by mail)	Rate of AEs reporting	Frequency distribution
Baker, G. R., Norton, P. (2002)	Report to Health Canada	One-time survey to health care facilities, colleges and associations	N=79 telephone N=48 mail	Literature review, telephone survey Mail survey	Rate of identifying patient safety issues or healthcare errors, and types of errors	Frequency distribution
U, D. 2001	Newsletter	Description	N.A.	N.A.	The Analyse ERR program	N.A.
Bernstein, M. 2003	Peer-reviewed Journal article	Review	N.A.	N.A.	Detection, prevention and disclosure of errors in neurosurgery	N.A.
Wilson, W 2002	Newspaper	Opinion	N.A.	N.A.	Issues on near misses	N.A.
Vincent, C. 2002	Peer-reviewed Journal article	Review	Various national surveys	Analyse existing report	Patients' report on Diagnostic accuracy, appropriate treatment, monitoring adverse events, and impact of AEs	Frequency distribution.

Developing Protocols and Guidelines

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome Measures	
Pazirandeh, M. 2002	Peer-reviewed journal article	Pre-post survey	N=672 1 st survey N=258 2nd survey	Interview, Screening for BMD	Increase order for BMD tests associated with consumer education	None significant change in pre-post physician order
Haley, R.W., Culver D.H., et al 1985	Peer-reviewed journal article	Retrospective chart review	US gen hospitals with or without infection surveillance	Chart review from 1970-76	Reduced rates in nosocomial infection associated with infection surveillance	P<0.05
Jarvis, W.R., 1996	Peer-reviewed journal article	Review article	N.A.	Published international literature	Costs associated with nosocomial infections mortality and morbidity associated with nosocomial infections	% for morbidity and mortality Mean healthcare cost per each type of infection
Baker, G. R., Norton, P. (2002)	Report to Health Canada	One-time survey	N=79 N=48	Literature review, telephone survey Mail survey	Rate of identifying patient safety issues or healthcare errors, and types of errors	Frequency distribution
Nolan, 2000	Peer-reviewed journal article	Education and Debate	N.A.	Discussions	Strategies for the design of safe system of care	N.A.
Orser, B.A., Chen R.J., et al , 2000	Peer-reviewed Journal article	A self reporting survey	N=687 (mailed to 2,266 members, response rate 30%)	Self-reporting survey (by mail) Structured questions and open ended questions	85% of the participants experienced at least one drug error / "near miss". 50% would report the error if a reporting program existed.	Frequency distribution

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome Measures	
Institute of Medicine	Report	Evidence based review	N.A.	Literature review of existing publications	a strategy for government, industry, consumers, and health providers to reduce medical errors calls for a national patient safety center	Consensus of experts

ORGANIZATIONAL LEVEL STRATEGIES

Managing Human Resources and Leadership Commitment to Safety Culture

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome Measures	
Aiken, L.H., Clarke S.P., et al, 2002	Peer-reviewed Journal article	Cross-sectional analysis	N=10,184 nurses N=232,342 discharged patients	Survey and administrative data	^a Risk-adjusted patient mortality and failure to rescue ^b Nurse-reported job-dissatisfaction and job-related burnout	^a P<0.05 ^b P<0.05
Lichtig, L.K., Knauf, R.A., 1999	Peer-reviewed journal article	Case-control study	N=462	Report Review	^a Length of stay associated with nursing staff skill mix and shortage ^b Increase rate of nosocomial infection associated with nursing staff shortage	^a P<0.01 ^b P<0.01
Roberston, R.H., Hassan, M., 1999	Peer-reviewed journal article	AHA Annual Survey of Hospitals	196 California hospital	Hospital database	Staffing intensity association with COPD patient outcomes	<0.05
CIHI	Report	Registered Nursing Database Mining	Nursing workforce in Canada	Registered nurse database 1997-2001	HR nursing projection	Projection on workforce, impact of retirement
University of Toronto and CIHI	Hospital Report Card	CIHI database and Patient satisfaction survey	120 Ontario Hospitals	Database and questionnaire A balanced scorecard method	Quality of care. Hospital rated by stars comparing with provincial average. Areas include patient satisfaction, patient care, finances and change strategy	Ranking by the relative performance

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome Measures	
The Change Foundation	Online Report	Workshops	Study ongoing, sample size not Available.	Pre-post questionnaire	Human Resource Strategic Planning	Study ongoing, not available.
Baumann	Report	Literature Review Quality workplace model Focus groups	Focus group in Eastern CA, Quebec, Ontario, and western CA. N=136	Review	Healthy workplace for nurses	Recommendation and Frequency distribution for focus group results
Marx D, 2001	Book	A model for the introduction of safer care	Not specified	Literature review on just culture	Chapter 5 on definition of just culture and how to achieve it	None
Herbert 2001	Peer-reviewed journal article	Review and case study	2 cases	Policy review disclosure of AE	Sunnybrook and Women's Health Sciences Center cases illustrating the AE disclosure policy	None
Harris AD 2000	Peer-reviewed journal article	A 74 question one time survey	N=199 health care workers in two tertiary hospitals	One time questionnaire	Healthcare workers understanding of hand washing	Frequency distribution
Baker, G. R., Norton, P. (2002)	Report to Health Canada	One-time survey	N=79 respondent in telephone survey N=48 respondent mail survey	Literature review, telephone survey Mail survey	Rate of identifying patient safety issues or healthcare errors, and types of errors	Frequency distribution

Public Disclosure

Author	Publication -type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome measures	
Brennan, T.A., 1990	Peer-reviewed Journal	Cross-sectional analysis	N=327 (records)	Medical record review	Rates of malpractice litigation	Frequency distribution
Brennan et al, 1991	Peer -reviewed Journal	Case-control study	N=31,429	Medical record review	Incidence of AEs	P<0.01
Donchin et al, 1995	Peer-reviewed Journal	Prospective cohort study	4 months data collection in a 650 bed hospital	24-hour bedside observation	Incidence of AEs in ICUs	P<0.05
Vincent et al, 2001	Peer-reviewed Journal	RCT	N=500	Record review	Incidence of AEs	P<0.001
Studdert & Brennan, 2001	Peer-reviewed journal	Review article	N.A.	Review of existing study on methods to gather AEs	Review and demonstration using Colorado data	N.A.
Bernstein 2003	Peer – Reviewed Journal	Review	N.A.	N.A.	Detection, prevention and disclosure of errors in neurosurgery	N.A.
Herbert 2001	Peer-reviewed journal article	Review and case study	2 cases	Policy review disclosure of AE	Sunnybrook and Women’s Health Sciences Center cases illustrating the AE disclosure policy	None
Ehman 2003	News	News report in CMAJ	N.A.	Saskatchewan College of Physicians and Surgeons require physicians to report AE	N.A.	N.A.

Author	Publication -type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome measures	
Runciman, 2003	Peer-Reviewed journal article	Review of International system in responding to AEs	Non specific	Theme comparison among Australia, Canada, new Zealand, Sweden and UK	Critical review of current non-fault, and malpractice systems	N.A
CMPA 2000	Brief report	Actuarial analysis of CMPA data over 10 years	58,000 CMPA members - physicians	Fees to protect malpractice of CMPA members	Fee changes over 10 years adjusting for inflation. Ontario 31% higher than national average	Comparison of fees across Canada
Croskerry 2001	Peer-reviewed journal article	Review on AE in ER	Not specified	Literature review on AE in ER based on a presentation made at CAEP	Unique characteristics in ER predisposing to AE, suggesting a CAEP reporting website	None
Merry 2001	Book	Systematic review: society's response to medical accident	Not specified	Case report, statistics on errors, discussion of error versus violation, and examination of the tort system	Distinguish negligence from errors due to complexity of care. Reduction of AE in surgery/anesthesia	In Chapter on high prevalence of AEs

Educating Health Care Providers of Safety Culture

Author	Publication-type	Methods			Results	Statistics
		Study type	Sample size (N)	Data level (type of tool)	Outcome measures	
Davis D.A., Thomson, M.A., et al, 1995	Peer-reviewed Journal	Cochrane Review (99 studies RCT; before/after)	N/A	Audit, review	Positive effects of education on physician performance	P<0.05
Halm, E.A., Borowsky, S., Benzer, L., et al. 2000	Peer-reviewed journal article	Case-control trial	N=250	Chart review and physician survey	Physician adherence to guidelines	P<0.001
AHRQ 2001	Report	Evidence based review	Varying among 11 patient safety strategies	Literature review of existing publications	Ranking on implementation costs, and complexity of each of the 11 strategies	Consensus of experts
Croskerry, 2001	Peer-reviewed journal article	Review on AE in ER	Not specified	Literature review on AE in ER based on a presentation made at CAEP	Unique characteristics in ER predisposing to AE, suggesting a CAEP reporting website	None