Commission of Inquiry on Hormone Receptor Testing

Part II Submissions

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Submitted by: Stewart McKelvey

Solicitors for: HIROC

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Tab 11

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Management's role in shaping organizational culture

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Management's role in shaping organizational culture

Aim The present study addresses the importance of the manager's role in the development and maintenance of organizational culture. It describes the types of cultures that exist and manager characteristics that are essential to facilitating a healthy workplace.

Background While many managers do not deny the importance of organizational culture in employee satisfaction, few fail to realize the direct impact they have in shaping it. It is oftentimes believed that cultures are predetermined; however, this is a false assumption. It is crucial that managers at all levels are aware of their roles and responsibilities in upholding positive workplace environments that can increase employee satisfaction. Dissatisfaction is the major cause of turnover and can have detrimental cost and environmental effects on the agency.

Evaluation Four critical components of culture (i.e. trust and trustworthiness, empowerment and delegation, consistency and mentorship) are discussed, as is the role of managers in turning these into positive cultural traits. The viewpoints of several authors, such as Stephen Covey, Mark McCormack and Charles Handy, are explored in relation to the development of organizational culture. Additional theories – Kanter's 'Theory of Organizational Empowerment', Locke's 'Goal-setting Theory' and the 'Social Exchange Theory' – supplement these viewpoints.

Conclusions Managers are always under the magnifying glass, with each action carefully scrutinized by subordinates. They must exercise caution when making decisions, ensuring that fairness and equitability exists among staff, and that ethical standards are upheld on a continual basis. The four cultural components, viewed as managerial traits of trust and trustworthiness, empowerment, consistency and mentorship coexist at all times regardless of the type of culture. Managers must put support systems and other mechanisms into place that allow employees the opportunity to empower themselves and to flourish, thus increasing their own effectiveness as well as that of the organization.

Keywords: culture, employee satisfaction, management, organizations, role of manager

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Introduction

Culture represents the personality of an organization, having a major influence on both employee satisfaction and organizational success. It 'expresses shared assumptions, values and beliefs and is the social glue that holds an organization together' (Trevino & Nelson 1999, p. 207). While every organization has a culture, it is sometimes elusive and open to different interpretations. According to Deal and Kennedy (2000), 'a strong

culture is a system of informal rules that spells out how people are to behave most of the time. In a weak culture, employees waste a good deal of time just trying to figure out what they should do and how they should do it' (p. 15). While most managers do not deny the importance of organizational culture in employee satisfaction, few fail to realize the direct impact they have in shaping it.

When the culture is strong, managers take the lead in shaping and supporting it. Those who take this approach are called 'symbolic managers because they spend much time thinking about the values, heroes,and rituals of the culture, and because they see their primary job as managing value conflicts that arise in the ebb and flow of daily events' (Deal & Kennedy 2000, p. 141). Several authors have addressed the manager's role in developing a healthy culture for his or her organization, and commonalities include the manager's exemplification of trustworthiness and trust, empowerment and delegation, consistency and mentorship. These themes will be discussed in relation to the 'power/role/task/person' cultures within organizations described by Handy (1985).

A framework for organizational structure

Handy (1985) – philosopher, educator, economist and business guru – has addressed the organizational phenomena that contribute to both the successes and downfalls of business organizations. His work, which identifies four cultures (i.e. power, role, task and person), provides a framework for examining and understanding organizational culture. Each type has its own unique characteristics, each can be effective, and each can exist along with the others. As a framework for management within health care organizations, each of the four cultures contributes to creating a healthy workplace.

Power culture

A power culture is ruled by a central power source, such as an owner or President, and is most frequently found in entrepreneurial organizations. Trust and personal communication are important characteristics, thus it is important for employees to have interpretations of the job that are similar to those of the leader. Minimal bureaucracy exists, so that staff function with few rules, policies and procedures. While applications within health care organizations have been limited, modified applications could make important contributions to the empowerment of nurses and other staff members in health care settings.

Role culture

The role culture, more familiarly known as a bureaucracy, is the category in which most hospital organizations fall. The strength of role organizations resides in 'its pillars, its functions or specialties' (Handy 1985, p. 190). Each unit (e.g. Emergency Department, Labor and Delivery, Medical-Surgical Services) is a pillar supporting the organization. Policies and procedures control the organization, and employees operate based on job descriptions. There is 'a narrow band of senior management...' and if the 'separate pillars do their job, as laid down by the rules and procedures, the ultimate result will be as planned' (p. 190). Advancement within this type of organization is predictable, and the use of a clinical ladder as a staff evaluation tool is justified.

Task culture

In a task culture, the focus is on a particular job or function. Although health care organizations currently operate largely within the context of a role culture, task cultures are often developed simultaneously. This culture aims to assemble the right people with the right resources, so that a job can be accomplished. This may be in the form of action committees, which meet for a specific purpose (e.g. scheduling and staffing issues), and then disband when the task is complete. Not only it is possible, but also it is quite common for a health care organization to have its core culture (role), in addition to an underlying subculture (task).

Person culture

The person culture, which is uncommon, 'exists only to serve and assist the individuals within it' (Handy 1985, p. 195). While a health care organization cannot exist solely on this idea, there may be some appropriate applications. One prime example is within a hospital's mentoring system. Initially, the 'student' is chiefly concerned with acquiring the personal skills necessary to survive in a particular workplace, while the mentor may only be serving in that capacity in order to earn points on a clinical ladder towards promotion. Each is gaining something from the situation. While some actions may be promoting staff interests and growth, these are supported with hope that the ultimate outcome will aid in the enhancement of organizational goals, such as shifting away from a personal culture and towards one of more unity, such as the role or task cultures.

Management's responsibilities

There is no one omnipotent culture. What works this year may not work in the next. Every hospital system must operate according to its policies and procedures, regardless of whether they are profit *vs.* non-profit or public *vs.* private. As there is a systematic process to health care delivery, it is safe to assume that hospital organizations have a role culture at their core. The cultures of task and person frequently exist as well. To enhance what is accomplished, integrating the power culture might be given increased consideration by health care organizations. While these types of cultures may seem to be predetermined, in no way does that mean that the manager is off the hook. On the contrary, it is the responsibility of all levels of management to facilitate a positive workplace environment. Managers must value the traits of trustworthiness and trust, empowerment and delegation, consistency and mentorship. These are the building blocks of any flourishing organization.

Trustworthiness and trust

Covey (1991) is a modern-day theorist that seeks to change conventional practices in organizational management. In his book, 'Principle-centered Leadership', Covey (1991) discusses the components of trustworthiness and trust within an organization. Trustworthiness is 'more than integrity; it also connotes competence' (p. 171). Managers can be honest with their staff, consumers, suppliers and stakeholders; but if managers are viewed as incompetent, they will not be deemed trustworthy.

While trustworthiness is a result of character and competence, trust is the actual act of believing in someone and having confidence in them. The level of trust in an organization can foretell its success because it is a crucial element linked to employee performance and organizational commitment (Laschinger *et al.* 2000). Trust includes the willingness to take risks because the act of trusting makes one vulnerable to others' actions. The trustor must rely on the assumption that others will act in a favourable manner. Gilbert and Tang (1998) state that 'trust refers to employees' faith in organizational leaders and the belief that ultimately organizational actions will benefit employees' (p. 322).

In establishing trust, entrepreneur, McCormack (1984, p. 36), believes that as a manager, you must 'mean what you say'. 'If you say you're going to do something, do it. If you can't do it, think it's more trouble than it's worth, or don't want to do it, don't say you will. Make up any excuse, but don't even say, "I'll try"'. Employees need to be able to have faith in what they are being told.

Trust does not only flow upward from the employees to management, but also vice versa as well. Symbolic managers place a greater level of trust in their staff and depend on them to guarantee successful outcomes (Deal & Kennedy 2000). Handy (1985) adds that 'Trust is risky...' but 'like a leap into the dark, trust must be given if it is to be received' (pp. 328–329). A manager must have confidence in its employees before he or she can trust them. This trust can be earned in several ways, such as performing well, being reliable and by not making threats to leave to bigger and better companies.

Finally, employees take into account the ethical behaviour of managers when establishing their trust in the organization. Employees tend to directly relate the ethics of the company into how they're personally treated. When organizational leaders represent high ethical standards, job commitment increases (Trevino & Nelson 1999). Managers are confronted daily with ethical decisions, such as proper resource allocation, upholding safe patient/staffing ratios and maintaining confidentiality not only of patients, but also of employee matters as well. Employees look to their managers to make sound moral decisions. When these decisions teeter on the edge of morality, respect is lost. Furthermore, an unscrupulous manager may find it difficult to successfully and adequately discipline unethical behaviour by his or her subordinates. It is important to uphold the standards of the nursing profession at all times, and it is the manager who must reinforce this credence by acting as a role model.

Empowerment

The first components of trust and trustworthiness must be prevalent before empowerment can be successfully achieved. Empowerment is the process of enabling others to do something. 'Principle-centered Leadership' implies that personal contribution is a great motivator (Covey 1991). People want to feel valued and the principle of empowerment contributes to an employee's sense of worth. A manager can empower others by including them in problem solving. Many managers today seek quick-fix solutions to chronic problems, and they fail to see the long-term consequences of their short-ranged decisions. Throughout his book, Covey (1991) constantly refers to the 'preparing of the harvest'. In this reference, he explains, that 'in order to reap the harvest...we must first plant, water, weed, cultivate and fertilize it' (p. 164). Just as harvesting is a process,

so is the concept of problem solving. He asserts that by involving others in the problem, they become a dedicated participant in the decision-making and problem-solving process.

Many hospital organizations establish committees to review policies and procedures, assist with discharge planning, or to address other specific matters, thus forming the previously discussed Task culture (Handy 1985). Many people cringe when they are asked to serve on a committee, but the truth is that employees want to be valued and to feel they can make a difference. Nevertheless, for employees who shy away from committee involvement, employee empowerment can be gained when they are allowed input into the creation of their schedules and assignments.

Rosabeth Moss Kanter developed the 'Theory of Organizational Empowerment' in the 1970s. The premise of her theory is that when opportunities for empowerment are provided, employee attitude improves, and in turn, the organization will become more effective in achieving its goals (Laschinger *et al.* 2000). Kanter believes that there are several organizational structures that are important to the growth of employees' empowerment. It is essential that management provide its employees not only with adequate information and resources necessary to do a job, but also an effective support system and the opportunity to learn and grow. When these elements are intact, an increased sense of autonomy and self-worth exists, thereby improving productivity and organizational commitment (Laschinger & Wong 1999).

Not only are these components essential, but also they are fairly easy to provide. Information can be dispersed via committee, departmental, or hospital-wide meetings. Additionally, messages can be relayed via e-mail or by simply posting bulletins in the staff lounge. Regardless of the method, communication must remain constant between managers and their subordinates. Support can be provided by establishing mentor systems, while the opportunity to flourish can be provided by offering possibilities for advancement and by providing continuing education, for example.

Delegation

Delegation is yet another form of empowerment that managers can provide to their employees. McCormack (1984) states:

> 'People often delegate – or fail to delegate – for all the wrong reasons. They hold on to a task because they like doing it, or want to do it, or are afraid not to do it, and they will pass down some other task because they find it distasteful or 'beneath them' or have rationalized that it is not the best use of their time (p. 187)'.

He also adds that the more distasteful a task, the further down it is usually delegated. One bit of advice McCormack (1984) offers managers is to not ask anyone to perform a task or function that you are not willing to do yourself. For instance, a manager should not request that employees stay late to cover shifts, if they are not willing to put in extra hours themselves. The manner in which a manager delegates tasks can be critical when establishing leadership and trust among his or her subordinates. According to Cohen (2004), when a manager delegates tasks, employees are looking at '*who*' they delegate things to, '*what*' type of things they delegate, '*how often*' things are delegated, and '*why*' 'in their mind' they are delegated. If done correctly, it can earn the manager respect. On the contrary, however, it can be destroyed just as quickly.

Consistency

Covey (1991) discusses the importance of consistency within an organization, and introduces the term 'alignment'. Within an organization, this means that its structure, mission statement, shared values, management philosophies and all other aspects must be congruent (or aligned) with one another. These components align when an organization is centred on unwavering principles (such as trustworthiness, trust and empowerment). There will be no contradiction between what is said and what is actually done.

McCormack (1984, p. 190) criticizes nearly all management philosophies to date. He claims that what sounds good in a book, rarely works in real life. 'Once you factor in human beings – egos and personalities – even the most sensible theories begin to fall apart'. He adds that 'the only management philosophy that does work is the one that acknowledges that none of them do: be flexible and strive for consistency' (p. 190). While flexibility and consistency seem to be contradictory terms, they do, in fact, coexist in management. Flexibility is needed when policies, goals and mission statements, for example, call for revision. 'A flexible, responsive management virtually guarantees consistency. It is inflexibility that causes erratic behaviour.... To manage consistently you have to behave consistently.... Inconsistency in management breeds all sorts of unnecessary anxieties in the people being managed' (pp. 191–192).

As previously mentioned, workers prefer a system in which rewards and discipline are handed out accordingly. When either one is doled out by managers, consistency must be prevalent. Regarding discipline, each employee must understand the rules and behaviour that is expected within the organization. Those requirements must remain consistent if employees are expected to learn them (Rowland & Rowland 1997). Discipline must be handled fairly and consistently at all times. There should be established guidelines indicating the steps of the disciplinary process. For instance, the first violation may warrant a warning, while the second may warrant some form of remediation, and so on. Whatever the disciplinary process may be, employees must be aware of its existence and the manager must adhere to it, to ensure that employees are treated fairly and equally. Lastly, it is important for managers to remember that they are role models. They cannot effectively discipline their staff if they are guilty of the same punishable actions.

Like discipline, consistency must also be prevalent when rewarding staff, whether it is in the form of verbal praise or small tokens of recognition. Employees must feel that these things are given out for substantial reasons, such as hard work, rather than feeling that 'only the boss's friends get the rewards'. 'If expected reactions do not occur or rewards are not forthcoming, a behaviour will cease. If, however, the behaviour is rewarded, it will be reinforced and social bonds will be created' (Riggs & Rantz 2001, p. 48). Employees will not have complete trust for their managers nor will they be motivated to work as hard, if they feel that the reward system is lacking in fairness and consistency. For instance, if employees receive recognition for perfect attendance 1 month, then they should receive it for subsequent months as well. Or, if a manager has tickets to an event to pass out, they should be sure to include employees on all shifts. Oftentimes, it is the employees who are 'lucky' enough to be working a certain shift that gets the free handouts. Rewards should not be given out simply to those who are at the right place, at the right time. Rewards should be fair and equitable. When they are not, trust diminishes along with employee satisfaction.

Mentorship

'Social Exchange Theory' is widely used in organizational studies to explain how social relationships materialize, endure and cease over time (Riggs & Rantz 2001). Within this theory, it is believed that social values are what influence particular behaviour. Because organizational culture is composed greatly of behaviours, 'Social Exchange Theory' can be applied to its development. This is possible because the attitudes, values, norms, behaviours and all other facets of culture are learned. Furthermore, according to Edwin Locke's Goal-setting Theory, 'Goals are a way to translate values into action. The theory is based on the concept that goals are determining factors for behaviour' (Beeman *et al.* 1999, p. 92). Both of these theories can be applied when establishing a mentor programme within an organization.

Socialization is often begun through orientation programmes, and ideally is reinforced throughout employment. It is during this time of orientation that the organization's values and principles can be communicated and instilled into the behaviours of new employees (Trevino & Nelson 1999). For example, nurses have their own 'language, rules and way of thinking unique to their organization. It is important the new nurse learn this language through socialization' (Beeman *et al.* 1999, p. 92). Mentors help their 'students' by establishing goals to be met during the training process. Locke's theory may be utilized to yield very specific outcomes congruent to the behaviours and norms expected within the organization. Oftentimes, it is during this process that employees realize that their personal values and standards may not coincide with those of the organization. In these instances, the employee or employer frequently terminates the working relationship.

Providing mentors to new employees also helps to alleviate some of the anxiety that goes along with being in a new environment. They feel that they are not alone because they have someone to 'teach them the ropes'. In addition to serving as a resource guide, mentors carry out many other functions as well. They teach others how to function within a leadership role, how to perform technical aspects of the job, they help others to gain acceptance within the organization, they model discipline and hard work, offer psychosocial support, communicate frequently and evaluate honestly (Savage 2001). A new employee usually trusts the person who mentors them, and may even feel a greater sense of commitment to the organization as they are answerable to another person. Having a mentor increases job satisfaction, decreases feelings of work alienation, is related to an increase in productivity, and results in an increased retention rate (Roemer 2002). 'Mentoring programmes help establish a sense of loyalty and attachment to a company; employees think twice about leaving when they feel those emotional ties' (Warren 2005, p. 28). This is significant because according to Thomas Group, Inc. (2004), the average cost incurred to recruit one registered nurse can exceed $25 000 per annum. It should be noted that this figure does not

include orientation costs associated with training a new staff nurse.

Managers must be responsible when selecting employees to serve as mentors. A poor mentor who lacks strong values and exhibits unwarranted behaviours, is likely to drive the new employee away. Good mentors are crucial because they are usually the first people to work with a new employee. Frequently, the mentor provides the first impression of what the organization is about. Also, when a new employee has difficulties or is unsure about his or her place within the organization, it is often the mentor who provides cohesion between the employee and the organization.

Keeping these factors in mind, managers should be aware that mentors, also called preceptors, must possess certain qualities in order to be successful. According to Hayes (1994), preceptors must have both 'personal' and 'professional' qualities. 'Personal' qualities include being helpful, caring, flexible, dependable, motivated and respectful. 'Professional' qualities of a preceptor include being interested in professional growth, confident, knowledgeable, involved in the agency and secure in the role. Moreover, a preceptor must take initiative, have good communication skills, be able to deal with conflict, and serve as a good role model. Preceptors need to be team players who are willing to provide assistance whenever and wherever needed (Anderson & Pulich 2002). It is important for the manager to place careful consideration into who should be selected as a preceptor, as one that is mediocre will make the new employee's transition more difficult. This can ultimately prolong the need for training and orientation, thus contributing to both employee frustration and increased administrative costs (Mundie *et al.* 2002).

Conclusion

Culture in an organization is very important, playing a large role in whether or not the organization is a happy, healthy place in which to work. While many managers acknowledge the significance of culture, few realize the roles and responsibilities that they have in its development. Regardless of the type of culture (i.e. power, role, task and person), the four components discussed – trustworthiness and trust, empowerment and delegation, consistency and mentorship – all contribute to the overall good of the organization. These factors cannot stand-alone. Not only do they coexist, but also empowerment and mentorship are based upon the foundation of trustworthiness and trust, and likewise, a strong mentor programme contributes to that level of trust as well (see Figure 1).

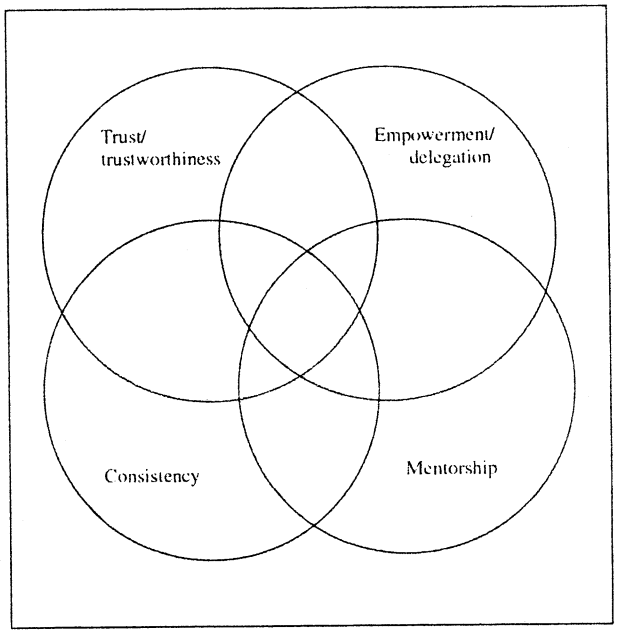

Figure 1
Cultural components are interdependent.

Managers must realize their function in establishing and maintaining an organization's culture. The attitudes, values and behaviours of an institution begin with its leadership. This is done through role modelling and communication at all levels. Managers must not forget the importance of being consistent when expressing these attitudes, values and desired behaviours. When one or more of these components are missing or are weak, the organization will eventually suffer. This is a consequence that our health care system cannot endure.

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Tab 12

Full Text

Lippincott Williams & Wilkins — Journal of Nursing Administration

The Impact of Culture Change on Nurse Retention

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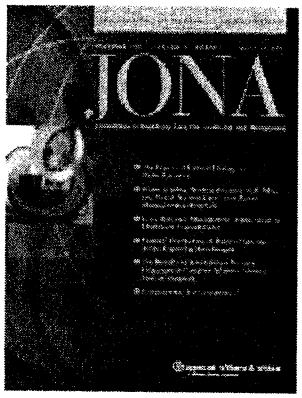

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Abstract

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Abstract

Given the nursing shortage, retaining qualified nurses is of primary importance to nurse executives. In this article, the authors discuss problems they experienced in retaining newly hired nurses on 3 surgical nursing units and describe how efforts to change the culture of the units resulted in dramatic improvements in nurse satisfaction and the retention of new hires.

In 2002, analysis of turnover rates among the 3 inpatient units that make up surgical programs at Children's Hospital Boston uncovered a

Graphics

disturbing finding. Although many of the program's nursing staff had been with the hospital for 10 to 25 years or more, turnover among newly hired nurses, which included new graduates and experienced nurses, had reached a surprising level. Of the 25 nurses hired into the program during the previous year, 54% voluntarily terminated employment in the first 12 months. Although this rate of turnover was consistent with rates of 35% to 61% reported for new graduates in their first year of employment,[1,2] it was markedly higher than the national turnover rate of 21.3%[3] and contrasted sharply with the 10% rate of turnover observed at Children's Hospital Boston as a whole.

To understand the reasons behind the high turnover rate, nurse leaders in surgical programs spoke with newly hired nurses about their experiences during the first year. The nurse leaders discovered common themes suggesting that the high turnover rate signaled problems with the culture of the surgical units. Over the next 6 months, the leadership team, which included the nursing director, nurse managers, clinical nurse specialists, and nurse educators, developed and implemented a program that not only changed the way newly hired nurses were oriented but also changed the culture of the nursing units. The program was based on 4 core beliefs-partnership, coaching and collaboration, communication, and a sense of belonging-and emphasized the responsibility of all staff for the successful transition of orientees. In the first year after the program's implementation, turnover among newly hired nurses dropped to 4%, a reduction that has been sustained in each subsequent year.

Nursing Turnover and the Work Environment

Minimizing nurse turnover is important from both a quality and a cost perspective because maintaining an adequate nurse workforce is essential to good patient outcomes [4] and replacing nurses who leave carries significant cost.[1] Because of its importance, numerous studies have examined nursing turnover and the factors that contribute to a high turnover rate. A meta-analysis conducted by Irvine and Evans [5] indicated that job characteristics (such as the level of autonomy and routinization), problems with role definition (including role conflict and ambiguity), and aspects of the work environment all contribute to low nurse satisfaction which, in turn, increases a nurse's intention to leave a job setting. A comprehensive review of the satisfaction literature shed more light on the multiple variables that impact nurse satisfaction and underscored the importance of administrative and management practices, the level of support for nursing and nursing practice within an institution, working conditions, the quality of interpersonal relationships, job/task requirements, pay, and fairness.[6]

A number of studies have examined the relationship between selected variables and nurse satisfaction and/or turnover. Findings related to several important variables are summarized below.

Management Style

Volk and Lucas [7] examined the relationship between management practices and anticipated turnover and found that a more participative (vs authoritarian) management style is associated with less anticipated turnover. Leveck and Jones [8] reported that unit management style affects group cohesion and job stress, both of which indirectly affect job satisfaction and staff retention. A comprehensive review of the literature on the relationship between management style and nursing retention found that transformational styles of leadership that focus on affiliation and strong communication; managers that are open and extroverted; and managers that encourage an atmosphere of autonomy, shared governance, group cohesion, and empowerment of staff promote nurse retention.[9]

Organizational Culture and Group Cohesion

Gifford et al 10 found that cultures that focus on building trust, which emphasizes cohesion and encourages participatory decision making and open communication between managers and staff, are associated with higher levels of job satisfaction; an intervention to promote group cohesion was associated with higher levels of staff satisfaction and a lower rate of turnover.11

Support for Nurses

The impact on job satisfaction of weak organizational support for nurses and nursing care was demonstrated by Aiken et al,12 who found that nurses working in hospitals with weak support were twice as likely to be dissatisfied with their jobs and had burnout scores higher than normal for medical personnel.

Sense of Belonging

Developing a sense of belonging, a factor that depends on the strength of interpersonal relationships within the work environment, is associated with higher levels of new graduate satisfaction.13

Why Nurses Stay, Why Nurses Leave

A survey of staff nurses in North Carolina asked nurses why they stayed with their employer. Good mentors and colleagues, satisfactory pay, desirable benefits, flexible scheduling, and positive relationships with physicians were the top 5 reasons cited by registered nurses (RNs).14 In a study of new graduates, Bowles and Candela 15 found that concerns related to patient care and the work environment were among the top reasons new graduates left a first job.

In light of these findings, the nurse leaders in surgical programs concluded that to decrease the turnover rate among newly hired staff, they needed to create a work environment that assured support for all nurses from the most experienced to the newest orientee and that held all staff accountable for a successful orientation.

The Surgical Units

The 3 inpatient surgical units care for a range of patients, including children having general surgery, orthopedic procedures, and organ transplants. In 2002, each unit had between 8 and 36 beds and together comprised 100 nurses. The units' nurse managers were experienced nurse leaders who had been in their roles for a number of years. Each unit had a stable core group of staff that had worked together for many years and was highly knowledgeable about surgical nursing practice. Because of their experience and expertise, the nurses in these core groups had been instrumental in helping the units maintain exemplary standards of care and achieve high levels of patient satisfaction. Historically, the units had enjoyed relatively low vacancy rates. However, in the years leading up to 2002, the number of vacancies and the number of new hires steadily increased and staff members on the units found themselves facing a new challenge-that of welcoming and integrating a new generation of nurses.

Before 2002, the orientation program for nurses entering a surgical unit at Children's Hospital Boston was similar to that found in many other institutions. Nurses attended several days of classes and then spent 6 to 8 weeks working under the guidance of a nurse preceptor, a role that was typically filled by one of the more experienced nurses on the unit. Until the leadership team took a closer look at turnover among new hires, the orientation program and the ways newly hired nurses were supported during their first year of practice had not been questioned.

Uncovering the Problem

When the turnover statistics came to light, the nurse leaders convened a series of retreats that were designed to identify what lay behind the high turnover rate and to discuss strategies for effecting change. The retreat participants included all members of the leadership team as well as experienced members of the nursing staff. During the retreats, the nurse managers, clinical nurse specialists, and nurse director each facilitated a preselected group of retreat participants that was charged with considering a "defined problem related to retention." The teams were asked to brainstorm factors that contributed to the problem and to propose a plan for change along with desired outcomes. Each team presented their change plan to the larger group, which then worked together to define next steps for implementing and evaluating the proposed changes. Experienced staff nurses attending the retreats also completed an evaluation tool in which they assessed

the success of the retreats, shared additional insights and concerns, and discussed their own learning needs.

Through the retreats, and subsequent conversations with newly hired nurses, the leadership team grew to understand some of the factors that contributed to high turnover among newly hired staff. They learned that the orientation program and other educational opportunities offered on the nursing units did a good job helping newly hired nurses develop the technical skills required for pediatric practice. What the nurses did not develop during their first year, however, were relationships or a sense of connectedness that helped them feel they belonged to their unit and to surgical programs. Even after being on a unit for 12 months, many nurses felt they were not accepted, particularly by the unit's more experienced veterans. These feelings of separateness were compounded by the independent way each unit operated, as orientation was handled separately by each of the units and other opportunities for cross-unit collaboration were limited. Newly hired nurses also felt that opportunities for ongoing professional development were limited, as nurse managers tended to appoint only the more experienced nurses to task forces, committees, and other initiatives that fostered professional growth.

The nurse leaders also learned of the emotional toll experienced by senior nurses who served as preceptors. In general, the preceptor role was filled only by very seasoned nurses, and as a result, some senior staff had repeatedly been tapped for the role. These nurses noted that although their role as preceptors was clearly defined, the roles that other staff needed to play in supporting new nurses were not. As a result, preceptors often felt the full weight of responsibility for a new nurse's experience. On rare occasions, the preceptor role was made more burdensome by the expectation that preceptors would also take a patient assignment or assume charge responsibilities as needed.

As the leadership team examined minutes and other data from the retreats, they recognized yet another factor that contributed to divisions among staff members. Over the years, a noteworthy age difference had developed between nurses serving as preceptors and those entering the units, and by the late 1990s preceptors and newly hired nurses were often a generation or more apart. The difference in age was manifested through varying expectations regarding shift rotations, opportunities for professional development, involvement in unit activities, and other aspects of work life. Upon reflection, the nurse leaders realized that, given the range of ages represented among their staff-a range that encompassed Baby Boomers in their 40s and 50s, members of Generation X in their 30s, and Nexters in their 20s 16-the different expectations were inevitable and likely contributed to the feelings of isolation and burden experienced by the new and experienced staff. Compounding the generational differences was an impression held by many newly hired nurses that their experiences and insights were undervalued by older nurses who were comfortable with the way things were done and were hesitant to change the "status quo."

Based on their findings, the nurse leaders concluded that the mechanisms in place to support newly hired nurses were insufficient and needed to be redesigned and enhanced. They recognized that the sense of isolation expressed by nurses new to surgical programs reflected a unit culture that emphasized expertise and independence more than collegiality and partnership. What newly hired nurses desired most was support from all levels of the nursing staff, a sense that they belonged to surgical programs and to their units, a chance to be involved in program and unit activities and projects, open communication and constructive feedback from nursing colleagues, and validation of their nursing competence-factors that the literature indicates are linked to nurse satisfaction and turnover. The nurse leaders recognized that new approaches to supporting newly hired nurses were called for and that these approaches would be successful only if every member of the staff were actively involved in supporting new nurses and assumed accountability for their success.

The New Orientation Program: A Vehicle for Culture Change

After the results of the retreats were analyzed, work to develop a new orientation program began. Backed by an advisory group composed of members of the leadership team, the nursing director and the education nurse specialist took the lead in defining the new program. As a first step, they reviewed the literature on effective orientation programs, which highlighted the importance of a structured preceptor experience [17,18] and of involving managers in the orientation process.[19] They then convened a focus group of preceptors to obtain their perspective and input on what should be included in a new orientation program.

Building on the suggestions obtained through the preceptor focus group and earlier retreats, the nursing director and

the education specialist developed goals and objectives to guide the new program's development. They agreed the new program should accomplish the following:

* Define clear role responsibilities for all staff in the areas of partnership, coaching and collaboration, communication, and promoting a sense of belonging, and hold staff accountable for fulfilling their role obligations
* Allow customization of the orientation experience based on a new nurse's learning needs and experiences in nursing
* Offer orientees multiple opportunities for support and feedback
* Expand the pool of nurses serving as preceptors and develop mechanisms for preceptor support
* Foster improved collaboration and relations among the surgical units

Once the objectives were established, work to define and develop specific program elements began, and in March 2002, the Partnership Unit-Preceptorship (PUP) program was launched.

Differences Between the Old and New Programs

The PUP program was substantially different from the orientation model used before 2002. Like the old program, PUP complements and expands upon a general, 3-day hospital orientation and focuses on helping newly hired nurses acquire knowledge and skills specific to surgical programs. Unlike the old program, however, the PUP program makes all nurses responsible for a successful orientation experience and emphasizes the importance of partnership and coaching relationships between new nurses and other members of the staff.

Before PUP was introduced, new hires could begin orientation on one of the surgical units at any time. As a result, they often missed out on the benefits of having an established peer group. With the PUP program, orientation across the units is synchronized so that new hires from each unit enter employment at the same time. Because they attend orientation classes together and meet weekly as a group throughout the orientation period, they quickly get to know each other and are able to draw on one another for support.

Unlike the old program, which was of fixed length, the PUP program allows an orientee's preceptorship to be of variable length depending on the nurse's learning needs. Preceptors no longer take a patient assignment or assume charge responsibilities and are expected to meet with the new nurse each week to reflect on the orientation experience, offer constructive feedback, and establish goals for the remaining weeks. The same preceptor remains with the new nurse throughout orientation-a change from the old program that occasionally assigned an orientee 2 to 3 different preceptors depending on unit needs.

The PUP program has changed the preceptor role in a number of other ways. Before the program was launched, 16 new preceptors were recruited from the 3 surgical units. All of the preceptors attended an in-depth training session in which they explored teaching and coaching techniques, examined the impact of unit culture on newly hired nurses, and discussed how they could help orientees feel welcome and successfully transition to independent practice. A support group for preceptors was also developed to encourage preceptors from the 3 units to share experiences, insights, and strategies related to their role. To address the generational differences between preceptors and orientees, the 16 new preceptors included nurses who had been in nursing for 5 years or less and who were closer to the average age of most orientees. In addition, the preceptors, along with the rest of the staff, attended seminars that examined generational differences and that reinforced the importance of appreciating the perspective of all nurses and adapting the work environment to meet the needs of different generations.

Shared Accountability

Perhaps the most significant change introduced by the PUP program was the expectation that all members of the nursing staff-from orientees to the nursing director-shared responsibility for ensuring a successful orientation experience and helping newly hired nurses transition to independent practice. The responsibilities for each member of the staff were aligned to core beliefs-partnership, coaching and collaboration, communication, and a sense of belonging-that underpin the orientation program. The role responsibilities were outlined in a document shared with the nursing staff (see Table 1) and discussed during retreats and staff meetings on each unit.

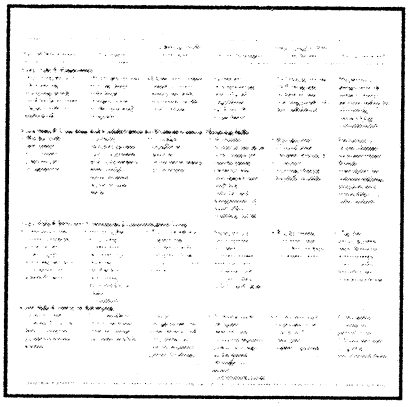

Table 1. Partnership Unit-Preceptorship (PUP) Orientation Program: Behaviors and Role Responsibilities Aligned to Core Beliefs

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Partnership

As noted earlier, partnership, or working with peers and colleagues to achieve shared goals, is a dominant theme of the PUP program. The program's developers realized that promoting partnerships was essential because collegial relationships among nurses would not develop and other necessary changes could not occur if staff worked in isolation. In the early stages of PUP, the nurse director, nurse managers, and education coordinator focused their efforts on modeling partnering behaviors by meeting regularly with orientees and preceptors to assess the progress of orientation and to discuss how it could be tailored to meet a particular nurse's needs. They also created opportunities for partnering between new and experienced staff. For example, as part of the PUP program, a newly hired nurse was assigned a nurse resource after orientation. The nurse resource was someone other than the nurse's preceptor and was charged with being available to answer questions, coaching the new nurse through unfamiliar experiences, and helping the new nurse address still unmet learning needs. Charge nurses were also expected to stay in close touch with new nurses and to adjust assignments as necessary to promote the new nurse's continued learning and development. Through these role changes, experienced nurses developed a greater sense of responsibility for the new nurse's successful transition to independent practice. Other changes to the orientation program, such as broadening the preceptor pool and more carefully matching orientees and preceptors, also helped promote partnering behaviors.

Coaching and Collaborating to Promote Critical Thinking

With the PUP program's introduction came the expectation that nurses at all levels must seek out coaching support and serve as coaches and mentors to those in need of guidance. Efforts to strengthen coaching skills began before the PUP program was initiated. Nurse leaders and leadership staff reviewed coaching skills in seminars, and preceptors studied coaching techniques in a newly designed preceptor training program.

Shortly after PUP was launched, other initiatives were introduced to promote coaching and collaboration, and to foster the development of critical thinking skills. These included nursing clinical bedside rounds and staff "huddles." In clinical bedside rounds, nurse leaders and staff meet to review a patient's plan of care and draw on one another's experience and knowledge to identify what is working well and what can be improved. Staff huddles involve impromptu meetings of all staff on a shift. A huddle can be called by any nurse who needs help managing an assignment or who observes that a colleague is falling behind. During the huddle, the nurses review their patient assignments and make changes as necessary to ensure that everyone has the support they need. These and other initiatives not only reinforce expectations regarding collaboration but also create a safety net for staff and help newly hired nurses develop the critical thinking skills needed for safe and effective patient care.

Sense of Belonging

Several programs were created to help foster a sense of belonging among new staff and to help staff develop relationships with peers and colleagues on the other surgical units. One of these programs is the preceptor support group that was described earlier. Another is the Lunch Bunch support group, a program for nurses who have finished orientation but have not yet completed 2 years of practice. The Lunch Bunch support group meets weekly to discuss issues of concern to the developing practitioner, such as physician/nurse collaboration, conflict resolution, and time management. The education coordinator and the nurse director facilitate the sessions and encourage participants to discuss their experiences and share recommendations for improving how things are done on the units. Because many of these recommendations have been successfully adopted, Lunch Bunch sessions are now viewed as an important vehicle for problem solving. They have also helped send the message that the input of new nurses is valued and is essential to ongoing efforts to improve the practice environment.

Perhaps most important to developing a sense of belonging are the actions of experienced staff. The PUP program prompted many discussions among staff about unit culture, and over time veteran staff members began to appreciate the impact they have on newly hired nurses and the role they can play in creating a welcoming environment. With encouragement from the leadership team, staff nurses have learned that simple acts like inviting a new person to join them at lunch, sharing breaks, or coaching a new nurse through an unfamiliar procedure can go a long way toward developing a sense of belonging and enhancing group cohesion, factors that are important to both nurse satisfaction and retention.

Continuous Communication

One of the most significant changes resulting from the PUP program has been in the area of communication. A number of processes were instituted to help change the environment from one in which communication was limited to one that promotes dialogue and the exchange of ideas. These include the preceptor support group, the Lunch Bunch sessions, and the weekly meetings involving orientees, preceptors, and education coordinators. In addition, once PUP was launched, nurse managers and the nurse director began to more actively monitor each orientee's progress and became involved in identifying resources to meet learning needs. Even more important than these formal structures, however, has been the increased visibility of nurse leaders and the open door policy they now maintain. The presence and involvement of the nurse leaders has prompted more dialogue between managers and staff, has served as a model for open communication, and has reinforced expectations regarding communication, coaching, and partnering.

Results

As members of the staff adjusted to their expanded roles and responsibilities, the isolation that had been a hallmark of the newly hired nurse's experience was gradually replaced by a spirit of collegiality, partnership, and shared accountability. Within a year of the PUP program's introduction, the culture and work environment on the surgical nursing units changed significantly. This change is best demonstrated by the dramatic improvement in turnover rates for new hires (Figure 1). Between 2002 and 2004, 70 nurses, hired to fill vacant nursing positions and accommodate an expansion in surgical beds, completed the PUP program. Of these, only 2 nurses left their hiring unit within the first 12 months. This equates to an average turnover rate for newly hired nurses of 4% between 2002 and 2004-a marked contrast to the year before the PUP program, when 54% of new hires left during the first year. Throughout this time, the turnover rate among nurses who had been with surgical programs for longer than 12 months remained relatively stable, at a median rate of 8% between 2001 and 2004.

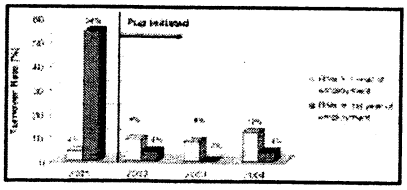

Figure 1. Turnover rates in surgical programs from 2001 to 2004.

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Feedback from nurses who have completed the PUP program is overwhelmingly positive. In written comments, nurses praise the orientation program and express appreciation for the support they receive from staff on the unit. The initiatives introduced to support nurses new to surgical programs-including the Lunch Bunch sessions, clinical bedside rounds, and huddles-have also been enthusiastically received and have become a part of each unit's routine.

Staff satisfaction surveys also offer evidence of positive change. Every other year, nurses at Children's Hospital Boston are asked to complete an online satisfaction survey developed and administered by Leading Indicator Systems Organizational Scan™ for the Healthcare Industry. In the survey, nurses rate their level of agreement with statements related to the work environment, opportunities for personal development, organizational values, and how staff work together and share knowledge.

A comparison of survey results from 2002 and 2004 for 2 of the surgical units demonstrated an increase in mean scores for almost all survey items (the 2002 sample size for the third unit was too small and did not allow comparison). Most notable were increases in scores for items related to the PUP core beliefs, including effective continuous communication loop (mean score for survey item, "I receive regular feedback on my performance" increased 27%), coaching and collaboration to promote critical thinking skills (mean score for survey item, "When one group learns a better way of getting a job done, the knowledge is shared" increased 32%), and partnership/sense of belonging (mean score for survey item, "Speaking up for strongly held beliefs brings results" increased 36%).

Discussion

The success of nurse leaders in decreasing turnover among newly hired nurses, which included new graduates and experienced nurses, offers a powerful illustration of the link between unit culture and nurse retention. Through careful planning, and at no additional cost, the PUP program successfully influenced many of the variables that affect nurse satisfaction and turnover, including leadership and management practices, group cohesion, and support for nurses and nursing practice.

Although multiple factors contributed to our success, we believe the following were critical:

* *Everyone believed change needed to occur.* Once the high turnover rate was identified, everyone on the leadership team realized significant change was necessary. Similarly, once staff nurses learned about the turnover statistics and the reasons behind them, they shared this sense of urgency and quickly became willing participants in the change process.
* *All members of the staff shared accountability for change.* As we examined the reasons for the high turnover, we began to appreciate that each person contributes to unit culture and must play a role in changing it for the better. The behavioral expectations that were developed as part of the PUP program (Table 1) served as guidelines for action and helped each staff member transition from believing in the need for change to becoming actively involved in the change process.
* *We realized that change cannot occur in isolation.* It did not take long for all of the staff to realize that although individual behavior change was important, lasting change would occur only if we worked as a team. Partnering with one another was critical. Partnering helped us gain respect for one another's opinions, allowed us to break down the walls that inhibit culture change, and also served as a catalyst for all of the other changes that occurred.
* *Positive behaviors were continually reinforced.* Nurse leaders quickly realized they needed to model and continually reinforce the core values and behavioral expectations laid out for each staff member. Nurse leaders and staff alike learned how to share positive and negative feedback, partner with one another to resolve problems, and serve as mentors and coaches for others. Over time, we have come to realize that the learning is continuous and is essential to the continued development of the units and surgical programs.

Along the way, we encountered several barriers, including some resistance to change, among several of the more

experienced nurses. This resistance was due in part to generational differences and to a reluctance to listen to the ideas of newly hired nurses. The nurse managers were also somewhat concerned that the scheduling changes necessary to accommodate the new orientation program would be difficult to implement. As the PUP program was introduced, we worked closely with the nurse managers to address their scheduling concerns and held frequent group discussions about the new program with managers and staff. Over time, our efforts to promote partnering among staff paid off, and even those who were most resistant to change became receptive to a new way of working and began to appreciate the perspective of others, including those newest to the unit.

The PUP program and the changes in the culture of surgical programs serve as a platform for all our ongoing efforts. Now that PUP is well established, we are focused on supporting and retaining nurses who are proficient practitioners and want new challenges. Programs currently under development are directed toward helping these nurses develop skills that will allow them to take on leadership roles within surgical programs and other parts of the hospital. We believe that investing our efforts in the continued development of staff is essential for nurse retention and will benefit surgical programs, the larger institution, and the nursing profession as a whole.

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Tab 13

Full Text

Dual or Dueling Culture and Commitment: The Impact of a Tri-hospital Merger

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Abstract

Objectives: This article addresses differences in RNs' commitment to their employing hospital versus the umbrella corporate organization, and the role of organizational culture during a tri-hospital merger. This study is the first to investigate the construct of dual commitment in healthcare organizations.

Background: Fiscal restraints, decreasing reimbursement, and increasing competition have made organizational mergers and acquisitions prevalent. As corporate culture changes, organizational variables previously related to organizational commitment may no longer apply.

Methods: RNs employed on general nursing units at 3 hospitals involved in a merger process completed 2 versions of Mowday's Organizational Commitment Questionnaire. Commitment to hospital and corporate system were examined. Semi-structured interviews, participant observation, and analysis of company documents assessed the organizational culture changes that have occurred.

Graphics

Results: Thirty-one percent of the nurses returned completed questionnaires; 9 were interviewed. RNs from the acquiring hospital demonstrated a significantly stronger commitment to the corporate system than the nurses from the acquired hospitals. The RNs at all 3 hospitals showed significantly greater commitment to their own particular hospital than to the umbrella corporate system.

Conclusions: Moderate level of commitment reflected uncertainty of job status, work overload, and feelings of unappreciation. These attitudes prevent nurses from exerting efforts on behalf of the organization.

Fiscal restraints, decreasing reimbursement, and increasing competition among US hospitals have resulted in hospital downsizing and mergers. The resultant restructuring and job redesign for registered professional nurses (RNs) has left them anxious regarding job security and frustrated over delivering quality patient care in the new and emerging corporate culture in which they find themselves employed.

Merger and acquisition activities involving healthcare in the United States increased by 87% from 1995 to 1997. 1 Consolidation of healthcare facilities then followed a steady decline until 2000, when a resurgence of merger and acquisition activity occurred. 2 Cartwright and Cooper 3 state that the success of any organizational merger or acquisition has been gauged by the reactions of the individuals who have been affected by these changes. They cite the use of behavioral indices to assess the impact of the merger or acquisition on employee outcomes such as intent to turnover, job satisfaction, commitment, and stress.

This study evaluates the variables of organizational culture and the commitment of registered professional nurses who were involved in a merger process. To date, there is no empirical evidence demonstrating the impact of hospital mergers on RNs in terms of their commitment to the hospital in which they are employed; their commitment to the newly created umbrella healthcare organization and/or dual commitment (both hospital and overarching corporate system); and the changes in organizational culture that occur during a merger process.

Merger History

In 1998, a legal and formal corporate partnership of one home healthcare service organization and 5 not-for-profit hospitals in New York State was formed (Table 1). The vision for this newly formed corporate system was announced as an integrated, comprehensive healthcare delivery system aimed at providing a full continuum of care with a commitment to excellence in service, education, and research. Of the 5 not-for-profit organizations, one hospital is solely devoted to pediatric care while another hospital is a small suburban hospital that will remain at its present site and in its present form. The remaining three hospitals primarily serve as acute care adult facilities. The president for the corporate system was the former chief executive office (CEO) from Hospital A. Hospital B is smaller than Hospital A but provides the same range of acute care patient services to much of the same population. Hospital C serves a rapidly growing suburban community where the hospital has great potential for additional growth. Hospital A is designated as the "acquiring hospital" while hospitals B and C are those that were "acquired" or merged into the newly formed corporate system.

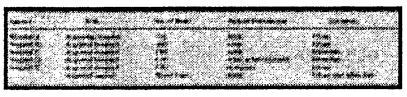

Table 1. Merged Corporate System

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Organizational Culture

For this study, organizational culture was defined as the norms, values, and beliefs that a given group has developed to cope with its problems of external adaptation and internal integration. These norms, values, and beliefs work well enough that staff consider them to be valid and teach them to new members of the group as the correct way to perceive, think, feel, and act 4 and have been used in various studies as the core of cultural analysis. 5-9

Norms refer to unwritten rules that guide employee behavior. Norms of behavior convey a sense of identity to workers: this is who we are and this is how we do things. Norms encourage commitment to the organization's goals and provide guidance in decision-making. Of significance, Deal 10 notes that generally, when an innovation or change conflicts with the culture of the unit or organization, it is the culture that holds fast and the innovation or change that fails. Thus, the first step in facilitating innovation or change is to assess the prevailing culture of each unit that will be affected by that change.

Values comprise the things that are most important to us thus affecting individual and group behavior in terms of desired or preferred outcomes. Values focus on what employees believe is the rationale for their behavior and decisions. Culture that is based upon select values will manifest itself in the behavior of both employers and employees.

Masland 11 refers to the manifestations of organizational culture as windows to the influence of culture within the institution. These elements of culture are interdependent and include: values and beliefs; heroes who epitomize those values and beliefs; rites and rituals that prescribe how all critical activities are to be carried out; ceremonies that celebrate the successes of the culture; stories and storytellers to keep the mythology of the culture alive; and symbols, metaphors, and artifacts of the culture. This cultural change lies at the heart of any successful transformation of a healthcare organization. 12 It is important to identify which cultural factors have historically made an organization great and to retain those factors whenever feasible.

Restructuring and Mergers in Healthcare Delivery Systems

Restructuring an organization takes a great deal of energy and commitment that must be assumed not only by the management team, but by employees as well if they are to be motivated and become committed to the changes that have taken or will take place. Merging organizations need to incorporate the cultural strengths of each organization involved and sensitively address the merger of each corporate culture. This restructuring and merging of several organizations should ideally be viewed as a "blended family," rather than as a "takeover" by the dominant culture where the cultural norms and beliefs are dictated. Landau-Stanton 13 uses the analogy of organizational change being similar to the cultural transition of immigrant families coming to the New World in the 1900s. Some members prefer to "stay in the old country" and continue the stability and expectedness of well-known norms, while others are drawn to the belief that "life will be better in the new place." Still others vacillate between the new and the old.

Some organizations may follow a cultural imposition plan rather than a cultural integration plan. 14 The success or failure of mergers in relation to culture compatibility or incompatibility has been well documented in the literature. 15-25 This is not to say that a different organizational culture is bad; in fact, a different culture can add value to the partnership. Success of "culture marriages," though, are highly dependent on the ability of administrators to integrate their cultures both at the organizational and subunit level.

Dual Commitment

An important aspect to be considered in the wake of mergers, acquisitions, and restructuring is the concept of dual commitment. Organizational commitment has been defined as a state in which an individual identifies with an organization, its goals, and values, has a strong desire to maintain involvement with the organization, and is willing to work extra hard on its behalf. 26 Commitment has also been the focus of nursing research studies and publications in relation to organizational change. 27-31 The question raised is: "What is the level of commitment a person has to the organization in which he or she

is currently working as compared to the umbrella organization and how is that commitment differentiated and measured?" For example, a nurse at Hospital A may commit to both the hospital and to the umbrella organization, while a nurse from Hospital B may only commit to the hospital in which he/she is currently employed and not to the umbrella organization. Although this concept of dual allegiance has been explored as it relates to the business environment, 32 particularly unions, 33 its application to the healthcare industry has not been addressed.

Methods

A correlational, descriptive study was designed to assess the effects of a multi-hospital merger and restructuring on registered professional nurses in acute care settings who are employed on general medical-surgical nursing units involved in the merger process. Data regarding commitment was obtained using 2 versions of Mowday's, Steers', and Porter's 34 Organizational Commitment Questionnaire (OCQ). One version assessed organizational commitment to the current hospital in which the nurse was employed; the second version assessed commitment to the umbrella corporate system. The questionnaires were identical except for the reference to Hospital A, B, or C or the corporate system. Focused organizational ethnography, including the use of semi-structured interviews, participant observation, and analysis of company documents was also used to study each hospital as a cultural setting and to collect data about the cultural changes that have taken place at each hospital over the past few years since the merger began.

Three of the five hospitals were chosen for this study: Hospitals A, B, and C. These hospitals were selected because the merger process will have the greatest impact in terms of staffing and patient services for acute care of adults. A study supported by the Agency for Health Care Policy and Research found that acquired hospitals were closed in 17% of the mergers, while in 41% of the mergers, the acquiring hospital converted the acute general medical-surgical beds of the acquired hospital to nonacute inpatient uses such as psychiatric services or long-term care. 35 Hospital B, one of the acquired hospitals and most similar to Hospital A, the acquiring hospital, had the greatest chance of either closure or conversion of acute care adult services to other functions.

All full-time and part-time RNs who provide bedside care on all shifts and were routinely assigned to one of the medical-surgical nursing units from the three different hospitals (Hospitals A, B, and C) within the corporate system were invited to participate in this study. These units were selected as being the ones most likely to be affected, or had already been affected by the merger with a reduction in hospital beds and medical and surgical services. Ninety-eight nurses representing the 3 hospitals responded to the questionnaires; 9 of these nurses further consented to be interviewed.

Data collection took place from November 1999 through January 2000, approximately 3.5 years after the merger was initiated. The total response rate was 31% for questionnaire completion despite extensive efforts to increase responses. Some data was lost due to lack of questionnaire completion. Several nurses failed to differentiate their employing hospital from the corporate system. Nine out of 12 nurses who consented by postcard to be interviewed were able to be contacted and were interviewed using a semi-structured approach.

Measures of central tendency were used to describe the sample. As expected, the majority of respondents were female, with ages ranging from 23 to 62 with a mean age of 39.95. The length of employment within the merged corporate system ranged from less than 6 months to 26 years, thus reflecting a broad range of employment both during and after the initial merger was announced.

Results

The mean score values for each version of the OCQ are presented in Table 2. Data reflect a slightly stronger commitment by the nurses at Hospital A to the newly formed corporate system, as might be expected given the status of Hospital A as the acquiring hospital with the former CEO of Hospital A at the helm of the newly formed corporate system. In addition, the mean score for Hospital B shows a higher commitment by their RNs to the individual Hospital than to the corporate system.

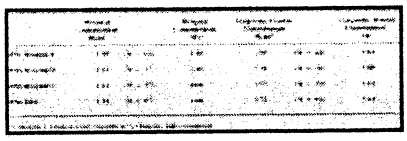

Table 2. *Mean Values for Commitment to Hospital and Corporate System**Scale score 1-3 indicates low commitment, 5-7 indicates high commitment

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Overall, none of the hospitals displayed a strong commitment by the nurses to either their individual hospital or to the corporate system. Inspection of the data shows that both Hospitals A and C are closer in commitment to the corporate system than Hospital B, while all hospitals show a greater commitment to the Hospital than to the corporate system. At this point in the merger, the RNs in this study at all 3 hospitals still retain their strong sense of organizational identity to their employing hospital.

It is of interest to note that nurses at all 3 hospitals ranked the following items on the OCQ consistently high or consistently low related to organizational commitment to their Hospital. Item 13, *I really care about the fate of Hospital _____*, had the highest overall mean, indicating strong agreement, and also had one of the highest scores for each of the 3 hospitals. This same item as it related to the corporate system also ranked high or had high agreement for each of the 3 hospitals.

Values are an inherent part of any corporate culture and should articulate with the mission and philosophy of the organization as a whole. Question 5 of the OCQ, *I find that my values and Hospital _____'s and the corporate system's values are very similar*, is reflective of the conflict between values of the individual versus those of the hospital and corporate system. The demographic data failed to show statistical correlation between variables such as age, tenure, and education with commitment to either the hospital or corporate system.

The qualitative data serve to confirm the quantitative analysis. One nurse from Hospital B describes the feeling of isolation from one hospital to another and in relation to the corporate system:

We still feel very separate. We don't seem to be walking down the same path . . . I think we're all running separate. I really do.

Given the organizational history of the 3 hospitals, this investigator felt that the nurses at all 3 hospitals may be committed only to their primary Hospital or to their primary Hospital and also to the corporate system as well. A paired *t*-test was therefore used to test for the difference in organizational commitment scores between each Hospital and the corporate system (Table 3).

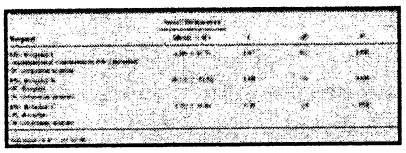

Table 3. *Paired* t *Tests for Equality of Means for Organizational Commitment to the Hospital and Organizational Commitment to the Corporate System**Significant at *P* < .01 for all

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Although the paired *t* test results for Hospitals A and B are statistically significant, Hospital B demonstrates the widest

difference in the means between organizational commitment to the hospital and commitment to the corporate system (Figure 1). The nurses at Hospital B tended to identify more strongly with their hospital than with the newly formed corporate system. One nurse from Hospital B states, "Hospital B's downfall was the merger. It seems the corporate system is trying to transform us into Hospital A and we're losing our identity."

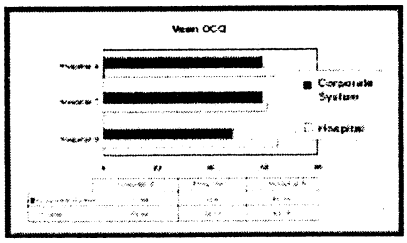

Figure 1. Comparison of the difference in means by hospital of organizational commitment to the hospital and corporate system. Note: Scale Score: range of means 0-100; low to high commitment.

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Positive Pearson correlations were also found to be statistically significant (r = .769, P = .01) for commitment to individual hospital and corporate system. Hospital A, the acquiring hospital, demonstrated the highest correlation between organizational commitment by RNs to the hospital and corporate system (r = .93). This correlation was strong but lower for the RNs in Hospital C (r = .87), but significantly weaker for the RNs in Hospital B (r = .36). The demographic data did not provided statistically significant correlations for nurses at any of the hospitals, either within each hospital or across hospitals.

Organizational Culture Changes and Manifestations

Organizational culture changes were manifested in several ways. One important facet of culture change that exhibited itself most readily was that of organizational identity, especially in relation to Hospitals B and C, or in other words, the "acquired" hospitals.

Fieldnotes: Upon entering each hospital through its primary entrance, one is visually greeted in a variety of ways. Both Hospitals B and C have small signs in their entrances designating them as a corporate system hospital. Their own identity (ie, Hospital B or Hospital C) is not identified anywhere on the walls. While the same is true in Hospital A, one is greeted with a huge sign in their entrance designating the hospital as a corporate system hospital. Another large banner displaying Hospital A's strong affiliation with a local university medical school is also readily apparent. Hospitals B and C do not have as strong an affiliation with the same medical school.

The process of developing one corporate culture and one corporate identity is also described by several nurses:

They've got to make people feel like they belong; that can only take time.

I don't see this camaraderie. I don't see this joining.

I think you have groups that are Hospital B loyal and groups that are Hospital A loyal. People [the general public] still realize it's Hospital B or Hospital C.

The nurses at Hospitals B and C also identified a former CEO as being a major contributor to their history of corporate culture. As storytellers, these nurses recounted stories describing the breakfast meetings and "walk-around meetings" this CEO had with his employees. This is in keeping with Wilkins'36 theory that stories help to create a strong corporate culture, and in this case, exemplify a former corporate culture that nurses could identify with and commit to. This CEO, who by

Beyer and Trice's 37 definition was viewed as a hero in the hospital culture, personified the values and beliefs of the hospital. The nurses at Hospitals B and C appear to be looking for a new "hero" to take his place. Although the CEO of the corporate system might be a logical choice, the nurses at the acquired hospitals do not appear ready to embrace him. A lack of trust seems to be a primary issue as expressed by these nurses:

I don't trust administration [of the corporate system]. They say they won't have any more layoffs but you turn around and someone else is gone. They [the administration] only care about the bottom line, the money. It's always the money. They don't care about us or what we do. I'd like to trust him [the CEO], but I can't.

Implications

The nurses involved in this merger process have seen dramatic changes in the local healthcare delivery system. The organizational commitment construct becomes especially important as employees are asked to commit or exert efforts on behalf of the organization. Bolon 38 states that one cannot commit to an organization if one is not familiar with the organization's mission, goals, and objectives.

First and foremost, the employee, in this case the nurse, must be able to identify with the goals and values of the corporate system as identified via the mission statement. Values and beliefs inherent in the new culture must be clearly articulated and woven into all meetings, policies, and procedures. A clear definition of culture related to the merger must be repeatedly articulated and modeled by managers who act as role models and disseminators of the new corporate culture. Fink 39 suggests additional ways to change the corporate culture and ease the merger transition:

1. Recognize that peer group consensus or the effect of other nurses or employees will be the major influence on acceptance and/or willingness to change.
2. Think of change as skill building and focus efforts on training as part of the change process.
3. Allow enough time for the corporate culture change to occur, as much as 10 years.
4. Encourage people to adopt the basic need for change.
5. Begin team building efforts as soon as possible.

Other strategies can also be used to enhance the vision and goals of the newly merged system. Every effort should be made not only to form committees that represent all merged facilities but to communicate this to employees as well. When the committee recommends a new policy or procedure, it is then introduced or "brought to you by . . ." those members who have served on these committees. Although Urden and Rogers 40 make the case that things are not always fair in a merger, efforts made to truly blend whatever aspects of the corporate culture are possible will reap benefits in terms of developing a culture of excellence for the organization as a whole. Development of a management council composed of managers across the various settings can address systems issues that will occur in blending multiple policies. Continuing monitoring and management of the acculturation process, as suggested by Malekzadeh and Nahavandi 41 should also be conducted through the use of focus groups, interactive interviews, or in survey format.

Problems with morale during the merger process may be the most difficult to overcome. Cianco 42 cites demoralization as the most common effect of survivors of layoffs with 81% of all hospitals reporting morale problems among staff. 43 Signs of survivor's syndrome may be seen in terms of increased absenteeism, aggressive behavior, lower productivity, impaired judgment, tension, anxiety, and fatigue. The employee "gives up" by demonstrating lack of commitment to their job and to their employer. Employees who demonstrate these behaviors may be showing signs of a grieving process: grieving for the way their jobs used to be performed, grieving for staff who no longer are there for support, anger at the way things are being handled, and anger for all the changes that have taken place with uncertainty looming largely in the future. Managers need to show compassion and understanding and should never dismiss the employee with an attitude of, "You should be grateful you still have a job." The survivors of any layoff that may occur during the merger process are the ones that will further the mission, vision, and goals of the new organization. Remaining employees are those who should therefore be nurtured into new levels of commitment and productivity by job recognition. Simple employee recognition tactics have been shown to increase productivity by 15%, 44 thus reaping big rewards for providing attention and recognition for work well done and as well as contributing to the new organizational culture.

Personal interactive sessions or small focus groups can have a great impact both in terms of stress reduction related to the merger and commitment. These may take the form of "breakfast meetings" where every level of the organization, from administration to housekeeping, could express their personal opinion about their present work environment and the future of the newly formed organization. Groups should be limited to 10 or 12 people with the meeting lasting approximately 1 hour. The vision of the organization as whole could then be connected to the day-to-day work lives and activities of the staff.

Conclusions

Organizational identity, the role of the CEO for the corporate system, and past CEOs for the hospital were important influences on organizational culture at each of the 3 hospitals. As the success of any merger depends on the blending of corporate cultures, these hospitals undergo a process of acculturation; the nurses themselves are seeking ways to enhance this acculturation process. They want input into the process and do not want to be bystanders or be told, "This is what the corporate culture is." They want to be active participants in developing a strong hospital or corporate system culture that unifies all of the hospitals involved in this merger.

On the other hand, these nurses also fail to see that building a corporate culture during a merger process takes much time and effort for all concerned. Although it is both difficult and time-consuming to create a positive corporate culture and develop a high level of organizational commitment in the wake of this merger process, it is relatively easy to reverse the effects of any positive culture or commitment aspects in a very short time. Kanter's 45 position that employees will invest in an organization when they consider themselves to be a part of a larger organization still remains to be seen at all 3 hospitals. The nurses who were interviewed wanted additional information to feel more in touch with the larger corporate system and with the other hospitals now associated with them in this merger process. Implications from this study go beyond healthcare delivery systems and are applicable to any business merger or acquisition activity.

As more hospital and healthcare facilities merge and undergo restructuring processes, it is important to examine the effects of these changes on the personnel involved. The merger process at the corporate system is still progressing as department heads are named and committees form to merge policies and practices in all departments at all the hospitals involved. This process has resulted not only in financial or economic changes but has impacted the local political scene as well.

A longitudinal study with a larger sample size is in the planning process to determine changes in both organizational culture and commitment over time. Over the past year, general nursing units have been moved within hospital, but the process of merging nursing units across hospitals has just recently begun. The former CEO of Hospital A has also resigned, and a new CEO from outside the western New York area has been hired. The pediatrics hospital was threatened with a merger into Hospital A. Hospitals B and C are now unionized. Nurse administrators and nurse managers have resigned, and a different restructuring design is now in place. These are just some of the changes that currently impact the ongoing merger process and the work life of nurses. The effect of the merger on nurse managers also merits investigation.

Although the general consensus of the effects of the merger on the RNs is best summed up by a nurse from Hospital B, "We can live with it . . . so far," additional research is warranted to further assess these organizational changes. Education of the nursing staff in regard to organizational culture and their commitment to both their employing hospital and the corporate system in order to enhance the vision and goals of the organization must also be undertaken. With a healthcare system in crisis and a nursing shortage at a critical level, retaining nurses with a significant level of commitment becomes of utmost importance to nursing and corporate management.

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Tab 14

The Impact of Hospital Amalgamation on the Job Attitudes of Nurses

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Abstract

In this longitudinal panel study we examined nurses' reactions to hospital amalgamation in both the hospitals being acquired and the acquiring hospitals. Data were collected in 1992, two years prior to the amalgamation announcement; in 1995, in the initial phase of the hospital amalgamation; and in 1997, during the amalgamation implementation. Compared with the pre-amalgamation period, nurses in both the acquiring and the acquired hospitals reported a significant decrease in job satisfaction, organizational commitment, and organizational trust, and a significant increase in turnover intentions. Except for organizational commitment, nurses in the acquiring hospitals reported a greater deterioration in job attitudes indicating that they were more adversely affected by the amalgamation than nurses in the hospitals being acquired. Perceived organizational support and, to a lesser extent, immediate supervisor support played an instrumental role in promoting successful adjustment to the amalgamation. There was only limited evidence that perceived job insecurity and control-oriented coping mediated the relationship between the support variables and job attitudes.

Résumé

Dans cette étude de panel, nous examinons les réactions des infirmières aux fusions des hôpitaux, à la fois dans les établissements acquéreurs et acquis. Les données ont été recueillies en 1992, deux ans avant l'annonce des fusions; ensuite en 1995, lors de leur annonce; et enfin en 1997, pendant leur mise en oeuvre. Les infirmières, tant dans les hôpitaux acquéreurs que dans les hôpitaux acquis, ont éprouvé une baisse considérable de leur satisfaction professionnelle, de leur engagement envers leur employeurs, et de leur confiance en leurs gestionnaires, de même qu'un désir accru d'abandon du métier ou de l'insitutiton en question. En particulier, la détérioration des attitudes a été plus marquée dans les hôpitaux acquéreurs, ce qui indique que ces infirmières se sont senties davantage mises à l'épreuve que celles dans les hôpitaux acquis. Cependant, l'adaptation à la fusion a été minimisée lorsque le soutien de l'établissement était bien perçu et, à un moindre degré, lors d'une constatation de soutien réel provenant de leurs supérieurs immédiats. Nous n'avons pas trouvé de preuve concluante que la perception de l'insécurité dans le travail, et les stratégies pour garder celle-ci sous contrôle, aient influencé le rapport entre les paramètres du soutien et les attitudes envers le travail.

The Canadian health care system underwent dramatic change in the 1990s, largely in response to significant reductions in transfer payments from the federal government. This was especially the case in Ontario as the provincial government attempted to deal with cuts in health care transfer payments and at the same time address its own budget deficit and reduce its debt. The Health Services Restructuring Commission was established by the Conservative government in Ontario to travel across the province and assess each community's health care system and determine how to deliver health care more efficiently. This committee recommended the closing of several hospitals (10 in Toronto alone) and the amalgamation of many others. The community of Wind-

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sor was unique in that it anticipated the need to restructure the provision of health care to the community in the early 1990s. Accordingly, in 1992, the city hired Price Waterhouse to work with the local health council to review health services and provide recommendations on how to streamline the system. In 1994, the committee recommended that the community would best be served by two hospitals instead of the existing four. This meant the transfer of services and staff from the two hospitals designated to be closed to the two remaining hospitals. The amalgamation was begun in early 1995 and took several years to complete.

In this paper we present the findings of a longitudinal panel study designed to assess the impact of the hospital amalgamation on health-care workers. Nurses employed in the four Windsor hospitals completed a questionnaire in 1992, two years prior to the amalgamation announcement; in 1995, in the initial phase of the amalgamation; and again in 1997, when the four hospitals were still in operation but many services had been transferred from the acquired hospitals to the acquiring hospitals.

The overall purpose of this study was to assess the reactions of nurses to the hospital amalgamation. The impact of mergers and acquisitions on employees has received little attention in the research literature (Cartwright, 1997; Cartwright & Cooper, 1992; Newman & Krzystofiak, 1993), and this is especially the case for hospital mergers in Canada (Brousselle, Denis, & Langley, 1999). The few studies that have been conducted on mergers and acquisitions have primarily focused on the reactions of the employees in the organization being acquired. Very few studies have compared the impact of mergers and acquisitions on employees in both the acquired and the acquiring organizations. Moreover, Cartwright (1997) noted the need to incorporate pre-merger measures, although she pointed out that this may be impossible because it would require forecasting a merger in advance. The study reported here addresses these issues because we were able to: (a) compare the reactions of nurses in the hospitals being acquired with the reactions of nurses in the acquiring hospitals; (b) identify changes in job attitudes over time by comparing the job attitudes of nurses two years prior to the amalgamation announcement with their attitudes at the beginning of the amalgamation and again two years after the amalgamation had begun; and (c) determine those factors that influence job attitudes in an amalgamation context.

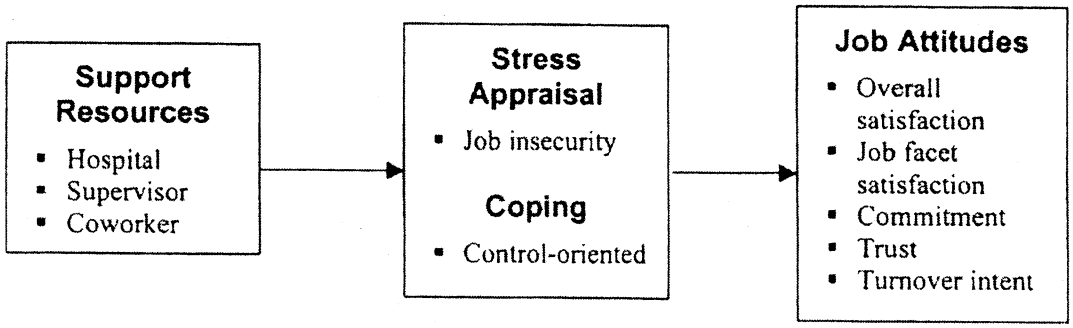
The first objective of this study was to compare the job attitudes of nurses in the acquired hospitals with the job attitudes of nurses in the acquiring hospitals over the five-year period. The specific job attitudes we examined were overall and facet job satisfaction, organizational commitment, trust in the organization, and turnover intention. There is empirical evidence that mergers result in decreased job satisfaction, reduced commitment and trust, and increased turnover (Newman & Krzystofiak, 1993; Schweiger & DeNisi, 1991). We expected that nurses in both the acquiring and acquired hospitals would be negatively affected by the changes associated with amalgamation. Therefore, compared with the 1992 baseline measures, we predicted that nurses in both the acquiring and the acquired hospitals would report greater dissatisfaction with their jobs in general as well as with various aspects of their jobs, decreased commitment to their hospital, reduced trust in their hospital, and greater intention to leave during the amalgamation. However, because nurses in the acquired hospitals were experiencing greater changes than nurses in the acquiring hospitals, we expected that there would be a greater change in attitudes compared with the baseline measures for those nurses in the hospitals being acquired compared with those nurses in the acquiring hospitals.

> Hypothesis 1a: There will be a significant decrease in job satisfaction, organizational commitment, and organizational trust and a significant increase in turnover intention during the amalgamation compared to two years prior to the amalgamation announcement.

> Hypothesis 1b: Nurses in the acquired hospitals will report a significantly greater change in attitudes than nurses in the acquiring hospitals.

The second objective of this study was to identify factors that influence nurses' job attitudes during an amalgamation. Lazarus and Folkman's (1984) stress and coping model provided the theoretical framework for this part of the study. According to this model, how people adjust to a potentially stressful situation is determined by the resources available to them, their appraisal of the situation as harmful or threatening, and their coping behaviours. According to the model, resources influence stress appraisal and coping which, in turn, determine people's immediate and long-term reactions to the event or situation. Lazarus and Folkman (1984) contend that "it is not change per se that constitutes stress, but rather the way it is appraised and dealt with by the individual" (p. 258). The Lazarus and Folkman stress and coping model has been widely used by researchers to examine how people react to potentially stressful situations, including the reactions of layoff survivors to organizational downsizing (Armstrong-Stassen, 1994, 1998, in press; Havlovic, Bouthillette, & van der Wal, 1998), the reactions of layoff victims to job loss (DeFrank & Ivancevich, 1986; Gowan, Riordan, & Gatewood, 1999; Kinicki, Prussia, & McKee, 1997; Leana & Feldman,

Figure 1.
Determinants of reactions to amalgamation.



1990), and the reactions of employees to mergers and acquisitions (Scheck & Kinicki, 2000; Terry & Callan, 1997, 2000; Terry, Callan, & Sartori, 1996). The conceptual model for this study is shown in Figure 1.

Perceived Support as an Antecedent of Stress Appraisal and Coping

For the support resources, we assessed nurses' perceived support from three sources: their hospital, their supervisor, and their coworkers. House (1981) suggested that social support could mitigate the effect of potentially stressful situations by causing people to perceive the situation as less threatening and less stressful. House also suggested that even if a person initially appraises a situation as stressful, social support may lessen the tendency of perceived stress to lead to negative consequences by facilitating coping.

The model presented in Figure 1 posits a direct effect of social support on stress appraisal and coping. Several competing theoretical models of how social support operates have been posited in the literature (for an overview of these see Barrera, 1986, 1988; Lin, 1986). One of these, the buffering model, postulates that social support has a moderating, and not a main, effect. An example of such a model is the job demands-control-support model proposed by Karasek and Theorell (1990). In their review of 22 studies that examined the moderating effect of social support, Kahn and Byosiere (1992) concluded that the pattern of results was consistent for main effects rather than moderating effects. Dormann and Zapf (1999) found only 10 studies that investigated work-related social support using a longitudinal research design. These researchers concluded that, "All in all, although some of the studies were exceptionally well-done examples of stress research, there was not a single study that convincingly demonstrated the moderating effect of social support in a longitudinal study" (p. 875). Although the job demands-control-support model is intuitively appealing, empirical support for the model has been minimal and the model has come under criticism from some researchers (de Jonge & Kompier, 1997; Fletcher & Jones, 1993; Terry & Jimmieson, 1999). Of the six studies found that specifically examined the Demands X Control X Support interaction posited by Karasek and Theorell, four (Bourbonnais, Comeau, & Vézina, 1999; de Jonge, Janssen, & van Breukelen, 1996; Melamed, Kushnir, & Meir, 1991; Vahtera, Uutela, & Pentti, 1996) found main effects but no significant Demands X Control X Support interactions. Two (Dollard & Winefield, 1998; Parkes, Mendham, & von Rabenau, 1994) found only very limited support for the three-way interaction (for example, of the total of eight Demands X Control X Support interactions that Dollard and Winefield examined, only one was significant). In the present study, support is viewed as an antecedent variable. Carlson and Perrewé (1999) tested four different models: support as an antecedent, an intervening, a moderating, and an independent variable. Their findings indicated that support was best viewed as an antecedent variable to perceived stressors.

We predicted that the support resources assessed at the beginning of the amalgamation would be significantly negatively related to stress appraisal and positively associated with the use of proactive coping strategies. There is empirical evidence that perceived support from

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one's organization, immediate supervisor, and coworkers reduces the perceived threat or the appraised stressfulness of a situation (Armstrong-Stassen, 1994; Chisholm, Kasl, & Mueller, 1986; Hayes, Smith, & Schmieder, 1992; Jayaratne & Chess, 1984; Terry & Callan, 2000; Terry et al., 1996). There is also empirical evidence that perceived support facilitates the use of more proactive or control-oriented coping responses (Dunkel-Schetter, Folkman, & Lazarus, 1987; Terry & Callan, 2000; Terry, Rawle, & Callan, 1995).

> Hypothesis 2: Support resources will be significantly negatively related to stress appraisal and significantly positively related to control-oriented coping.

Stress Appraisal as a Mediator of the Resources—Attitudes Relationships

Stress appraisal was operationalized as perceived job insecurity. Jacobson (1991) noted that perceived threat to one's job continuity reflects Lazarus and Folkman's cognitive appraisal of threat. Armstrong-Stassen (1994; in press) and Brockner and Wiesenfeld (1993) noted that perceived job insecurity, that is, the perceived threat of job loss, represents the potential threat component of stress appraisal. Perceived job insecurity has been found to be negatively related to job satisfaction (Ashford, Lee, & Bobko, 1989; Hartley, 1991; Heaney, Israel, & House, 1994), organizational commitment (Ashford et al., 1989; Dekker & Schaufeli, 1995; Hartley, 1991), and trust (Ashford et al., 1989; Hartley, 1991; Roskies & Louis-Guerin, 1990) and positively related to turnover intention (Ashford et al., 1989; Borg & Elizur, 1992; Greenhalgh, 1982; Rosenblatt & Ruvio, 1996). In accordance with Lazarus and Folkman's conceptual model and Figure 1, we predicted that perceived job insecurity would mediate the relationship between resources and the job attitude variables.

> Hypothesis 3: Perceived job insecurity will mediate the relationship of support resources with job satisfaction, organizational commitment, trust in the organization, and turnover intention.

Coping as a Mediator of the Resource—Attitudes Relationships

Lazarus and Folkman (1984) define coping as "the cognitive and behavioral efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person" (p. 141). The present study focused on control-oriented coping. Control-oriented coping consists of actions and cognitive reappraisals that are proactive, take-charge in nature (Latack, 1986). This is highly similar to Lazarus and Folkman's problem-focused coping. Control-oriented coping has been found to be positively related to job satisfaction (Latack, 1986; Schaefer & Moos, 1991; Terry & Callan, 2000; Terry et al., 1996), and organizational commitment (Armstrong-Stassen, 1994) and negatively related to turnover intention (Armstrong-Stassen, 1994; Latack, 1986). We predicted that control-oriented coping assessed during the initial phase of the amalgamation would mediate the relationship between the support resources and nurses' job attitudes assessed during the amalgamation.

> Hypothesis 4: Control-oriented coping will mediate the relationship of resources with job satisfaction, organizational commitment, trust in the organization, and turnover intention.

Method

Participants and Procedure

The participants consisted of (a) those nurses who had participated in the 1992 (T1), 1995 (T2), and 1997 (T3) studies and whose questionnaire codes could be matched, and (b) those who were employed in the same hospital in 1997 as they were in 1992. There was a total of 146 nurses who met these two criteria—53 employed in the hospitals being acquired and 93 employed in the acquiring hospitals. Over 97% of the participants were women. In 1997, the average age of the nurses in the hospitals being acquired was 43.71 years (SD = 5.25) and they had worked at their respective hospitals an average of 16.08 years (SD = 7.49) and as a nurse an average of 20.21 years (SD = 5.85). The average age of the nurses employed in the acquiring hospitals was 43.86 years (SD = 6.45) and they had worked at their respective hospitals an average of 15.62 years (SD = 7.08) and as a nurse an average of 19.08 years (SD = 7.31).

The data collection procedures were the same for all three time periods. The four hospitals provided the researchers with the names of nurses employed by each hospital. Questionnaire packets for each nurse were distributed on the individual units of each hospital. The questionnaires were mailed back to the research unit where the respondent's name was replaced with a code number. These code numbers were used to match up the respondent's 1992, 1995, and 1997 questionnaires. The overall response rates for T1, T2, and T3 were 37%, 43%, and 43%, respectively.

Measures

Unless otherwise noted, the measures consisted of a 5-point Likert response format. All of the attitude

measures were assessed in 1992, 1995, and 1997 except for organizational commitment, which was assessed in 1995 and 1997 only. All of the multi-item scales showed strong reliability (internal consistency) for all three time periods.

Support resources. Perceived organizational support was assessed with the 17-item version of the Survey of Perceived Organizational Support (SPOS) developed by Eisenberger, Huntington, Hutchison, and Sowa (1986). This scale measures employees' beliefs concerning the extent to which the organization is committed to them, values their contribution, and cares about their well-being. We modified the wording slightly by changing the word "organization" to "hospital." Alpha coefficients for T1, T2, and T3 were 0.95, 0.94, and 0.94, respectively. Perceived supervisor and coworker support was measured with the Supervisor and Co-worker Support scales developed by Caplan, Cobb, French, Harrison, and Pinneau (1975). Alpha coefficients for the Supervisor Support scale at T1, T2, and T3 were 0.85, 0.87, and 0.86, respectively. Alpha coefficients for the Coworker Support scale at T1, T2, and T3 were 0.83, 0.85, and 0.83, respectively.

Stress appraisal. Perceived job insecurity was assessed with six items, including three modified from Jick's (1979) job insecurity index and two from Jacobson's (1991) job insecurity measure. The items referred to the perceived likelihood of being laid off, degree of worry about one's job security, and how much confidence the person has that the organization will remain a place of steady employment. These items were scored so that a high score reflects high job insecurity. Cronbach alpha coefficients for T1, T2, and T3 were 0.86, 0.88, and 0.88, respectively.

Coping. Control-oriented coping was assessed with 12 items from the Latack (1986) Control-oriented Coping Scale. This is one of the few coping scales that was specifically developed to assess coping with work-related stressors. Respondents were asked to describe how they were reacting to the workforce changes in the Windsor hospitals. The response categories ranged from "Do not do this" to "Do this a great deal." Sample items are: "Think of ways to use this situation to show what I can do" and "Try to work faster and more efficiently." Cronbach alpha coefficients for T1, T2, and T3 were 0.83, 0.82, and 0.82, respectively.

Job satisfaction. We assessed overall job satisfaction with the 20-item version of the Minnesota Satisfaction Questionnaire (MSQ) developed by Weiss, Dawis, England, and Lofquist (1967). Alpha coefficients for T1, T2, T3 were 0.87, 0.88, and 0.89, respectively. Respondents were asked to rate the extent to which they were satisfied with various aspects of their present job. Job facet satisfaction was measured with the Satisfaction with Kind of Work, Amount of Work, and Career Future subscales of the Index of Organizational Reactions (Dunham, Smith, & Blackburn, 1977). Alpha coefficients for Satisfaction with Kind of Work were 0.89, 0.89, and 0.91. Alpha coefficients for Satisfaction with Amount of Work were 0.86, 0.87, and 0.88. Alpha coefficients for Satisfaction with Career Future were 0.75, 0.79, and 0.77.

Organizational commitment. We measured organizational commitment with the Affective Commitment scale developed by Meyer, Allen, and Smith (1993). Affective commitment reflects an employee's emotional attachment to, identification with, and involvement in the organization (Meyer & Allen, 1997). We modified the wording slightly so that the statements referred to "this hospital" rather than "this organization." Alpha coefficients at T1, T2, and T3 were 0.80, 0.80, and 0.81, respectively.

Organizational trust. We assessed organizational trust with three items: the two-item Organizational Trust scale developed by Ashford et al. (1989) and an item from the Cook and Wall (1980) trust scale. We modified the wording so that the statements referred to "this hospital" instead of "this organization." The alpha coefficients for T1, T2, and T3 were 0.91, 0.91, and 0.92, respectively.

Turnover intention. We assessed turnover intention with the three-item Propensity to Leave scale developed by Lyons (1971). This scale was specifically designed to assess the turnover intention of nurses. Alpha coefficients for T1, T2, and T3 were 0.87, 0.86, and 0.86, respectively.

Control variables. We included three control variables: hospital status, negative amalgamation change experience, and hospital tenure. Hospital status (employed in a hospital being acquired or in an acquiring hospital) was determined from the employee list provided by the hospitals and designated as part of the code number assigned to a completed questionnaire. To assess whether or not the person had been directly affected by the changes, we asked them "Have you been directly affected by current hospital changes?". The responses were yes and no (coded 1 = yes; 2 = no). This question was followed up by an open-ended question that asked those respondents who had answered yes to describe the changes they had experienced. All of the responses reflected negative changes such as being bumped or displaced, unit downsized or closed, position made redundant, workload increased, and work hours cut back. To assess hospital tenure, nurses were asked to indicate how long they had been employed at their present hospital. Because bumping based on seniority was allowed across hospitals, nurses with less tenure could

Table 1
Means, Standard Deviations, and Repeated Measures MANCOVA F-values

	Nurses in Hospitals Being Acquired $n = 53$			Nurses in Acquiring Hospitals $n = 93$					
	1992 Mean (*SD*)	1995 Mean (*SD*)	1997 Mean (*SD*)	1992 Mean (*SD*)	1995 Mean (*SD*)	1997 Mean (*SD*)	Hosp. Effect *F*-value	Time Effect *F*-value	Hosp. x Time *F*-value
Hospital Support	2.39 (.62)	2.49 (.74)	2.30 (.62)	2.58 (.63)	2.50 (.64)	2.31 (.64)	<1.00	6.52**	1.92
Supervisor Support	2.96 (.95)	2.91 (.97)	2.70 (.88)	3.28 (.87)	3.07 (.91)	3.01 (.97)	4.73*	<1.00	<1.00
Coworker Support	3.82 (.87)	3.66 (.77)	3.42 (.74)	3.75 (.70)	3.68 (.69)	3.59 (.70)	<1.00	3.42*	1.54
Job Insecurity	2.54 (.84)	2.64 (.95)	2.63 (.97)	2.74 (.80)	2.53 (.82)	2.60 (.87)	<1.00	<1.00	2.01
Control Coping	3.12 (.54)	3.20 (.57)	3.23 (.54)	3.16 (.60)	3.20 (.47)	3.21 (.48)	<1.00	4.28*	<1.00
Overall Job Satisfaction	3.36 (.48)	3.35 (.56)	3.21 (.60)	3.49 (.47)	3.41 (.47)	3.19 (.57)	<1.00	5.21*	<1.00
Kind of Work Satisfaction	3.71 (.75)	3.65 (.89)	3.51 (.83)	3.76 (.73)	3.77 (.74)	3.53 (.84)	<1.00	3.20*	<1.00
Amount Work Satisfaction	2.78 (.80)	2.74 (.80)	2.86 (.83)	2.80 (.81)	2.84 (.84)	2.47 (.81)	<1.00	2.85†	5.15**
Career Future Satisfaction	2.62 (.93)	2.45 (.86)	2.42 (.75)	2.65 (.75)	2.71 (.70)	2.40 (.71)	<1.00	5.59**	2.26
Organizational Commitment	—	3.10 (.73)	2.62 (.73)	—	3.08 (.62)	2.82 (.63)	<1.00	6.85**	3.26†
Organizational Trust	1.93 (.74)	2.31 (1.01)	1.96 (.76)	2.38 (.80)	2.42 (.75)	2.03 (.74)	3.29†	4.05*	4.01*
Turnover Intent	2.07 (.89)	2.34 (1.03)	2.78 (1.28)	2.11 (.89)	2.13 (.99)	2.80 (1.00)	<1.00	7.48***	1.40

Note. This sample consists of those nurses whose 1992, 1995, and 1997 questionnaire codes could be matched up and who remained employed in the same hospital over the five-year period.
† $p < .10$ * $p < .05$ ** $p < .01$ *** $p < .001$

be displaced by a nurse from another hospital with more tenure.

Demographic variables. The demographic variables included age, length of time employed as a nurse, length of time employed on the unit, and education.

Data Analysis

To identify significant changes in nurses' job attitudes, we conducted repeated measures ANCOVA with time as the within-subjects factor, hospital (acquiring or acquired) as the between-subjects factor, and hospital tenure as the covariate. To examine the hypothesized mediating role of perceived job insecurity and coping on the support-attitude relationships, we followed the procedures suggested by Baron and Kenny (1986) and conducted a series of regressions. We entered the control variables in Step 1 and then the support variable in Step 2. In Step 3, we entered the mediating variable. Perfect mediation occurs when the support variable has no effect once the mediating variable is entered whereas partial mediation occurs when the effect of the support variable on the job attitude is less when the mediating variable is added to the equation.

Results

The MANCOVA findings indicated there was no overall hospital effect for the support variables, perceived job insecurity, and control-oriented coping at T1 (Pillai's Trace $F_{(5,118)} = 1.27$, $p = 0.28$), T2 (Pillai's Trace $F_{(5,126)} < 1.00$, $p = 0.99$), or T3 (Pillai's Trace $F_{(5,123)} < 1.00$, $= 0.75$). There was also no overall hospital effect for the attitude variables at T1 (Pillai's Trace $F_{(6,115)} = 1.78$, $p = 0.11$). However, there was a significant overall hospital effect for the attitude variables at T2 (Pillai's Trace $F_{(7,101)} = 2.12$, $p < 0.05$). There was also a significant overall hospital effect for the attitude variables at T3 (Pillai's Trace $f_{(7,111)} = 2.55$, $p < 0.05$).

The repeated measures ANCOVA results comparing nurses in the hospitals being acquired with nurses in the acquiring hospitals over the five-year period are presented in Table 1. There was relatively strong support for H1a. There were significant decreases in overall job satisfaction, satisfaction with kind of work and career future, organizational commitment and trust, marginally significant decrease in satisfaction with amount of work ($p = 0.06$), and a significant increase in turnover intention.

There was weaker support for H1b which predicted that nurses in the hospitals being acquired would report significantly greater change in job attitudes than nurses in the acquiring hospitals. There was a significant Hospital X Time effect for satisfaction with amount of work and organizational trust and a marginally significant Hospital X Time effect ($p = 0.07$) for organizational commitment. Contrary to what was predicted, nurses in the acquiring hospitals reported a significant decrease in satisfaction with amount of work between T2 and T3 whereas nurses in the hospitals being acquired reported a slight increase in satisfaction with amount of work at T3. For organizational trust, nurses in the acquiring hospitals reported a higher level of trust in their hospital at T1 than nurses in the hospitals being acquired. At T3, there was a significant decrease in organizational trust on the part of nurses in the acquiring hospitals so that the levels of organizational trust were highly similar for the two groups during the amalgamation. Although both groups of nurses reported a significant decrease in organizational commitment at T3, nurses in the acquired hospitals reported a much greater decrease in organizational commitment between T2 and T3 than did nurses in the acquiring hospitals. Overall, nurses in the acquiring hospitals reported a greater decrease in job satisfaction and organizational trust and a greater increase in turnover intentions than nurses in the hospitals being acquired. Organizational commitment was the only attitude variable in which nurses in the hospitals being acquired reported a greater decrease than nurses in the acquiring hospitals.

The correlations between the T2 support variables, perceived job insecurity, and control-oriented coping and the T3 attitude measures are presented in Table 2. H2 predicted that the support resources would be significantly negatively related to perceived job insecurity and significantly positively related to control-oriented coping. This hypothesis was supported. Nurses who perceived greater support from their hospital, their supervisor, and their coworkers perceived significantly less job insecurity and were more likely to engage in control-oriented coping than nurses who lacked these support resources.

H3 predicted that perceived job insecurity would mediate the relationship between the support resources and job attitudes. To establish mediation, the following conditions must hold: the support variable must be significantly related to both the attitude variable and the mediating variable, and the mediating variable must be significantly related to the attitude variable (Baron & Kenny, 1986). We have already noted that the three support variables were significantly negatively related to perceived job insecurity. Perceived organizational support was significantly related to all of the attitude variables except satisfaction with amount of work and perceived supervisor support was significantly related to all of the attitude variables except satisfaction with amount

Table 2
Correlations for the T2 Support, Job Insecurity, Coping Measures with the T3 Attitudes

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1. Hospital															
2. Change	.11														
3. Tenure	-.03	.20													
4. T2 Hosp Support	.02	.02	.06												
5. T2 Supr Support	.07	.08	.13	.54											
6. T2 Cowk Support	.01	-.03	.05	.02	.12										
7. T2 Job Insecur	-.06	-.14	-.41	-.24	-.19	-.17									
8. T2 Cont Coping	.04	.01	.02	.34	.27	.17	-.09								
9. T2 Job Satis	-.02	.13	.13	.43	.26	.14	-.18	.03							
10. T3 Satis Kind Wk	.04	.13	.10	.33	.30	.09	-.10	.26	.56						
11. T3 Satis Amt Wk	-.18	.23	.11	.13	.06	.01	-.09	-.03	.53	.51					
12. T3 Satis Future	.02	.26	.21	.48	.16	.09	-.33	.15	.56	.40	.40				
13. T3 Org Commit	.16	.11	.25	.43	.21	.19	-.28	.13	.35	.34	.25	.48			
14. T3 Org Trust	.03	.17	.15	.61	.33	.08	-.21	.18	.47	.36	.28	.56	.56		
15. T3 Turn Intent	-.04	-.15	-.06	-.40	-.24	-.09	.08	-.20	-.59	-.47	-.45	-.48	-.57	-.45	

Note. For hospital status 1 = hospital being acquired and 2 = acquiring hospital. Affected by change was coded with 1 = yes (experienced negative change) and 2 = no. Correlation coefficients > .16, $p < .05$, correlation coefficients > .21, $p < .01$, correlation coefficients > .27, $p < .001$.

of work and career future. Coworker support was significantly related to only one of the attitude variables: organizational commitment. Perceived job insecurity was significantly related to overall job satisfaction, satisfaction with career future, organizational commitment, and organizational trust. Therefore, the possible organizational support-job attitude relationships that perceived job insecurity could mediate were perceived organizational support and overall job satisfaction, satisfaction with kind of work and career future, organizational commitment, and organizational trust. The possible supervisor support-job attitude relationships that perceived job insecurity could mediate were perceived supervisor support and overall job satisfaction, organizational commitment, and organizational trust. The only possible coworker support-job attitude relationship that perceived insecurity could mediate was perceived coworker support and organizational commitment.

There was evidence that perceived job insecurity partially mediated the relationship between organizational support and satisfaction with career future, between supervisor support and organizational commitment, and between coworker support and organizational commitment. These results are presented in Table 3.

All three support resources were significantly related to control-oriented coping. Control-oriented coping was significantly related to satisfaction with kind of work, organizational trust, and turnover intention. As noted above, perceived organizational support was significantly related to all of the attitude variables except satisfaction with amount of work, supervisor support was significantly related to all the attitude variables except satisfaction with amount of work and career future, and coworker support was only significantly related to organizational commitment. Therefore, the possible support–job attitude relationships that control-oriented coping could mediate were perceived organizational support and satisfaction with kind of work and organizational trust, and perceived supervisor support and satisfaction with kind of work, organizational trust, and turnover intentions. There was evidence that control-oriented coping partially mediated the relationship between both organizational support and supervisor support and satisfaction with kind of work. These findings are shown in Table 4.

We expected that the support variables would affect job attitudes only through their influence on perceived job insecurity and coping. The mediation tests indicated that perceived job insecurity mediated only three of the 21 support–job insecurity–job attitude relationships and control-oriented coping mediated only two of the 21 support–coping–job attitude relationships. However, the zero-order correlations indicated that perceived hospital and supervisor support were significantly related to the

Table 3
Hierarchical Regression Examining the Mediating Effects of Perceived Job Insecurity for Satisfaction with Career Future and Organizational Commitment

Attitude	Satisfaction with Career Future		
Predictors:			
Step 1:			
Hospital Status	-.02	-.03	-.03
Affected by Changes	.24**	.18*	.18*
Hospital Tenure	.15	.13	.07
Step 2:			
Organizational Support		.46***	.42***
Step 3:			
Perceived Job Insecurity			-.18*
F	4.58**	37.80***	4.74*
R^2	.09	.29	.32
R^2 change		.20	.03
Attitude	**Organizational Commitment**		
Predictors:			
Step 1:			
Hospital Status	.16	.15	.14
Affected by Changes	.06	.05	.04
Hospital Tenure	.23**	.21*	.14
Step 2:			
Supervisor Support		.17*	.14†
Step 3:			
Perceived Job Insecurity			-.17†
F	4.29**	37.40***	18.36***
R^2	.09	.12	.14
R^2 change		.03	.02
Attitude	**Organizational Commitment**		
Predictors:			
Step 1:			
Hospital Status	.16	.16	.16
Affected by Changes	.05	.06	.05
Hospital Tenure	.24**	.22*	.15
Step 2:			
Coworker Support		.17*	.15
Step 3:			
Perceived Job Insecurity			-.18*
F	4.30**	4.35*	3.75*
R^2	.09	.12	.15
R^2 change		.03	.03

† $p < .10$ * $p < .05$ ** $p < .01$ *** $p < .001$

Table 4
Hierarchical Regression Examining the Mediating Effects of Control-oriented Coping for Satisfaction with Kind of Work

Attitude	Satisfaction with Kind of Work		
Predictors:			
Step 1:			
Hospital Status	.05	.05	.05
Affected by Changes	.12	.10	.10
Hospital Tenure	.09	.09	.09
Step 2:			
Organizational Support		.32***	.25**
Step 3:			
Control-oriented Coping			.17*
F	1.43	14.69***	3.92*
R^2	.03	.13	.16
R^2 change		.10	.03
Attitude	**Satisfaction with Kind of Work**		
Predictors:			
Step 1:			
Hospital Status	.01	.00	.00
Affected by Changes	.15†	.09	.09
Hospital Tenure	.10	.08	.07
Step 2:			
Supervisor Support		.59***	.59***
Step 3:			
Control-oriented Coping			-.02
F	1.23	12.10***	4.96*
R^2	.03	.11	.14
R^2 change		.08	.03

† $p < .10$ * $p < .05$ ** $p < .01$ *** $p < .001$

job attitude variables. This suggested that the support variables were directly related to job attitudes in addition to having an indirect relationship through perceived job insecurity and control-oriented coping as the Lazarus and Folkman (1984) model posits. We therefore decided to conduct additional hierarchical regression analyses to identify the significant predictors of nurses' job attitudes at T3. We entered the control variables in the first step, the T1 job attitude variable (in the case of organizational commitment it was the T2 measure) in the second step, the support variables in the third step, and perceived job insecurity and control-oriented coping in the fourth step. This procedure controls for the pre-amalga-

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mation job attitude so that predictors that are significant are reflecting their effect on the change in the job attitude during the amalgamation period.

The amount of variance in the job satisfaction variables accounted for by the predictor variables was 26% for overall job satisfaction, 31% for satisfaction with kind of work, 30% for satisfaction with amount of work, and 41% for satisfaction with career future. Perceived organizational support and T1 overall job satisfaction were significant predictors of T3 overall job satisfaction and perceived organizational support, supervisor support, negative change experience, and T1 satisfaction with career future were significant predictors of T3 satisfaction with career future. Only the T1 measure of satisfaction with kind of work was a significant predictor of T3 satisfaction with kind of work and only the T1 measure of satisfaction with amount of work and hospital were significant predictors of T3 satisfaction with amount of work. Perceived organizational support and T2 organizational commitment were significant predictors of T3 organizational commitment and perceived organizational support and T1 organizational trust were significant predictors of T3 organizational trust. Perceived organizational support, negative change experience, and T1 turnover intention were significant predictors of T3 turnover intentions. Thus, perceived organizational support had a significant effect on the change in job attitudes during the amalgamation period. These analyses are available upon request from the authors.

Discussion

Consistent with the theoretical literature on mergers and acquisitions and the limited empirical evidence, we found a significant deterioration in the job attitudes of nurses and an increase in turnover intentions during the amalgamation phase compared with the pre-amalgamation period. What is noteworthy about these results is that nurses in the acquiring hospitals appeared to be more adversely affected by the amalgamation than nurses in the hospitals being acquired. Organizational commitment was the only attitude variable for which nurses in the hospitals being acquired expressed a greater decrease than nurses in the acquiring hospitals. Compared to the beginning of the amalgamation period, nurses in acquiring hospitals reported a greater decrease in overall job satisfaction, satisfaction with kind of work and career future, and organizational trust during the amalgamation period than nurses in the hospitals being acquired. Nurses in the acquiring hospitals also reported a greater increase in turnover intentions than nurses in the hospitals being acquired. For satisfaction with amount of work, nurses in the hospitals being acquired actually reported an increase whereas nurses in the acquiring hospitals reported a significant decrease. This may be because services were being transferred to the acquiring hospitals during this period whereas services in the hospitals being acquired were slowly being phased out. For those nurses who reported increased workload in response to the question about being directly affected by the changes associated with the amalgamation, close to 75% were from the acquiring hospitals.

These findings indicate that the negative effects of amalgamation are not confined to the nurses in the hospital being acquired; there is also an adverse impact on nurses in the acquiring hospitals. If anything, the results suggest that nurses in the acquiring organization may be even more adversely affected than nurses in the organization being acquired. This may be because nurses in the acquiring hospitals had also experienced considerable turbulence in their workplace. Prior to the amalgamation, all four hospitals had experienced budget cutbacks resulting in the closing of beds and units, reduced work hours, and nurse layoffs. The provision of bumping across the four hospitals meant that nurses with greater seniority in the hospitals being acquired could displace nurses with less seniority in the acquiring hospitals. Moreover, nurses in the acquiring hospitals were just as likely as nurses in the hospitals being acquired ($\chi^2 = 1.72$, $p = 0.19$) to report being directly negatively affected by changes associated with the amalgamation.

This study provides strong evidence for the vital role that perceived organizational support plays in an amalgamation. Nurses who believed that their hospital was committed to them, valued their contribution, and cared about their well-being perceived significantly less job insecurity, engaged in more control-oriented coping, and reported significantly higher job satisfaction, organizational commitment, and organizational trust and were less likely to be thinking of leaving their job than nurses who perceived little support from their hospital. Perceived organizational support at the beginning of the amalgamation phase was a consistent determinant of change in job attitudes during the amalgamation period two years later. These findings have clear implications for organizations that may be considering an amalgamation or merger. Upper-level management may be able to minimize the negative effects of an amalgamation by demonstrating to employees that they care about employees' well-being and value their contribution to the organization.

Perceived support from one's immediate supervisor was also important in maintaining nurses' positive job attitudes during the amalgamation. However, coworker support was unrelated to all of the job attitudes except

organizational commitment. Although some researchers have found that both supervisor and coworker support are important resources, there is some evidence that support from one's supervisor is more effective in reducing stress reactions than support from one's colleagues (Buunk, 1990; Chisholm et al., 1986). Taylor, Buunk, and Aspinwall (1990) suggested that supervisor support may be more effective than coworker support in decreasing stress reactions because, in addition to providing emotional support, a supervisor provides informational support which may be particularly valuable when the individual is faced with ambiguous or uncertain situations.

We expected that there would be a significant increase in perceived job insecurity but job insecurity remained relatively stable over the five-year period. Moreover, there was no significant difference in perceived job insecurity for nurses in the hospitals being acquired and nurses in the acquiring hospitals. It is possible that job insecurity had become heightened for both groups of nurses in the early 1990s when there was a rapid change from a shortage to a surplus of nurses and that subsequent organizational changes related to the amalgamation initiative had little further impact. The lack of a significant difference between hospitals may be due to the seniority-based bumping privileges. Given that the average length of hospital tenure was similar between acquiring and acquired hospitals, nurses with less tenure were just as likely to be found in the acquiring hospitals as in the hospitals being acquired.

We found only weak support for our prediction that perceived job insecurity and control-oriented coping would mediate the influence of the support variables on job attitudes. There was greater evidence of a direct relationship between perceived hospital and supervisor support and job attitudes. Nurses who perceived higher levels of support from their hospital and their immediate supervisor at the beginning of the amalgamation phase reported significantly greater job satisfaction, higher organizational commitment, more trust in their hospital, and lower turnover intentions during the amalgamation period two years later than nurses who perceived lower levels of support. Our operationalization of stress appraisal as perceived threat of job loss may have been problematic, especially given that perceived job insecurity did not change over the five-year period. In fact, the level of perceived job insecurity was below the midpoint of the scale, suggesting that the perceived threat of job loss was not overly great. Greenhalgh and Rosenblatt (1984) noted that perceived job insecurity spans the range from permanent loss of the job itself to loss of important features of the job. It is possible that perceived threat to various job features, such as opportunities for promotion, work unit changes, relocation, and freedom to schedule work, would have been more appropriate to assess rather than perceived threat of job loss.

The findings of this study are based upon self-report data that may be susceptible to common method variance. However, this is less of a problem because the data were collected over a five-year period. Although the decreases in job attitudes between 1995 and 1997 coincided with the amalgamation initiative, it is not entirely possible to conclude categorically that these reactions were solely due to the amalgamation initiative. One possibility is that the reactions reflected the cumulative effect of all the changes that had been occurring in the health care system since the early 1990s. Another limitation is the issue of the generalizability of the findings. These four hospitals had been dealing with considerable change and uncertainty since the 1990s. The reactions to the amalgamation may have been influenced by the several years of turmoil that preceded the amalgamation. Employees may respond differently to an amalgamation between two organizations where one or both of the organizations have had a relatively stable history.

One of the major strengths of this study is the examination of job attitudes over a five-year period beginning with an assessment of job attitudes two years prior to the amalgamation announcement. Because so little research has been conducted on employees' reactions to amalgamation, especially over time, this study makes an important contribution to our currently limited knowledge in this area. The key findings from this study are that employees in the acquiring organization may be equally or even more negatively affected by an amalgamation. The focus in much of the literature has been on the impact of the amalgamation on employees in the organization being acquired. Our study shows that we also need to be concerned about the effect on employees in the acquiring organization. We found that support resources, especially organizational support, play an instrumental role in how well employees adjust to an amalgamation. It is possible that other resources, such as individual predispositions, and other types of coping strategies may also be important in promoting successful adjustment. We examined the impact of amalgamation on the job attitudes of nurses. Future research should include other outcome variables, such as in-role behaviour (job performance) and extra-role behaviours (organizational citizenship behaviour, client service). We have witnessed a recent increase in the number of mergers and amalgamations taking place in Canada in the airline, mining, oil, and auto industries as well as financial institutions. Clearly, the impact of mergers and amalgamations on employees in both the acquiring and the

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acquired organizations requires greater attention on the part of researchers given the recent trends.

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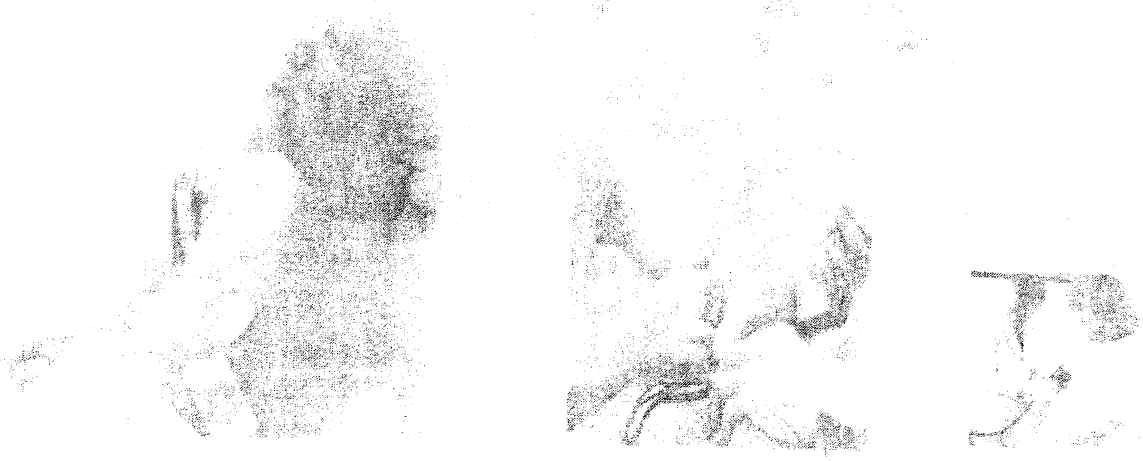
Tab 15

Building a Safer System

A National Integrated Strategy for Improving Patient Safety in Canadian Health Care



National Steering Committee on Patient Safety
Comité directeur national sur la sécurité des patients

NATIONAL STEERING COMMITTEE ON PATIENT SAFETY
COMITÉ DIRECTEUR NATIONAL SUR LA SÉCURITÉ DES PATIENTS

Building a Safer System:

A National Integrated Strategy for Improving Patient Safety in Canadian Health Care

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System Issues Working Group
Legal / Regulatory Issues Working Group
Measurement / Evaluation Working Group
Education / Professional Development Working Group
Information / Communication Working Group

Administrative Group — Patient Safety

(Please see Appendices A and B for names and affiliations)

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The Royal College of Physicians and Surgeons of Canada
Saskatchewan Health

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Executive Summary

"We envision a system of care in which those who give care can boast about their work, and those who receive care can feel total trust and confidence in the care they are receiving."

Donald M. Berwick, MD, MPP
(as quoted by the Institute for Healthcare Improvement, 2002)

In April of 1992, a four-year-old girl in Halifax was scheduled to receive the last in a series of chemotherapy treatments for leukemia. She was diagnosed two years earlier but, on that day in April, her physicians considered her cured. The medications, including *Vincristine*, were administered in the operating room as she was also receiving dental surgery and one anesthetic procedure could allow both treatments to proceed at the same time. Unfortunately, several factors contributed to the *Vincristine* being injected intrathecally (into a spinal catheter) instead of intravenously (into a vein). *Vincristine* is lethal when injected intrathecally — she died a week later (Jones, 1996 as cited in Baker and Norton, 2001).

Regrettably, other Canadian patients[1] have subsequently died from a spinal injection of *Vincristine* and also many more Canadians are injured or die as a result of health-care errors. Dramatic advances in the diagnosis and treatment of disease have exponentially increased the complexity of care processes while outdated modes of communication, employee training, and product design persist. The aging population, resource limitations, a critical shortage of qualified health-care personnel in a growing list of locations and specialties, and challenges created by mergers and restructuring within health organizations are combining to create unequaled strain and an increasing likelihood of errors in the system.

Canadian health-care personnel are increasingly aware of the frequency and significance of these largely preventable adverse events. They want to move the discussion out from behind closed doors and devise workable solutions. International jurisdictions, such as the United States, have already recognized that health-care safety concerns are real, that their systems are prone to error and failure, and that measures must be taken to reduce the risk. Canada is significantly behind the United States, the United Kingdom and Australasia in accepting that patients are at significant risk, in wanting to learn about the relevant issues, and in investing in the creation of a culture of safety.

Recognizing the need for further dialogue, The Royal College of Physicians and Surgeons of Canada hosted a one-day forum on patient safety as part of their Annual Conference in September 2001. Over 50 leaders representing government, health-care associations, and other non-government organizations attended a roundtable discussion on developing a national strategy to improve safety. A National Steering Committee and five working groups were subsequently formed at the direction of the roundtable participants; their work is summarized within the report.

Building a Safer System: Principles for Action

Key assumptions have been described in the principles for action to provide a foundation for the specific strategies that will be recommended for implementation.

- The Canadian health-care system is guided by the principles of national health insurance as set out in the Canada Health Act, and is implemented primarily at the provincial/territorial level. The system is complex, dynamic and characterized by many competing pressures, particularly the relationship between funding and quality of care. An unprecedented level of collaboration across all sectors must occur to ensure a co-ordinated and effective strategy for improving patient safety.

[1] The term « patient » is intended to encompass everyone who receives health services across the continuum of care.

- Safety is a fundamental aspect of quality health care. To improve safety, the health-care system must develop, maintain and nurture a culture of safety.
- Health-care personnel, patients, and all others within the system must be informed participants in understanding that human error is inevitable and that underlying systemic factors, including ongoing system change, contribute to most near misses, adverse events and critical incidents.
- Specific educational and professional development programs that focus on evidence-based practice, periodic audit, and a team approach to practice and learning can reduce the likelihood of human error.
- The health-care system must facilitate comprehensive identification of hazards that pose threats to our people (e.g. patients, staff and health-care personnel). Systemic identification should be carried out reactively, in response to a recognized adverse event or outcome, and more importantly, proactively, before problems have occurred. This identification must be followed by reporting and recording of these hazards (and any associated adverse events and near misses) to a network of databases.
- The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems or potential problems is encouraged and rewarded. No blame will be apportioned to individuals following reporting, subject to limited qualifications. These limited qualifications include failure to report safety hazards or critical incidents and premeditated or intentional acts of violence against people, equipment or property.
- The health-care system must encourage partnerships among all consumers and providers of care. Partnerships will require the health-care system to become more flexible, with a shift away from traditional hierarchical operating structures. These partnerships, including those of individuals, professions and organizations, are necessary for effectively improving all operational/systemic deficiencies.
- The health-care system must demonstrate its ability to build on what is already known in other sectors, learn from experience, and be willing and able to implement major reforms when indicated. Such a system will endeavor to analyze relevant information, develop cost-effective evidence-based safety initiatives and standards of care that are critical to the improvement process, and regularly receive feedback on the results of targeted strategies.
- The health-care system must promote appropriate disclosure to all partners (e.g. patients, the public, health-care personnel and governments) of safety information relative to health issues. Such disclosure must be supported by changes to the legal and regulatory systems that also facilitate effective systems for the prevention and/or management of hazards.

Key recommendations

Nineteen recommendations have been developed to represent the breadth of collaborative work that must be undertaken within the national integrated strategy. The recommendations, grouped into five major categories, are not all listed here in order of priority (please see page 34 for suggested governance and funding with priority recommendations).

Establish a Canadian Patient Safety Institute to Facilitate a National Integrated Strategy for Improving Patient Safety

(1) Establish and support a non-profit *Canadian Patient Safety Institute*[2] (draft title). Membership will be multidisciplinary and consist of clinical, academic and administrative experts in the fields of safety and health care from across Canada.

(2) Base new practices, technologies and programs that are recommended by the *Canadian Patient Safety Institute*, or other such bodies, on evidence, and subject them to scientific evaluation. The evaluation would include potential benefits and costs.

(3) Implement system changes that have a demonstrated ability to improve patient safety.

(4) Formalize responsibility and accountability for patient safety within the management structures and clinical processes of all health-care organizations.

[2] The term « institute » has been selected to reflect the collaborative and non-regulatory mandate of the proposed organization. The title should be considered as draft and for discussion purposes.

(5) Develop and implement responsive patient-focused programs for the receipt, review and management of concerns within health-care organizations.

Improve Legal and Regulatory Processes

(6) Adopt non-punitive reporting policies within a quality-improvement framework across the health-care system.
(7) Standardize the legislation on privacy and confidentiality of personal health information across Canada to facilitate access to patient-safety data, while respecting the privacy of patients and providers.
(8) Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human resource processes.
(9) Review, and where applicable, revise *The Evidence Act* and related legislation within all Canadian jurisdictions to ensure that data and opinions associated with patient-safety and quality-improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. The protection would extend to this information when used internally or shared with others for the sole purpose of improving safety and quality. Wording within the applicable Acts should ensure that all facts relating to an adverse event are recorded on a health record that is accessible to the patient or designated next of kin, and are not considered privileged.
(10) Hold further discussions regarding the tort and health-care insurance systems and their effects on patient safety, with the aim of making recommendations that would contribute to a culture of safety in Canadian health care.

Improve Measurement and Evaluation Processes

(11) Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses.
(12) Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in Recommendation (11).
(13) Secure funding from federal/provincial/territorial jurisdictions to invest in information technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data.
(14) Adopt "patient safety" as a cross-cutting theme or designated area for research competitions supported by the Canadian Institutes for Health Research, Canadian Health Services Research Foundation and/or other granting organizations, to encourage Canadian researchers to undertake studies in this area.

Establish Educational and Professional Development Programs

(15) Develop and implement health-care education and professional-development programs for improving patient safety.
(16) Develop educational and continuing professional development programs to improve patient safety in collaboration with national accrediting bodies, academic institutions, provincial licensing authorities (for peer-assessment reviews) and health-care facilities/organizations/scholarly societies.

Improve Information and Communication Processes

(17) Publicly report measures of health-care quality and safety.
(18) Develop educational materials on personal measures for improving safety in health care for distribution to the public.
(19) Create a website to facilitate the sharing of patient-safety resources and discussions.

The proposed national integrated strategy is a co-ordinated and comprehensive framework that builds on current structures and processes with a strong emphasis on providing multidisciplinary teams with the education and resources to diffuse patient safety expertise across Canada.

Immediate steps are being taken to begin the building of a safer system; however, these steps lack integration and co-ordination. For effective system-wide improvements, short- and long-term funding must be committed from federal and provincial jurisdictions. Other health-care stakeholders must identify and offer their expertise and participation in support of applicable recommendations.

Sommaire[1]

"Nous imaginons un système de santé dans le cadre duquel les prestataires de soins peuvent se targuer de leurs réalisations et les personnes qui reçoivent les soins se sentent en pleine confiance quant aux soins dispensés."

Donald M. Berwick, MD, MPP
(tel que cité par la Institute for Healthcare Improvement, 2002)

En avril 1992 à Halifax, une fillette de quatre ans souffrant de leucémie en était à sa dernière séance de chimiothérapie. Diagnostiquée deux ans plus tôt, la fillette était, en ce jour d'avril, guérie selon ses médecins. Les médicaments, notamment la *vincristine*, lui ont été administrés dans la salle d'opération où elle subissait également une intervention chirurgicale dentaire, car la procédure anesthésique rendait possible l'exécution simultanée des deux traitements. Malheureusement, la *vincristine* a été administrée en injection intrathécale (par un cathéter médullaire) plutôt qu'en injection intraveineuse (dans une veine). En administration intrathécale, la *vincristine* est mortelle, et la fillette est décédée une semaine plus tard (Jones, 1996, comme il est rapporté dans Baker et Norton, 2001).

Il est également déplorable que d'autres patients[2,3] canadiens aient perdu la vie par suite d'une injection rachidienne de *vincristine*, et que de nombreux autres subissent les répercussions d'une erreur médicale ou en décèdent. Des avancées spectaculaires dans le diagnostic et le traitement des maladies ont accru de façon exponentielle la complexité des processus de prestation des soins, pendant que persistent des modes désuets de communication, de formation des employés et de conception des produits. Le vieillissement de la population, l'amenuisement des ressources, la pénurie aiguë de professionnels de la santé qualifiés dans un nombre croissant de lieux et de spécialités, et les problèmes causés par les fusions et la restructuration dans les organisations de la santé sont tous des facteurs qui, combinés, exercent une tension sans précédent sur le système, d'où le risque accru d'erreurs.

De plus en plus, les intervenants canadiens en santé sont conscients de la fréquence et de la portée de ces incidents indésirables, évitables en grande partie. Ils souhaitent que le débat à ce propos ne se tienne plus à huis clos et que des solutions pratiques soient conçues. À l'échelle internationale, des pays, comme les États-Unis, admettent déjà que les préoccupations quant à la sécurité des soins de santé sont fondées, que leurs systèmes favorisent en quelque sorte l'erreur et la défaillance, et qu'il importe d'adopter des mesures pour réduire le risque d'erreurs. Comparativement aux États-Unis et à d'autres pays, le Canada stagne loin derrière quant à reconnaître que les patients courent un risque de taille, à connaître les divers aspects de la question et à s'engager dans la création d'une culture de la sécurité.

Conscient de la nécessité d'approfondir le débat à ce sujet, Le Collège royal des médecins et chirurgiens du Canada a organisé une tribune d'une journée sur la sécurité des patients dans le cadre de sa Conférence annuelle en septembre 2001. Plus de 50 chefs de file, représentant l'administration publique, des organisations de la santé et d'autres organisations non gouvernementales, ont participé à cette table ronde sur l'élaboration d'une stratégie d'amélioration de la sécurité d'envergure nationale. Sous l'impulsion des participants à la table ronde, le Comité directeur national et cinq groupes de travail ont vu le jour, et le présent rapport rend compte de leurs travaux.

[1] Le texte intégral du rapport est aussi disponible en français sur demande
[2] Le terme « patient » englobe ici quiconque reçoit des services dans tout le continuum des soins de santé.
[3] Noter que le générique masculin est utilisé dans le seul but d'alléger le texte

Accroître la sécurité du système : principes d'action

Les principes d'action s'appuient sur des hypothèses essentielles, décrites ici, qui forment le fondement des stratégies particulières dont la mise en œuvre est proposée.

- Le système de santé canadien est régi en vertu des principes de la *Loi canadienne sur la santé*, qui est appliqué principalement à l'échelle provinciale et territoriale. Le système, complexe et dynamique, subit de nombreuses tensions concurrentes, particulièrement celles créées par la relation entre le financement et la qualité des soins. Un niveau de collaboration inédit entre tous les secteurs est essentiel à l'élaboration d'une stratégie coordonnée et efficace d'amélioration de la sécurité des patients.
- La sécurité est un aspect fondamental des soins de santé de qualité. Pour améliorer la sécurité, le système de santé doit créer, maintenir et rehausser une culture de la sécurité.
- Les professionnels de la santé, les patients et tous les autres intervenants du système doivent être au fait que l'erreur humaine est inévitable et que des facteurs systémiques sous-jacents, notamment les changements perpétuels, contribuent à la survenue de la plupart des erreurs évitées de peu, et des incidents critiques.
- Les programmes d'éducation et de perfectionnement professionnel visant tout particulièrement la pratique et l'apprentissage fondés sur les résultats cliniques et scientifiques, sur des vérifications périodiques et sur le travail en équipe peuvent réduire les risques d'erreur humaine.
- Le système de santé doit faciliter le relevé exhaustif des risques qui mettent en péril les personnes qui y ont recours (p. ex. les patients, la direction et le personnel). Le relevé méthodique doit s'enclencher en réaction à un incident ou résultat indésirable connu, mais doit avant tout s'inscrire dans le cadre d'une démarche proactive, soit avant que les problèmes ne se produisent. Cette étape doit être suivie du signalement et de la consignation de ces risques (et de tous les incidents indésirables et événements évités de justesse qui y sont associés) dans un réseau de bases de données.
- Le système de santé doit créer un climat de confiance, où l'ouverture et la franchise dans le recensement et le signalement des problèmes ou problèmes potentiels sont encouragées et récompensées. Par suite d'un signalement, personne ne se verra reprocher quoi que ce soit, sauf dans des situations particulières, comme l'omission de rapporter des risques de sécurité ou des incidents critiques et la commission préméditée ou intentionnelle d'actes de violence à l'égard d'une personne, de l'équipement ou de biens.
- Le système de santé doit favoriser la formation de partenariats entre les consommateurs et les prestataires de soins. Pour ce faire, le système de santé devra être plus souple, en délaissant la structure opérationnelle hiérarchique au profit d'un mode de fonctionnement horizontal. Ces partenariats, qu'ils fassent intervenir des personnes, des professions ou des organisations, sont nécessaires pour corriger toutes les défaillances opérationnelles et systémiques.
- Le système de santé doit démontrer son aptitude à tirer parti de ce qui se fait déjà dans d'autres secteurs, à tirer un enseignement de l'expérience et à être disposé et capable de mettre en œuvre d'importantes réformes le cas échéant. Un tel système s'attache à analyser l'information pertinente, à élaborer des initiatives de sécurité et des normes de soins rentables et fondées sur des données probantes, qui sont essentielles au processus d'amélioration, et à examiner, à intervalles réguliers, la rétroaction sur les résultats de certaines stratégies.
- Le système de santé doit promouvoir la divulgation adéquate à tous les partenaires (p. ex. aux patients, au public, aux intervenants en santé et aux gouvernements), de l'information sur la sécurité en rapport avec les questions de santé. Cette présentation de l'information doit être favorisée par des changements dans les systèmes juridique et

réglementaire qui facilitent également l'instauration de mécanismes efficaces de prévention et de gestion des risques.

Principales recommandations

Dix-neuf recommandations ont été élaborées afin de représenter le plein éventail du travail de collaboration à entreprendre dans le cadre d'une stratégie nationale intégrée. Regroupées en cinq catégories principales, ces recommandations ne sont pas toutes présentées par ordre de priorité.

Veuillez consulter, à la page 34, les suggestions sur la gouvernance, les recommandations prioritaires et le financement.

Établir un Institut canadien sur la sécurité des patients afin de faciliter la mise en œuvre d'une stratégie nationale intégrée visant à améliorer la sécurité des patients.

(1) Établir et appuyer un *Institut canadien sur la sécurité des patients* [4] (appellation provisoire) sans but lucratif. L'Institut serait formé d'un regroupement multidisciplinaire d'experts cliniques, universitaires ou administratifs dans les domaines de la sécurité et des soins de santé, de toutes les régions du Canada.

(2) Fonder les nouvelles pratiques, technologies et programmes proposés par l'*Institut canadien sur la sécurité des patients*, ou d'autres organismes semblables, sur des données probantes et les soumettre à une évaluation scientifique. Cette évaluation comprendrait les avantages et les coûts éventuels.

(3) Mettre en œuvre des changements de nature démontrée à améliorer la sécurité des patients.

(4) Mettre en application de façon officielle la responsabilité et l'obligation de rendre compte quant à la sécurité des patients au sein des structures de gestion et des processus cliniques de toutes les organisations de la santé.

(5) Concevoir et instaurer des programmes adaptés aux besoins, centrés sur le patient, quant à la réception, à l'examen et à la gestion des préoccupations sur la sécurité dans les organisations de santé.

Améliorer les processus légaux et de réglementation

(6) Adopter des lignes directrices de signalement non punitif dans le cadre d'un mécanisme d'amélioration de la qualité à tous les niveaux du système de santé.

(7) Uniformiser la législation sur la protection de la vie privée et la confidentialité des renseignements personnels en santé au Canada pour faciliter l'accès aux données sur la sécurité des patients tout en respectant la vie privée des patients et des prestataires de soins.

(8) Mettre davantage l'accent sur l'amélioration par l'éducation et les mesures correctives, plutôt que par l'attribution d'un blâme ou des mesures punitives, dans les processus juridiques, réglementaires et de gestion des ressources humaines.

(9) Examiner et, le cas échéant, modifier la *Loi sur la preuve* et la réglementation apparentée dans toutes les provinces du Canada pour faire en sorte que les données et les observations personnelles quant à la sécurité des patients et à l'amélioration de la qualité, ainsi que la documentation connexe et les rapports sont à l'abri de la divulgation en cas de poursuite judiciaire. Cette information ne pourrait être divulguée si elle est utilisée au sein d'un établissement ou d'une organisation ou si elle est partagée avec d'autres personnes aux seules fins d'améliorer la sécurité et la qualité. La formulation des lois applicables devrait permettre que tous les faits en rapport avec un incident indésirable soient consignés dans un dossier de santé mis à la disposition des patients ou du plus proche parent désigné, sur demande, et qu'ils ne soient pas considérés comme étant confidentiels.

(10) Approfondir l'étude de la question de la responsabilité civile délictuelle et des régimes d'assurance maladie, et de son

[4] Le terme « Institut » a été choisi pour souligner l'aspect de *collaboration* et *de non-réglementation* du mandat de l'organisme suggéré. Son appellation n'est qu'une ébauche conçue afin de lancer un débat à ce propos.

incidence sur la sécurité des patients, en vue de formuler des recommandations contribuant à la création d'une culture de la sécurité dans le système de santé canadien.

Améliorer les processus de mesure et d'évaluation

(11) Entreprendre l'analyse des systèmes de surveillance des événements indésirables, des incidents critiques et des incidents évités de justesse.
(12) Proposer des types de systèmes de surveillance, comportant notamment les indicateurs pertinents de la sécurité des patients, à élaborer et à appuyer dans le système de santé canadien. Les propositions seraient fondées sur les constatations de l'analyse proposée au point (11).
(13) Obtenir du financement des gouvernements fédéral, provinciaux et territoriaux pour établir une infrastructure de la technologie de l'information nécessaire à l'uniformisation de la collecte, du signalement et du suivi des données sur la sécurité des patients.
(14) Que la « sécurité des patients » devienne un thème transversal ou un domaine désigné de recherche dans le cadre de concours soutenus par les Instituts canadiens de recherche en santé, la Fondation canadienne de la recherche sur les services de santé et d'autres organismes bailleurs de fonds, avec la volonté des chercheurs canadiens d'entreprendre des études dans ce domaine.

Créer des programmes d'éducation et de perfectionnement professionnel

(15) Élaborer et mettre sur pied des programmes éducatifs ou de perfectionnement professionnel sur l'amélioration de la sécurité des patients.
(16) Concevoir des programmes éducatifs et de perfectionnement professionnel continu sur l'amélioration de la sécurité des patients en collaboration avec les organismes d'agrément, les établissements universitaires, les ordres professionnels provinciaux (examen par les pairs) et les institutions, organisations et sociétés savantes en santé.

Améliorer les processus d'information et de communication

(17) Rendre compte publiquement des interventions axées sur la qualité et la sécurité des soins de santé.
(18) Concevoir de la documentation éducative sur les mesures personnelles d'amélioration de la sécurité des soins de santé et la transmettre au public.
(19) Créer un site Web pour faciliter la mise en commun des ressources sur la sécurité des patients et diffuser les débats à ce propos.

La stratégie intégrée d'envergure nationale proposée ici s'inscrit dans un cadre coordonné et global qui tire parti des structures et processus existants tout en insistant fortement sur la nécessité d'offrir aux équipes multidisciplinaires l'éducation et les ressources nécessaires pour rehausser l'expertise en matière de sécurité des patients dans tout le Canada.

On a déjà immédiatement entrepris des mesures visant à améliorer la sécurité du système; malheureusement, ces mesures manquent d'intégration et de coordination. Pour apporter des améliorations à tout le système, il faudra que les gouvernements fédéral, provinciaux et territoriaux y consacrent des fonds à brève et à longue échéance. La participation d'autres parties prenantes dans le domaine de la santé est également nécessaire à la mise en œuvre des recommandations applicables.

Introduction

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."

Margaret Mead
(as quoted by Helvarg, 1995)

Health-care interventions such as the prescribing and administering of medications, surgical procedures, laboratory tests or radiological investigations often require complex interactions of personnel and technology to be completed safely and effectively. Although health-care professionals are dedicated to achieving positive patient outcomes, they are human and therefore fallible. An error in this setting can result in significant disability or death; yet the health-care industry continues to rely heavily on personal vigilance rather than implement known mechanisms that can significantly reduce unintended actions.

International jurisdictions such as the United States of America, United Kingdom and Australia have already recognized that health-care safety concerns are real, that their systems are prone to error and failure, and that measures must be taken to reduce the risk. The US Institute of Medicine Report *To Err is Human* (1999) was an important stimulus for a call to action and created unprecedented media, public, and political attention with the estimate that between 44,000 and 98,000 of their citizens die each year as a result of medical errors. Many of the report recommendations have received widespread support with federal, state and local health-care organizations implementing a variety of key strategies.

The British report, *An Organization with a Memory* (National Health Service, 2000), estimated that adverse events, in which harm is caused, occur in approximately 10% of patient admissions, or about 850,000 times a year. The National Health Service has developed, and is implementing, a comprehensive quality program that includes a major emphasis on improving patient safety.

The *Quality in Australian Health Care Study* (Wilson et al, 1995) reported that 16.6 % of admissions were associated with an adverse event, and, of these, 51% were considered highly preventable. The release of the study ultimately led to the formation of the Australian Council for Safety and Quality in Health Care (2000). The role of the Council is to lead national efforts to promote systemic improvements in the safety and quality of health care, with a particular focus on minimizing the likelihood and effects of adverse events.

There is an acknowledged lack of definitive information on the rate of adverse events in Canadian health care. One study (Wanzel, Jamieson, et al, 2000) examined the incidence and nature of complications on a general surgery service and found that 75 (39%) of 192 inpatients suffered a total of 144 complications. The complications were considered trivial in 42 cases (29%), of moderate severity in 90 cases (63%), life threatening in 10 cases (7%), and were fatal in 2 cases (1%). Of particular relevance is the finding that 26 (18%) of the complications were deemed potentially attributable to error.

The Canadian Institute for Health Information and the Canadian Institutes of Health Research recently announced a jointly funded research study to examine the extent of adverse events in Canadian acute-care hospitals and the availability of data that could be used to support continuous monitoring. The information

"In the course of reviewing our own mistake, we also sought information across the country about other, similar, tragedies...there have been at least three other child deaths in this country since 1989 as a result of *Vincristine* being injected in error into the spinal fluid. These occurred in Nova Scotia, Quebec and Ontario. Each was fully investigated in the institution where it occurred, both internally and by provincial coroners. Yet we found that the details of these errors have not been comprehensively shared between provinces, between coroners' offices or between hospitals. We were not able to learn from our mistakes, nor did we have the opportunity to learn from those of our colleagues."

Mrs. Lynda Cranston (1997)

will be obtained through a systematic review of hospital charts from various centres in five provinces. Drs. G. Ross Baker and Peter Norton will lead the study with the results, anticipated in 2004, providing an important baseline and reference for patient-safety activities.

A full appreciation of the impact of adverse events cannot be attained from statistics alone, but must also include the human perspective from the patient's viewpoint. Each person who receives health care brings his/her unique physical, mental and emotional characteristics to the interaction. Patients are vulnerable and rely on the educational, regulatory and organizational institutions to do all that is possible to ensure that each diagnostic and therapeutic intervention is as safe as possible. The circumstances surrounding the death of a four-year-old girl from Nova Scotia provide an example of where the health-care system failed to "First, do no harm."

In April 1992, a pediatric patient was to receive the last in a series of chemotherapy treatments for leukemia. She had been diagnosed two years earlier but, on that day in April, her physicians considered her cured. The medications, including *Vincristine*, were administered in the operating room as she was also receiving dental surgery and one anesthetic procedure could allow both treatments to proceed at the same time. Unfortunately, several factors contributed to the *Vincristine* being injected intrathecally (into a spinal catheter) instead of intravenously (into a vein). *Vincristine* is lethal when injected intrathecally — she died a week later (Jones, 1996 as cited in Baker and Norton, 2001). Although many health-care providers across the country had heard of this incident, no move was made to implement safety changes that could prevent such a tragedy from occurring again.

A very important lesson in patient safety was not applied across Canada; similar circumstances resulted in the death of a seven-year-old patient at the BC Children's Hospital in 1997. Mrs. Lynda Cranston, President and CEO of the facility at the time, publicly announced the error and revealed the disturbing news that the health-care system had not learned from the tragic mistakes of others.

The circumstances may vary from example to example, but the reality is that patients across Canada sustain injuries and in some cases die from preventable adverse events. A great deal of collaborative work has yet to be done to build a safer health-care system in Canada.

Amidst the reports of adverse events and examples of personal tragedies, there are examples of excellence in health care and other high-risk industries that can be used as models to improve patient safety. In preparing this report, individuals from a variety of health-care backgrounds and locations across Canada participated in a national collaborative to identify the key actions that will have the greatest impact on reducing adverse events. The National Steering Committee on Patient Safety is pleased to present this information within a comprehensive and integrated strategy for making patient safety a national priority.

Background to the Formation of the National Steering Committee on Patient Safety

Mandate, Structure and Deliverables

As part of its Annual Conference in September 2001, The Royal College of Physicians and Surgeons of Canada hosted a one-day forum on patient safety that was attended by national and international health-care leaders and other experts in the field. The same forum also featured a closed event entitled *Roundtable on Patient Safety and Error in Medicine: Toward a Canadian National Strategy*. Over 50 leaders from government, health-care associations and other non-government organizations attended the roundtable to discuss the development of a multidisciplinary approach to tackle the issue of patient safety in Canada (please see Appendix C). Several important results emerged from these discussions.

- **National Consensus**
  Participants reached a unique national consensus on the need to develop a co-ordinated strategy for the purpose of improving patient safety and, therefore, the quality of health care in Canada.
- **National Steering Committee on Patient Safety**
  Participants agreed to create a steering committee to develop an integrated national strategy for patient safety.
- **Five Working Groups**
  Participants recommended the creation of five working groups to address the key aspects of patient safety.

  - System Issues
  - Legal / Regulatory Issues
  - Measurement / Evaluation
  - Education / Professional Development
  - Information / Communication

- **Twelve-Month Timetable**
  Participants charged the Steering Committee with developing and proposing a framework for a Canadian solution in 12 months' time. The committee was mandated to work collaboratively and consult widely to develop a clear set of goals and objectives, detailed action plans and a realistic projection of the time, financial and human resources required to implement these plans.

The National Steering Committee on Patient Safety, a self-standing group reporting to participating organizations, announced its membership in October 2001:

- Dr. **John Wade**, FRCPC, Chair, Dean Emeritus, Faculty of Medicine, University of Manitoba
- **G. Ross Baker**, Ph.D., Associate Professor, Department of Health Policy, Management and Evaluation, University of Toronto
- Honourable Judge **Allan Lefever**, Judge, Provincial Court, Alberta; President, Heart and Stroke Foundation of Canada; Co-chair, Health Charities Council of Canada (to May 2002)
- Dr. **Larry Ohlhauser**, President and Chief Executive Officer, Healthcare Solutions and Innovations (to March 2002)
- Dr. **John Millar**, FRCPC, Vice-President, Research and Population Health, Canadian Institute for Health Information.
- Ms. **Wendy Nicklin**, Vice-President, Nursing and Clinical Programs, The Ottawa Hospital
- Dr. **Walter Rosser**, FCFP, Professor and Chair, Department of Family Medicine, Faculty of Medicine, Queens University
- Dr. **Denis Roy**, FRCPC, Chief Executive Officer, *Centre hospitalier de l'Université de Montréal*
- Ms. **Bonnie Salsman**, Pharmacist and Hospital Pharmacy Management Consultant

Dr. **Peter Fraser**, 1st Vice-President, Canadian Medical Protective Association, and a family physician in active clinical practice, Oromocto, New Brunswick, joined as a member of the Steering Committee in January 2002. In May 2002, Mr. **John Bulman**, C.M., Chairman of the Board, Wawanesa Mutual Insurance Company, and a Commissioner with the Manitoba Securities

Commission, succeeded Judge Allan Lefever as the public representative on the committee.

The mission of the Steering Committee was:

- To place patient safety at the top of the leadership and management priority list
- To promote a culture of patient safety in health care
- To create an accountability framework for patient safety
- To identify ways to collect data and information useful for improving patient safety
- To create a process for development of a research agenda for patient safety
- To create an agenda for educating the public, payers and providers about patient safety
- To identify tools and improvements that enhance safety for patients, clients and communities

An Administrative Group was also formed and included the chief executive officers of the Association of Canadian Academic Healthcare Organizations, Canadian Council on Health Services Accreditation, Canadian Medical Association, Canadian Medical Protective Association, Canadian Pharmacists Association, College of Family Physicians of Canada, and The Royal College of Physicians and Surgeons of Canada, and Assistant Deputy Minister Ian Shugart from Health Canada. Please see Appendix B. The role of this group was to ensure appropriate and effective administrative support for the activities of the Steering Committee and working groups.

Participating organizations at the September 2001 roundtable were invited to submit names for possible appointment to each of the working groups. Five members of the Steering Committee each acted as primary co-chairs with one other person appointed by each of the working groups. Each of the five working groups was given a specific question to answer within a report that clarified the relevant issues, recommended realistic solutions and projected the resources required to implement the plan within the larger framework developed by the Steering Committee.

Five Working Groups

- **System Issues:** To what extent does the design of the health-care system contribute to adverse events and how can new designs reduce or eliminate human error?
- **Regulatory / Legal Issues:** How can the manner in which the regulation and monitoring of health-care professionals and their institutions, and the legal systems, improve patient safety?
- **Measurement / Evaluation:** How can the scope and impact of the problem be better measured?
- **Education / Professional Development:** How can improvements to the education and continuing professional development of health-care professionals reduce adverse outcomes and enhance patient safety?
- **Information / Communication:** How can better communication between various players in the health-care system, and across jurisdictions, improve the quality of patient safety?

The working groups, laboring under very tight timelines, reported to the Steering Committee by early April 2002. Their hands-on expertise and experience in health care created invaluable insights and recommendations that have been incorporated throughout this report. Please see Appendix A for a complete list of the members of the working groups.

The work of the National Steering Committee on Patient Safety was initiated and has been supported by Health Canada, 8 provincial and territorial ministries of health, and 26 Canadian health-care organizations. Their collaborative approach and ongoing assistance were instrumental in the development of the enclosed report (Please see Appendix C for a list of the participating organizations at the 2001 closed roundtable on patient safety).

Understanding the System

"Adverse events result from the interaction of the patient, the patient's disease, and a complicated, highly technical system of medical care provided not only by a diverse group of doctors, other care givers, and support personnel, but also by a medical–industrial system that supplies drugs and equipment. Reducing the risk of adverse events requires an examination of all these factors as well as of their relation with each other."

Leape, L.L. et al (1991)

A High-Risk Environment

Health care is provided 24 hours a day, seven days a week. Dramatic advances in the diagnosis and treatment of disease have made care processes more complex; however, many organizations are hampered by outdated modes of communication, record keeping, employee training and traditional hierarchical authority structures. The aging population, resource limitations, a critical shortage of qualified health-care personnel in a growing list of locations and specialties, and challenges created by mergers and restructuring within health-care organizations, are creating unequalled strain on the systems, thus, increasing the likelihood of adverse events, sometimes with lethal consequences. Fortunately, due to the efforts and vigilance of health-care personnel, many of these events are prevented or mitigated.

How Hazardous is Health Care?

Most health-care encounters are error-free; however, international researchers have documented preventable injuries and deaths in every setting where measurement was attempted.[1] There is no reason to believe that the Canadian health-care system would be dramatically different. The anecdotal reports of patients and health-care professionals provide ample evidence of an environment prone to error.

No industry is more complex than the health-care industry. Yet, there has only been a recent acknowledgement that patient safety must be a high priority. Many methods and systems within health care are not capable of reliably delivering high-quality care to every patient (Leape as cited in *Lessons in Patient Safety*, 2001). While health-care workers have always tried to protect patients from harm in all aspects of care, the increasing complexity of processes and rapid changes within the system have contributed to the need for a stronger emphasis on patient safety. It is no longer appropriate to think that previous and current processes to ensure safety are still effective in controlling adverse outcomes. Overall, the health-care system has been slow to recognize that perfect human performance is not possible; however, other industries can provide useful insights into the design and implementation of high-reliability processes.

Aviation is an excellent example in which a high-risk industry implemented co-ordinated and comprehensive strategies to reduce preventable accidents. Also, the study of human-factors engineering has led to an understanding that, although adverse events will occur in any human endeavor, they can be minimized

[1] Examples include Brennan, T. A., L. L. Leape, et al. (1991), Vincent, C., G. Neale, et al. (2001), Wilson, R. M., W. B. Runciman, et al (1995). A good review of the evidence is also contained in Chapter 2 of the *Institute of Medicine Report*, Kohn, L. T., J. M. Corrigan, et al., eds. (1999).

through the design of equipment or tools, design of the tasks themselves, the environmental conditions of work, the training of staff, and the selection of workers.

Airline regulators, plane manufacturers, and commercial airline carriers have combined human-factors engineering with the knowledge that failures in communication and co-ordination among team members have led to tragic aviation accidents. Their collaboration resulted in a wide variety of mandatory and voluntary processes that have dramatically improved passenger safety:

- Redundancy in key operating systems
- Simulator training to improve teamwork and prepare for sudden emergencies
- Restrictions on the number of consecutive hours worked
- Mandatory reporting of designated aviation accidents / incidents
- Voluntary reporting of near misses
- Extensive use of information technology for the provision of flight information and weather conditions
- Comprehensive and objective investigation of accidents with reporting of the probable cause
- Procedural checklists with alarms for key equipment and/or human failures

Aviation and health care have many similarities; unfortunately, many of the actions that have effectively improved passenger safety have not yet been adapted and implemented in the health-care system.

A Complex System

All systems can be described as a set of interdependent elements interacting to achieve a common aim. There are three key components to a system:

Structure

Each organization has a supporting framework of essential parts that are present and/or contribute to all actions or activities:

- Personnel
- Equipment/tools
- Environment
- Administration

Managing risk within this component involves applying preventive measures, such as constantly evaluating, training and planning for the various elements:

- Personnel (evaluate to ensure optimal numbers for workload, proper credentials and staff physical / mental well-being)
- Equipment (evaluate to ensure that needed devices are present, functioning properly, monitored for safety and regularly serviced with a plan for phased and emergency replacement)
- Environment (evaluate for physical designs that may inhibit or increase risks to those receiving or providing care)
- Administration (create an organizational culture of safety, evaluate and plan for effective policies and procedures — including a policy for reporting actual and potential risks to those receiving or providing care)

Process

All care and/or service is provided within one or more steps of a process. Essentially, a process can be defined as 'what is done and how it is done'. Examples of processes within the health-care system include communication, problem solving, decision-making and conflict resolution. The detection, mitigation or recovery from preventable adverse events is possible in the process component. For example, a nurse does not administer a medication if she/he has detected a miscalculation in the preparation of the dose. Key strategies include identifying high-risk activities and intervening with known strategies for reducing the predicted hazards.

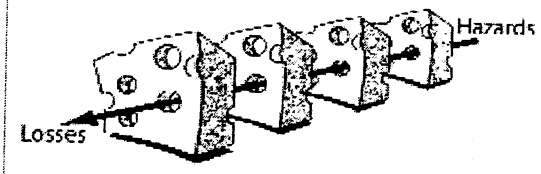
Outcome

The product, result or effect is also known as the outcome. In health care, outcomes may be measured in a variety of ways, but tend to reflect the physical and psychological well being of the patient, and also reflect associated costs. Efforts to manage risk within this component are focused on monitoring outcomes and decreasing the consequences of a preventable adverse event.

A systems approach to patient safety is based on the understanding that the individual practitioner is not a potential culprit to be blamed and punished, but rather that he or she is one participant interacting with many others in a highly complex environment. Adverse events are generally viewed as a consequence of the system; the goal is to improve the structure and/or process so the event is less likely to recur.

Hazards and Defenses

The "Swiss cheese" model of defenses (Reason, J.) illustrates the hazards of high-risk situations and the defenses created to reduce or block those risks. Defenses may be structural, such as staffing levels and equipment design, or process related, such as inter-professional communication and problem-solving skills.



The Swiss cheese model of how defenses, barriers, and safeguards may be penetrated by an accident trajectory

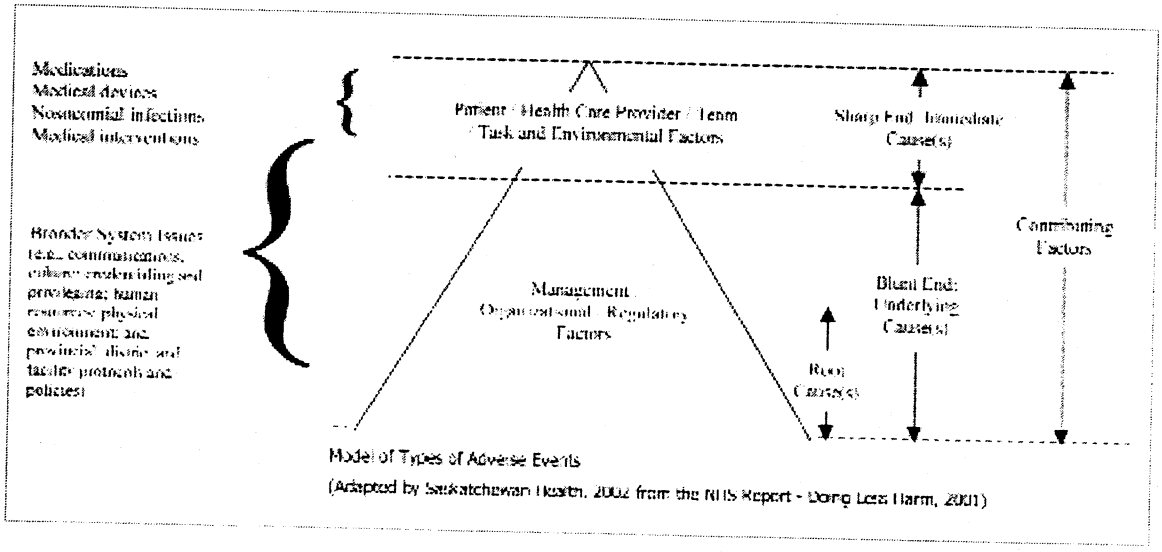
Reason, J. (2000)

Many layers of defenses work to reduce the chance of adverse events occurring, however, no single layer is totally effective, as there are "holes" or opportunities for failure at each point. On any given day, at any time, a circumstance may occur where the holes in the layers of defenses "line up" and error results.

An adverse event in health care is an injury related to health-care management, rather than to an underlying disease. The event is an unplanned and undesired harmful occurrence directly associated with care or services provided to a patient, such as an adverse reaction to a medication or a negative outcome of treatment. The occurrence may result from acts of commission (e.g. administration of the wrong medications) or omission (e.g. failure to institute the appropriate therapeutic intervention) and may be related to problems in practice, products, procedures, and/or other aspects of the system. The term 'medical error' is associated with a culture of blame, and is therefore not recommended for use.

The following model illustrates the key concepts of causation and contributing factors using five categories of adverse events (Medications, Medical Devices, Nosocomial Infections, Medical Interventions, and Broader System Issues) that are known at this time to have significant implications for patient safety. The five categories may evolve into a standardized adverse event classification system developed from national and international research in this field.

The model also incorporates the "sharp and blunt end" theory that has been accepted and broadly applied in health care as in other



Model of Types of Adverse Events

(Adapted by Saskatchewan Health, 2002 from the NHS Report - Doing Less Harm, 2001)

industries (Reason, 1997). The sharp (proximate) end, where practitioners interact with patients and each other in the process of delivering care, is where the practitioner may be distracted and miss a warning label or forget a step in a process. Unfortunately, the sharp end is also where the search for "fault" is often conducted. Blaming, and then punishing individuals, is not an effective approach for improving safety within the system and understandably causes reluctance among health-care personnel to openly report and discuss adverse events.

At the blunt (remote) end of the system are regulators, administrators, policy makers and technology suppliers. The blunt end is the source of the demands, resources and constraints that form the environment in which the practitioners work. Human-factor engineers have consistently shown that the ability of sharp-end practitioners to avoid adverse events or near misses (a situation where the patient had a narrow escape from injury or death) depends directly or indirectly on a host of blunt-end factors, rather than on the isolated "error" of human practitioners.

The cause of an adverse event is described as an antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome, such as an action (injection of the wrong drug). A cause may also be remote, such as an underlying structural factor that influences the action, thus contributing to the outcome. A root cause(s) analysis is a technique of systematic investigation of an adverse event or near miss to determine the immediate and underlying cause(s) and any other contributing factors.

Defining terms related to patient safety is a significant challenge as different individuals, professions, organizations and cultures have assigned their own interpretations to the various words. However, developing a shared, comprehensive understanding of nomenclature is essential for co-ordinating effective local, regional and national activities in the area of patient safety. (Please see Appendix D for a draft mini-glossary of patient safety terms for discussion purposes.)

The health-care system is a highly complex, integrated and interdependent environment. Broader system issues can significantly impact the number and type of adverse events associated with the delivery of health care. Some of the system issues that are relevant to the study of adverse events include:

- Reductions across the system in acute-care beds
- Increased complexity of diagnostic and therapeutic interventions that create a patient population with higher acuity
- Concerns regarding the safe and effective functioning of outdated equipment in a variety of Canadian health-care facilities
- Acknowledged shortages of qualified health-care personnel in specific sectors that increase workload pressures
- Less opportunity for the mentoring of novices in services with workload pressures and/or high turnover rates of staff
- Continual restructuring and non-stop change compromising the organizational ability to identify issues and implement timely and appropriate strategies to address deficiencies in a co-ordinated manner
- High-volume of interpersonal/interprofessional communications that may directly impact on the ability to detect, mitigate or recover from preventable adverse events
- A culture of blame and many traditional hierarchical organizational structures stifling the reporting of adverse events and any follow up quality improvement discussions
- Potential for inadequate processes for the credentialing and privileging of independent health-care professionals, as well as the credentialing and registration of self-regulated professionals who are employees, directly affecting the competency of practicing health-care personnel
- Health-care personnel who self-report that they are affected by excessive workload, burnout, fatigue, shifting work-hours, extended periods of on-call and weekend work
- Physical environment, such as technological developments that may enhance patient safety or add new risks if staff are not provided with appropriate orientation

- Environmental factors such as dim lighting and slippery floors that can increase hazards to patient safety
- The local, regional and provincial protocols and policies that include the regulation of practices such as the reuse of single-use medical devices / products
- The lack of a comprehensive information technology infrastructure that can identify, trend, and respond to adverse events

The deaths of two Ontario patients (1999 and 2002), caused by the accidental injection of undiluted potassium chloride, provide additional Canadian examples of how factors in the system can contribute to adverse events. Concentrated potassium chloride is often marketed in Canada in plastic ampoules and vials that resemble containers of sterile water, saline solution or other generally harmless substances. If a variety of vials are stored on the patient care unit, the staff are at risk of retrieving and injecting undiluted potassium chloride when another substance was intended. Removing the potassium chloride from the unit eliminates the possibility of this kind of unintended action.

The Ontario patients were in the same hospital approximately three years apart. Unfortunately, the potassium chloride was apparently not uniformly removed from unit stock after the first death. The same factors lay dormant until the next fatal injection. Learning from the experience of errors and sharing successful system remedies and effective safeguards in our medication-use systems will prevent recurrences of the same error (Cohen, 1999).

When different medications have similar product design and packaging, the system has created a greater likelihood of error. Manufacturers can play a key role in improving patient safety by collaborating with health-care personnel and developing unique containers, labels and packaging to easily differentiate the products.

The health-care system can be proactive and learn to seek out the contributing factors to prevent patient injury or death.

Improving the System

"Every process is perfectly designed to achieve the results it gets."

Paul B. Batalden, MD[1]

Building a Safer System: Principles for Action

Key assumptions have been summarized in the principles to provide a foundation for the specific strategies recommended for implementation:

- The Canadian health-care system is guided by the principles of national health insurance as set out in the Canada Health Act and is implemented primarily at the provincial/territorial level. The system is complex, dynamic and characterized by many competing pressures, particularly the relationship between funding and quality of care. An unprecedented level of collaboration across all sectors must occur to ensure a co-ordinated and effective strategy for improving patient safety.
- Safety is a fundamental aspect of quality health care. To improve safety, the health-care system must develop, maintain and nurture a culture of safety.
- Health-care personnel, patients, and all others within the system must be informed participants in understanding that human error is inevitable and that underlying systemic factors, including ongoing system change, contribute to most near misses, adverse events and critical incidents.
- Specific educational and professional development programs that focus on evidence-based practice, periodic audits, and a health-care team approach to practice and learning can reduce the likelihood of human error.
- The health-care system must facilitate comprehensive identification of hazards that pose threats to our people (e.g. patients, staff and health-care personnel). Systemic identification should be carried out reactively, in response to a recognized adverse event or outcome, and more importantly, proactively, before problems have occurred. This identification must be followed by reporting and recording of these hazards (and any associated adverse events and near misses) to a network of databases.
- The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems or potential problems is encouraged and rewarded. No blame will be apportioned to individuals following reporting, subject to limited qualifications. These qualifications include failure to report safety hazards or critical incidents and premeditated or intentional acts of violence against people, equipment or property.
- The health-care system must encourage partnerships among all consumers and providers of care. Partnerships will require the health-care system to become more flexible, with a shift away from traditional hierarchical-operating structures. These partnerships, including those of individuals, professions and organizations, are necessary for making effective improvements to all operational/systemic deficiencies.
- The health-care system must demonstrate

[1] Paul Batalden, *Dartmouth Medical School* and the *Institute for Healthcare Improvement*, has made this point several times in his teaching about the improvement of healthcare.

its ability to build on what is already known in other sectors, learn from experience, and be willing and able to implement major reforms when indicated. Such a system will endeavor to analyze relevant information, develop cost effective evidence-based safety initiatives and standards of care that are critical to the improvement process, and regularly receive feedback on the results of targeted strategies.

- The health-care system must promote appropriate disclosure to all partners (e.g. patients, the public, health-care personnel and government) of safety information relative to health issues. Such disclosure must be supported by changes to the legal and regulatory systems that also facilitate effective systems for the prevention and/or management of hazards.

Building a Safer System: A National Integrated Strategy for Improving Patient Safety

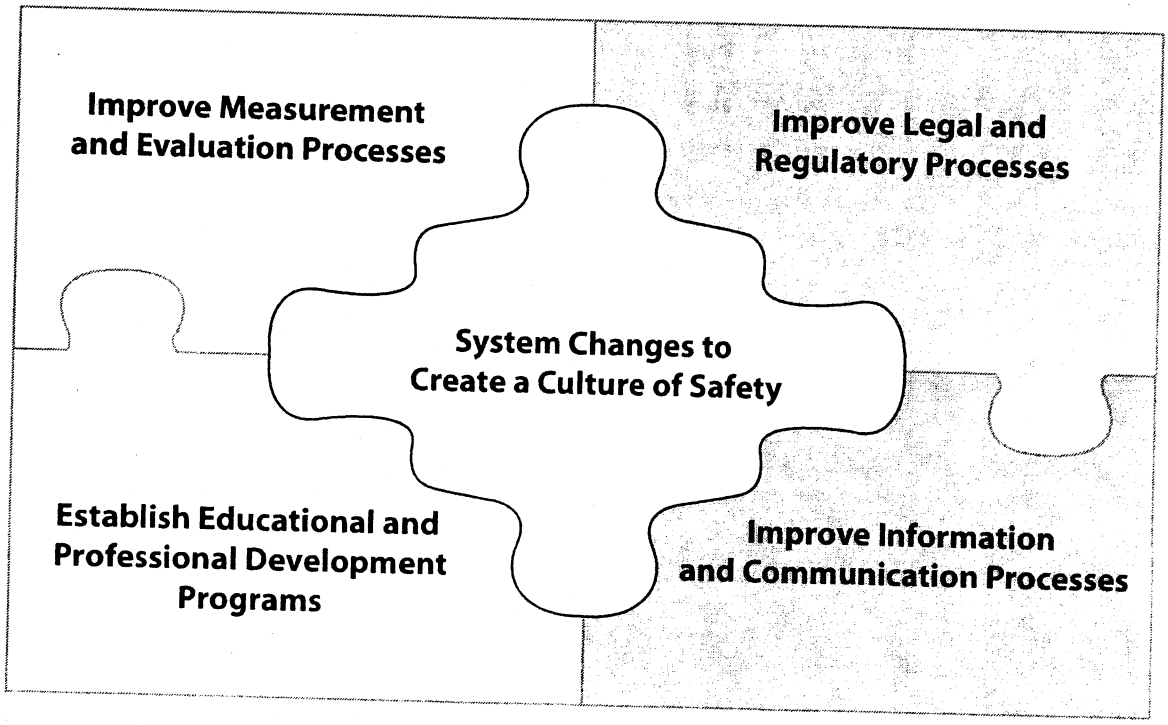
Providing safe care is fundamental to providing high quality health care to Canadians.

Understanding the complexity and issues within the system is the first step in building a consensus for system-wide change. The next step is to create and implement an integrated national strategy that gives a voice and role to patients; health-care personnel, organizations, educational institutions and professional regulatory bodies; and to federal/provincial/territorial levels of government.

Five major components to building a safer system

1. **Establish a Canadian Patient Safety Institute to facilitate a National Integrated Strategy for Improving Patient Safety**
   Current responsibilities for patient safety are widely distributed among various professional and regulatory jurisdictions that do not share a common understanding of the issues or a common vision for the future. One of the key system changes will be the creation of a co-ordinating body to facilitate an unprecedented level of collaboration among local, regional, provincial, territorial and federal health-care sectors.

Building a Safer System:
A National Integrated Strategy for Improving Patient Safety
in Canadian Health Care



Additional recommendations for system-wide strategies are included in this section.

2. **Improve Legal and Regulatory Processes**
   The current legal and regulatory environment in health care perpetuates a fear of blame and litigation. As a result, disclosure discussions and quality improvement processes may not involve an open dialogue and sharing of questions or concerns. Key recommendations will be made to create the environment for successfully improving patient safety.

3. **Improve Measurement and Evaluation Processes**
   The lack of a comprehensive information technology infrastructure limits our ability to identify, trend and respond to adverse events. Key recommendations will be made to provide the tools and resources for system-wide changes.

4. **Establish Educational and Professional Development Programs**
   The specific knowledge and skills to improve patient safety are currently not part of the education, training, and/or professional development programs for most health-care personnel. Recommendations will be made for a co-ordinated and multidisciplinary educational approach that will help to build a critical mass of expertise.

5. **Improve Information and Communication Processes**
   Access to accurate and understandable information will help the public and all other health-care stakeholders to first understand the system and then participate in improving it. Recommendations will be made to stimulate dialogue, understanding, and participation.

The five major components will lead to a culture of safety where words are translated into actions that reduce the risk to Canadian patients.

System Changes to Create a Culture of Safety

A culture and environment of safety cannot instantly be created, but will evolve over time under the guidance of a co-ordinating body, and with the commitment of all governments and health-care organizations to provide capital and operating resources for system reform.

Recommendation

1. Establish and support a non-profit *Canadian Patient Safety Institute* (draft title). Membership will be multidisciplinary and consist of clinical, academic and administrative experts in the fields of safety and health care from across Canada

The *Canadian Patient Safety Institute* will collaborate with the territorial, provincial and federal ministries of health and other authorities who may establish bodies, or designate patient-safety responsibilities to new or existing structures, such as the Health Quality Council in Saskatchewan. As safe patient care is fundamental to the provision of high-quality care, it is anticipated that the *Institute* will be part of, or closely related to, any national structures that may emerge for the purpose of measuring and/or improving the quality of Canadian health-care services. Integrating safety and quality discussions is an important aspect of recognizing and addressing the overlapping issues of misuse, overuse, and under use of health-care services, as well as other components such as patient satisfaction, access to and efficiency of health care.

The proposed *Institute* will focus on the role of facilitating rather than assuming operational responsibility for patient-safety actions. Recognized expertise in improving safety could be accessed by the *Institute* for the development of standardized templates and guidelines that could then be modified to meet the needs of local organizations across the country. Key templates would include reporting mechanisms, data collection terminology and strategies, and effective practices for reducing the risk of injury to patients. The

Institute will also work to minimize redundancy and overlap in patient-safety activities.

A number of clinical and organizational practices, new technologies or new programs, including educational programs and patient care activities, are likely to be recommended as a result of efforts to improve patient safety. Researchers, with established expertise and experience, should use appropriate research designs and analysis to evaluate these new practices, technologies and programs.

Recommendation

2. Base new practices, technologies and programs that are recommended by the *Canadian Patient Safety Institute*, or other such bodies, on evidence, and subject them to scientific evaluation. The evaluation would include potential benefits and costs

The *Canadian Patient Safety Institute* should collaborate with applicable researchers to ensure that these evaluations are readily available to interested health-care personnel and organizations. The Institute would not duplicate the work of existing assessment structures nor be involved in regulating the introduction of new products and/or procedures.

Recommendation

3. Implement system changes that have a demonstrated ability to improve patient safety

Canadian Patient Safety Institute
(draft title)

A *Canadian Patient Safety Institute* is needed to co-ordinate, facilitate, and stimulate designated activities within the national strategy. Actions would encompass a wide range of policy and evaluative responsibilities:

- Promote legal and regulatory changes that would enhance reporting of adverse events with multidisciplinary determination of contributing factors and recommendations for improvement.
- Liaise with governments and applicable health organizations for patient safety policy development or modification (including those on reporting and disclosure).
- Promote effective measurement and evaluation processes by
  - Collaborating with federal/provincial/territorial governments in establishing a comprehensive information technology infrastructure and reporting strategies that will facilitate improving patient safety
  - Reviewing the adequacy of Canadian data on patient safety as it becomes available, and providing feedback to local authorities on trends that are revealed
  - Facilitating the collection and dissemination of methods for effectively measuring adverse events as well as programs/projects for translating data into knowledge, and then action by all levels of health-care personnel
  - Recommending new practices or technologies with established effectiveness for improving patient safety
  - Contributing to the identification of a research agenda for measuring adverse events and gaining insights into causation (the detailed analysis to be done by academic evaluation units or consultants)
- Promote the development of national standards and benchmarks as well as process and outcome indicators of patient safety
- Support the development of a health-care education and professional development programs for improving patient safety
- Support the development of an information and communication program for improving patient safety.

Enhancing the safety of patients is the result of three interdependent actions: preventing adverse events, making them visible, and mitigating their effects when they occur. There is a growing body of evidence regarding the specific strategies that improve the system's ability to prevent, detect and moderate the effects of adverse events. Health-care organizations should review their processes for opportunities to improve and implement effective practices that are appropriate for their environment given practical and financial constraints

Medication administration is one example of a process that can benefit from system changes. Substantial evidence demonstrates that the rate of medication errors is lower in unit-dose systems than in traditional systems or ward-stock systems. A relevant study was conducted in 1991 at the Toronto Hospital for Sick Children (O'Brodovich and Rappaport, 1991), during their successful conversion to a unit-dose system. In this study, the observed medication-error rates (excluding wrong-time errors) decreased from 10.3% to 2.9% when the traditional drug distribution system was replaced with a unit-dose system. The study also demonstrated a 4% reduction in medication costs and a reduction in the percentage of nurses' time spent on medication-related activities.

In spite of the proven safety advantages and cost effectiveness of unit-dose systems, the majority of Canadian hospitals continue to utilize traditional medication-distribution systems that rely heavily on human vigilance. The *Hospital Pharmacy in Canada Annual Report, 1999/2000* states that only 26% of the 115 responding hospitals provide unit-dose drug distribution services or automated decentralized dispensing to 90% or more of their beds.

Recommendation

4. Formalize responsibility and accountability for patient safety within the management structures and clinical processes of all health-care organizations

As a key element of organizational and cultural change, clearly defined responsibilities and accountabilities must exist to ensure patient safety when adverse events, hazardous situations or near misses occur. Health-care organizations should reflect a commitment to patient safety in their vision, mission, values, budget, management structures and clinical processes.

Recommendation

5. Develop and implement responsive patient-focused programs for the receipt, review and management of concerns within health-care organizations

Complainants should be partners in the resolution process and participate in open communication with factual disclosure. Now, an adversarial system in which punishment is the desired end isolates the various players. A team meeting of stakeholders held in a timely manner after an adverse event has occurred will facilitate discussion, and in some cases mediation, with the objective of achieving a satisfactory resolution for all participants. Refusing to discuss concerns may result in the perception that legal action and/or a formal complaint to the licensing body are the only options for complainants.

Patients and their families may present their concerns to individual professionals (physicians, nurses, etc.), to management, to regulatory bodies, to governments, and perhaps to other stakeholders about the care received. Such concerns may expose hazards, adverse events or near misses related to system issues and/or problems in the performance of health-care personnel. As such, these concerns may provide an important opportunity for individual or system improvement.

A patient-focused concern management program with public reporting will help to build a transparent process for quality-of-care issues.

For additional information on understanding system issues, please see Appendix E — *The Framework Matrix: System Issues Working Group*.

Legal and Regulatory Processes

The current legal and regulatory environment in health care perpetuates a fear of blame and litigation that may result in adverse events not being recorded on the health record, or, at minimum, verbally communicated to an appropriate individual. Individual health-care personnel feel the burden to be 'perfect' in their knowledge, skills and judgment, and are generally not encouraged to openly disclose or discuss hazardous situations, adverse events or near misses. Even if the information is disclosed, there are competing interests. On the one hand, there is the necessity to be able to collect, analyze and share information; on the other, there is the need to protect the privacy and confidentiality of individuals, and to protect the information gathered in the organizational or regulatory review of an adverse event. Moving to a culture of safety will rely on improved reporting and discussion of contributing factors within and across jurisdictions.

Recommendation

6. Adopt non-punitive reporting policies within a quality-improvement framework across the health-care system

The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems, or potential problems, is encouraged and rewarded. No blame or fault should be apportioned to individuals following reporting, subject to limited qualifications such as failure to report safety hazards or critical incidents, and premeditated or intentional acts of violence against people, equipment or property.

Recommendation

7. Standardize the legislation on privacy and confidentiality of personal information across Canada to facilitate access to patient-safety data, while respecting the privacy of patients and providers

Provincial and federal departments should establish the legislative authority to obtain and share patient-safety information across all relevant jurisdictions. The improved access to data on patient safety will result in a greater understanding of the specific hazards to patients and of what strategies have been effective in addressing these risks. Opening the doors of communication will reduce the sense of isolation that each individual and organization faces today.

Legislative changes should facilitate not only information sharing, but also the opportunity to co-operate in a review of a specific patient case. It is possible, for example, for a single adverse event to be examined by the medical examiner's office, medical and nursing regulatory bodies, and the hospital or regional health authority where the event occurred. A collaborative review will facilitate a multidisciplinary determination of the contributing factors and one set of recommendations to enhance individual and/or system performance.

There is a perception that regulatory bodies approach preventable adverse events in health care by searching for and culling "bad apples", rather than seeking improvement through education and remediation. The perception of a "bad-apple approach" impedes the ability of regulatory bodies to effectively search for systemic issues and other root causes. All health-care regulatory bodies should move toward and adopt the practice of regulation that includes an expectation of continuous improvement, learning from effective practices, use of evidence-based decision-making, and fostering innovation with creativity.

Recommendation

8. Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human resource processes

A shift towards understanding and improving the underlying causes of adverse events in health care will broaden the focus to structural and process dimensions, in addition to individual performance. Corrections should aim to make it easier for the individual health-care professional to do the right things correctly (e.g. product design, process design, standardization) within the system.

There is a balance to be achieved between evaluating and improving the performance of an individual and addressing system issues. Regulatory bodies will continue to evaluate and address the competence and performance of their individual members, in collaboration with other measures to help improve patient safety. Incompetence, once discovered, must be corrected. On occasion, correction will involve restrictions on practice or even withdrawal from practice. When possible, underlying problems that affect performance should be identified and remedied, and remain the primary objective when addressing performance problems.

In 1993, the Federation of Medical Licensing Authorities of Canada (FMLAC) launched a project to address the issue of ensuring that physicians in practice maintain an appropriate level of performance for the duration of their professional lives. Four major areas of physician performance were identified as competence, behaviour, health/fitness to practice and use of resources. A Canadian Model for Monitoring and Enhancement of Physician Performance (MEPP) was developed, with emphasis on the need for the FMLAC to work together with other medical organizations in the prevention, assessment and remediation of performance problems of physicians. The model identified the important role that the licensing authorities have in the monitoring and provision of feedback to all physicians.

Personal and professional ethical frameworks also guide the decisions and actions of health-care professionals, both as individuals and members of institutions. Ethical behavior is fundamental to building a culture of safety and should be clearly linked to strategies for improvement.

Successfully changing the emphasis from blaming the health-care professional to a quality-improvement approach with a focus on learning from preventable adverse events will rely heavily on the effective education of the public and their subsequent support. The media will play a pivotal role in providing a balanced understanding of the issue and measures for improvement.

The use of civil litigation to hold an individual practitioner and/or health-care organization accountable is a valid and recognized option within the framework of accountability. For example, although the physician has a significant responsibility for the well being of his or her patients (including applicable medical decisions made), the hospital or organization where care was provided also has responsibility for the actions of its employees. This arrangement often creates an environment where two separate insurers and various health-care personnel are anticipating a legal proceeding. There is an added layer of complexity if a regulatory body is also investigating the circumstances. The parties should strive for increased co-operation and communication to resolve issues through mediation where possible. Perpetuating the adversarial legal environment does not serve the interests of the patient.

Health-care personnel within this environment are understandably concerned with providing information and/or participating in quality-improvement discussions that may subsequently be used in some other forum against their interests. Effective change from the present culture of blame to one that encourages a forum of disclosure and discussion of adverse events will require the agreement and support of the affected health-care personnel. Their careers may suffer devastating consequences from hearsay or premature conclusions based on inadequate information; therefore, safeguards should be established to ensure effective peer review of the facts.

In varying degrees, health-care professionals perceive a lack of personal protection for information given within quality improvement and/or peer review processes in different jurisdictions. When it does exist, such legal protection (privilege) is usually contained in the respective provincial *Evidence Act*, which generally provides that documents and information collected by committees cannot be compelled to be produced in court. However, the legislation may be

outdated, is often inconsistent, and does not adequately provide for the multidisciplinary approach to health care, nor the full continuum of care (e.g. community clinics, home care and emergency medical services).

Recommendation

9. Review and, where applicable, revise *The Evidence Act*, and related legislation within all Canadian jurisdictions to ensure that data and opinions associated with patient-safety and quality-improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. The protection would extend to this information when used internally or shared with others for the sole purpose of improving safety and quality. Wording within the applicable Acts should ensure that all facts relating to an adverse event are recorded on a health record that is accessible to the patient or designated next of kin, and are not considered privileged

The legislative changes will create an environment that is conducive to reporting and discussion of contributing factors and recommended practitioner or system changes. The information may then be added to a provincial or Pan-Canadian repository in a de-identified manner to ensure that the lessons learned are available across Canada without release of confidential patient or practitioner information.

Saskatchewan has introduced new requirements for critical-incident reporting that protect individuals and organizations from disclosing information about critical incidents and reports of those incidents. The facts of the incident remain available, but discussion about the events is protected. This legislation will facilitate centralized reporting of critical incidents and promote an environment where the health-care professionals involved can discuss their opinions and recommendations within a confidential quality-improvement environment.

Independent reports (e.g. Prichard and Dubin) have identified issues related to reform of the current tort system; insufficient attention has been paid to their content and recommendations. A wide variety of insurers are in place for independent practitioner and corporate liability concerns arising in health care. The competing interests and focus on litigation to obtain a settlement may deter open dialogue and discussion of an adverse event. A detailed review of the issues and possible solutions is beyond the mandate of this report; however, further research is clearly needed to examine the potential for tort and/or insurance reform to contribute to patient safety.

Recommendation

10. Hold further discussions regarding the tort and health-care insurance systems and their effects on patient safety, with the aim of making recommendations that would contribute to a culture of safety in Canadian health care

Although various legislative amendments are needed to change the legal and regulatory environment, building a culture of safety can, and should, proceed with the various strategies that can be implemented in the short term.

Measurement and Evaluation

An in-depth understanding of adverse events in health care will not be possible until comprehensive measurement and evaluation processes can identify where and why patients are at risk. Knowledge of the types of adverse events occurring in Canadian health care, and strategies for

reducing their incidence, should be shared among organizations across Canada. Strategies that contribute additional information and understanding should be given high priority.

Effective surveillance systems to assess the incidence of near misses, adverse events and critical incidents are important for assessing the performance of the system and for identifying areas for improvement. Critical incidents involve significant risk of or actual loss of life, limb, or function, and are considered 'critical' as they signal the need for immediate investigation and response. Existing mechanisms to identify these events and incidents are incomplete.

Canada lags behind several other countries in developing tools for measurement. A number of surveillance systems developed elsewhere may hold promise for local implementation; however, they must be evaluated to determine their usefulness in both hospital and ambulatory settings. Surveillance systems must also be comprehensive, accurate and incorporate safeguards for patient confidentiality.

Recommendation

11. Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses

The goal of the analysis is to identify which systems should be recommended for implementation in the Canadian health-care environment. There may be a need for several such systems to ensure that data can be translated to information, action and evaluation for all relevant processes. In addition, consideration of effective strategies for linking the information from surveillance to improvement activities is essential so that the results of these analyses contribute to improvements in care, not just to better reporting of adverse events.

A combination of Canadian, provincial, regional, organizational and program-based adverse-event surveillance and reporting systems will likely be necessary to obtain all relevant data. Key aspects to be reviewed include:

- Nature of participation (voluntary versus mandatory)
- Attitudes and perceptions of the health-care professionals
- Scope and coverage of the system
- Data ownership and reporting relationships
- Cost (including staff time and other resources)
- Definitions of events to be tracked and reported
- Timeliness and accuracy of the reports

The review should be contracted out to academic evaluation units or consultants who would be engaged to identify such systems and assess them based on comprehensive criteria and methodology. Since hospital-based surveillance systems are more advanced, it may be advisable to tender two assessments, one for institutional systems, and a second for community-based providers.

A report detailing the strengths, weaknesses and costs of each system should be forwarded to the *Canadian Patient Safety Institute* for further consideration. Health-care associations, professional groups and governments should also receive a copy.

Recommendation

12. Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in Recommendation (11)

The proposed review of surveillance systems will identify a number of highly rated options for implementation. However, the performance

of such systems needs to be tested prior to full-scale implementation by investing in pilot projects. Well-designed evaluations will identify the effectiveness of these systems in Canada and help to determine the resources necessary for their implementation. These pilots could include trials of organizational and regional reporting systems and the evaluation of computerized information and decision-support systems, including computerized physician order-entry systems. The evaluation should include:

- Assessments of feasibility
- Quality of data
- Cost effectiveness
- Contributions to identifying improvements to care

Pilot projects in different settings will help in assessing the compatibility of these systems with existing or planned regional health information networks and local information systems.

The development of patient-safety indicators should be linked to an appropriate framework in collaboration with the numerous other provincial and national activities in the area of indicator development.

Recommendation

13. Secure funding from federal/provincial/territorial jurisdictions to invest in information-technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data

Fiscal pressures across all health-care sectors have resulted in a lack of funding for important information technology opportunities, and valuable health-care dollars continue to be wasted on information-technology systems that cannot easily share data. Monitoring and improving patient safety will be fragmented and parochial until co-ordinated reporting and data management occurs.

It is essential that the federal, provincial and territorial departments of health work together to create a comprehensive information-technology infrastructure to support a network of reporting systems. These efforts should be aligned with current work to develop electronic patient information through the Canada Health Infoway initiative. Efforts should be made to ensure that standard data definitions and data collection protocols are developed.

Recommendation

14. Adopt "patient safety" as a cross-cutting theme, or designated area for research competitions supported by the Canadian Institutes for Health Research, Canadian Health Services Research Foundation and/or other granting organizations, to encourage Canadian researchers to undertake studies in this area

Major granting councils, or other funding agencies in Canada, fund little scientific research on adverse events, patient safety and system improvement. Additional focus on and funding of these topics would increase the interest of Canadian researchers. Such research would provide valuable information for improving safety and evaluating the effectiveness of current and proposed activities.

The *Canadian Patient Safety Institute* should convene a meeting with the leaders of the granting councils to identify ways to increase the scale of research, including applied and policy-relevant research studies. Both Canadian and international experts should meet to set a research agenda in patient safety and reduction of adverse events.

Education and Professional Development

To be useful, information must be analyzed and translated into action. Teams, not individuals, often deliver health care. For improvement in

the safety and quality of health care, education, professional development, and practice review are necessary. Local actions need skilled, multidisciplinary health-care teams to effect improvements in patient safety.

A co-ordinated strategy highlights professional development and education. All personnel in health care will be targeted for training about the reporting, educating and measuring loop. Information and dialogue on personal disclosure of an adverse event and strategies for dealing with ensuing emotions will be emphasized.

Building on previous efforts within a co-ordinated approach will increase the likelihood of effective changes. Some of the earliest patient-safety activities occurred within the specialty of anesthesia:

- The first practically-applied studies of human error in medicine
- The study of malpractice claims to identify risks
- The wide dissemination of information on patient safety
- The development of standards of care
- The development of simulation for research and education

Other contributions to patient safety included the availability of more controllable drugs with fewer side effects, improved education and training, safety enhancements to anesthesia machines and connections to various medical gases, and the evolution of a culture that places safety as the highest priority.

Lessons learned in the field of anesthesia can, and should, be implemented across other specialties.

Recommendation

15. Develop and implement health-care education and professional development programs for improving patient safety

A health-care education and professional development program at the under-graduate, graduate and postgraduate levels should be undertaken with the support of the *Canadian Patient Safety Institute*, and in collaboration with a variety of health-care associations, academic institutions and regulatory bodies.

- Conduct an assessment of current educational efforts to identify effective practices and foster the building of a national system designed to provide health professionals with the knowledge, skills and attitudes required to ensure the delivery of safe health care
- Stimulate local and regional projects and ensure that what is learned from the experience is shared broadly
- Build on current knowledge and skills in addition to meeting the unique needs of various health-care professionals and specialties by using a 'Request for Proposal' approach to develop specific programs, including:
  - interdisciplinary simulations of high-risk health-care interventions and emergency responses
  - continuing education programs for specialties such as obstetrical services
- Recruit a community of multidisciplinary health professionals who will be trained to become recognized as "safety-educated" champions, and who shall have the mandate to:
  - Collaborate on the national education standards
  - Create a core curriculum applicable to all areas of expertise with applicable accreditation bodies in the health disciplines incorporating the standards for education into their accreditation programs
  - Identify the tools and data needed to support the curriculum
  - Identify the means by which to achieve this goal within specific educational settings
- Stimulate a leadership program to mentor the "safety-educated" champions. The objective over three to five years would be

to have at least one trained leader in every hospital and major medical organization within the country. The program would include specialty-specific disciplines, and would encourage participants to lead and co-ordinate patient-safety programs locally and nationally
- Evaluate regularly the impact of educational programs on reducing the number of preventable adverse events

Recommendation

16. Develop educational and continuing professional development programs to improve patient safety, in collaboration with national accrediting bodies, academic institutions, provincial licensing authorities (for peer-assessment reviews) and health-care facilities/organizations/scholarly societies

A network of provincial and local education leaders should lead the education and professional development initiatives necessary for a transformation to a health-care culture of safety. Strategies for developing and enhancing the network should include:

- Sponsoring provincial or university health science "implementation" conferences on patient safety; participants could vary from all health-care personnel to a specific discipline or specialty
- Incorporating a patient-safety theme into continuing professional development programs and related clinical guidelines facilitated by provincial medical organizations and national specialty societies
- Promoting the development of a provincial steering or local co-ordinating committee for education development and implementation on patient safety (structure may be similar to the Ontario Guidelines Council)

Building Knowledge Through Information and Communication

Timely access to relevant patient-safety information is a fundamental philosophy of the *Canadian Patient Safety Institute*. The public, health-care personnel, organizations, educational institutions, regulatory bodies, professional associations, governments and other partners in health care need to receive relevant information and discuss what their roles and responsibilities may include. The ensuing dialogue and debate will form an important foundation for the effective implementation of the national strategy.

Public input on the areas for potential harm within the health-care system and suggested improvements in patient safety are essential components of building knowledge through information and communication. Listening to patients and their families talk about their experiences and observations as they navigate the health-care system will provide unique and powerful insights.

Recommendation

17. Publicly report measures of health-care quality and safety

Publicly reported measures of health-care quality and safety should include background information on the overall benefits of health care, but the emphasis will be placed on understanding hazards, adverse events and near misses in the system. Reports will be incorporated into a variety of federal / provincial / territorial and nongovernmental publications (such as those released by the Canadian Institute for Health Information). Information will also include:

- Estimates of the frequency and impact (including financial) of adverse events in health care both within and outside Canada
- Description of measures undertaken to reduce preventable adverse events and related costs
- Highlights of previous and new patient-safety initiatives in Canadian health care
- Strategies for improving patient safety (including those presented in this report)

Recommendation

18. Develop educational materials on personal measures for improving safety in health care for distribution to the public

The *Canadian Patient Safety Institute* will facilitate the development of educational materials, including patient pamphlets. The content should include information on patient rights and responsibilities, communication strategies for talking about patient-safety questions or issues, and personal measures that the public can adopt to reduce their risk of incurring a preventable adverse event. The documents should ensure that the public can understand the information presented.

Recommendation

19. Create a website to facilitate the sharing of patient-safety resources and discussions

Information must be accessible to all partners in health care on a 24-hour, 7-day-a-week basis. As the Internet serves this purpose well, technology can be utilized to facilitate on-line chats and/or sharing of lessons learned. The website should be developed with the support of the *Canadian Patient Safety Institute*. (Please refer to Appendix F for a more extensive information and communication action plan.)

Governance

To improve patient safety, structures at the local, provincial and national levels must be informed and effective. Key attributes would include:

- Leadership committed to creating a culture of safety
- Patient safety defined as an organizational priority, with formalized responsibilities and accountabilities
- Resources dedicated to improving awareness of and understanding of hazards
- Sustained efforts that strive to identify and implement effective practices for improving patient safety
- The mentoring of novices and support of local patient-safety champions
- Participation in partnerships to enhance local, provincial and national patient-safety strategies

Canadian Patient Safety Institute (draft title) — Governance Structure

Further consultation will occur on the governance structure; however, guiding principles include:

- Membership in the governing body based on a broad range of leaders and stakeholders who have an interest and expertise in patient safety, and not determined by representation from organizations
- Public representation on the governing body
- Succession planning implemented to ensure knowledgeable and effective leadership
- Conflict of interest guidelines implemented to ensure open and transparent processes
- Health-care professionals, organizations (including insurers), regulatory bodies, associations, institutions (including the academic community), manufacturers, and pharmaceutical corporations invited to play a role in supporting the work of the *Institute*
- Accountability to the public and federal/provincial/territorial governments

- A structure at arm's length from government and regulatory bodies
- A strong role in public education and advocacy
- A review and evaluation of the *Institute*'s effectiveness in five years

There would be defined mechanisms for organizations, including those who supported the mandate of the National Steering Committee on Patient Safety, to be affiliated with the *Institute* in a voluntary and non-representative way. The affiliation would be for the purposes of providing advice, implementing programs and fostering collaboration across the health-care continuum. Examples of Canadian initiatives are listed in Appendix G — *National/International Summary of Key Initiatives in Patient Safety*.

Funding

Significant initial and ongoing funding (minimum of five years) will be required from governments to transform the strategy from the planning stage to action on priority recommendations. Additional sources of funding, such as research grants from private or public sources, will be pursued to supplement the federal, provincial and territorial contributions. Success in improving patient safety will rely on building new structures and resources into the existing framework of clinical, administrative, regulatory and health department activities. A proposed interim budget of $500,000 and an annual budget of up to 10 million dollars would be prioritized for the following key recommendations within the five major components of the strategy. Preliminary budget estimates have been included to stimulate further dialogue and input.

Budget (estimate)	Priority Recommendations	Estimated Timeline
PHASE I — (Rec. 1) Interim budget $500,000	(1) Establish and support a non-profit *Canadian Patient Safety Institute* (draft title).	Interim Phase: Winter of 2002/03 (approximately 6 months)
PHASE II (Recs. 8, 11, 13, 15, 17 19) Operational up to $10,000,000 per year (minimum of five consecutive years)	(8) Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human resource processes.	2003/04
	(11) Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses. (13) Secure funding from federal/provincial/territorial jurisdictions to invest in information-technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data.	2003/04
	(15) Develop and implement health care education and professional development programs for improving patient safety.	2003/04
	(17) Publicly report measures of health-care quality and safety. (18) Develop educational materials on personal measures for improving safety in health care for distribution to the public. (19) Create a website to facilitate the sharing of patient-safety resources and discussions.	2003/04

Phase I

1. **Interim Structure**

   - Establish an interim governance structure of approximately eight to ten members
   - Establish an interim chief executive officer and other required secretariat staff
   - Focus the responsibilities of the interim governance and staff on developing the business plan for Phase II, including:

     - Detailed strategic and operational plans for a *Canadian Patient Safety Institute*
     - Detailed budget preparation
     - Staffing requirements for Phase II (permanent secretariat)
     - Other resource requirements, e.g., information technology

2. **Resource Requirements**

   Total $500,000

   - Interim CEO
   - Interim governance (based on eight to ten members)
   - Consultations (including legal) and communications
   - Interim secretariat and set-up

Phase II

The *Institute's* interim governance structure and staff will develop a detailed business plan for Phase II. A preliminary estimate of up to 10 million dollars per year, for a minimum of five consecutive years, is projected for the operation of the organization. Expenditures can be more accurately predicted within the Phase II business plan.

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Appendices

Appendix A

MEMBERSHIP OF WORKING GROUPS
TERMS OF REFERENCE
EXTERNAL CONSULTATIONS

January — April 2002

System Issues

Members:

Wendy Nicklin (Co-chair)	Vice-President, Nursing and Clinical programs, The Ottawa Hospital
Kim Vicente (Co-chair)	Professor of Biomaterial and Biomedical Engineering, University of Toronto
Jan Davies	Professor of Anesthesia, Foothills Medical Centre
Robin J.Ensom	Pharmacy Leader, St. Paul's Hospital-Providence Health Care (until March 2002)
Philip Hebert	Assistant Professor, Department of Family and Community Medicine, Sunnybrook and Women's Hospital
Carolyn Hoffman	Co-ordinator, Provincial Quality of Care, Saskatchewan Health
Gilles Lanteigne	Director, Canadian Council on Health Services Accreditation
Patricia Lefebvre	Pharmacist-in-Chief, McGill University Health Centre
Bonnie Salsman	Pharmacist and Hospital Pharmacy Management Consultant
Valerie Shannon	Director of Nursing, McGill University Health Centre
David U	President and CEO, Institute for Safe Medication Practices Canada
Ian White	Associate Professor, Department of Anesthesia, University of Manitoba
Carol Appathurai	Guest observer / Representative from Advisory Committee on Health Services, Conference of Federal/Provincial/Territorial Deputy Ministers of Health

Terms of reference:

To examine to what extent the design of the health-care system contributes to adverse events, and how new designs can reduce or eliminate human and system errors.

External consultations:

Jeannie Callum	Director of Transfusion Medicine, Sunnybrook and Women's College Health Sciences Centre
François Champagne	University of Montreal
Albert Eros	Regional Pharmacy Manager
Mita Giacomini	Affiliated with CHEPA and the Department of Clinical Epidemiology and Biostatistics, McMaster University
Michel P. Lalonde	Health Care Consultant

Shaun MacCormick	Chief of Staff / Medical Director, Colchester East Hants Health Authority
Clare MacNeil	Vice-President, Clinical Services, South Shore Regional Hospital
David McLeod	Vice-President, Ontario Hospital Association
Stewart McMillan	Medical Consultant, Saskatchewan Health
Joe Mikhael	Resident/CAIR
Heather Milan	Regional Pharmacy Manager, Winnipeg Regional Health Authority
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Mike Opadiran	eChart, University Health Network
Linda Poloway	Canadian Society of Hospital Pharmacists
J. Dean Sandham	Executive Director, Quality Improvement/Health Information

Working Group on Regulatory / Legal Issues
Working Group on Measurement / Evaluation
Working Group on Education / Professional Development
Working Group on Information / Communication

Regulatory/Legal Issues

Members:

Larry Ohlhauser (Co-chair)	President and CEO, Healthcare Solutions and Innovations (to March 2002)
Trevor Theman (Co-chair)	Assistant Registrar, College of Physicians and Surgeons of Alberta (from March 2002)
Louise Sweatman (Co-chair)	Director of Regulatory Policy, Canadian Nurses Association
Allan H. Lefever (Assisting chair)	Judge, Provincial Court of Alberta; President, Health and Stroke Foundation of Canada
William Beilby	Director, Department of Research and Education, Canadian Medical Protective Association
Tim Caulfield	Research Director, Law Centre, University of Alberta
Gordon Crelinsten	Senior Physician, McGill University
Pierre Deschamps	Research Director, Faculty of Law, McGill University
Janet Harding	Manager, Department of Pharmaceutical Services, Royal University Hospital, Saskatoon District Health
Dennis Kendel	Registrar, College of Physicians and Surgeons of Saskatchewan
Ginette Lemire-Rodger	Chief of Nursing, Ottawa Hospital
Anu MacIntosh-Murray	Faculty of Information Studies, University of Toronto
William D.B. Pope	Registrar, College of Physicians and Surgeons of Manitoba
Catherine Tolton	General Counsel and Corporate Secretary, Winnipeg Regional Health Authority

Terms of reference:

To examine the manner in which the regulation and monitoring of health-care professionals and their institutions and the legal systems can improve patient safety.

External consultations:

Brian Carter	Director, Corporate and Government Relations, IMS Health (Canada)
James Clarke	President, Canadian Association of Internes and Residents
Joan Gilmour	Osgoode Hall Law School, York University
Bruce MacLeod	Emergency Physician, University of Calgary

Thomas Paton	Director of Pharmacy, Sunnybrook and Women's College, Health Sciences Centre
Robert J.Robson	Senior Health Care Liability and Risk Management Consultant

Working Group on System Issues
Working Group on Measurement / Evaluation
Working Group on Education / Professional Development
Working Group on Information / Communication

Measurement/Evaluation

Members:

G. Ross Baker (Co-chair)	Associate Professor, Department of Health Policy, Management and Evaluation, University of Toronto
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Robyn Tamblyn	Associate Professor, Department of Medicine, McGill University
Geoff Taylor	Professor, Infectious Diseases, University of Alberta

Terms of reference:

To determine the steps necessary to implement patient-safety monitoring systems in Canada. These systems will be used for both ongoing surveillance and evaluating interventions to minimize injury.

External consultations:

Geoff Anderson	Researcher, University of Toronto
Matt Bowes	Secretary, Canadian Association of Internes and Residents
Jafna Cox	Queen Elizabeth II Health Science Centre
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L. Thompson	Health Services Utilization Commission, Saskatchewan
Rebecca Warburton	Health Economist, University of Victoria

Working Group on System Issues
Working Group on Regulatory / Legal Issues
Working Group on Education / Professional Development
Working Group on Information / Communication

Education/Professional Development

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Walter Rosser (Co-chair)	Professor and Chair, Department of Family Medicine, Faculty of Medicine, Queen's University
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Wayne Hindmarsh	Dean, Faculty of Pharmacy, University of Toronto
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Marianne Lamb	Associate Dean, Health Sciences, Queen's University (from February 2002)
John Parboosingh	Consultant (Professional Development) to the CEO, The Royal College of Physicians and Surgeons of Canada
Jeff Turnbull	Chair, Department of Medicine, Ottawa Hospital, General Campus

Terms of reference:

To examine how enhancements to the education and continuing professional development of health-care professionals can reduce adverse outcomes and enhance patient safety.

External consultations:

Association of Canadian Academic Healthcare Organizations
Association of Canadian Medical Colleges
Canadian Association of Internes and Residents (CAIR)
Canadian Association for Medical Education
Canadian Association of University Schools of Nursing
Canadian College of Clinical Pharmacy
Canadian Council for Accreditation of Pharmacy Programs
Canadian Council on Continuing Education in Pharmacy
Canadian Council on Health Services Accreditation
Canadian Healthcare Association
Canadian Medical Association
Canadian Medical Protective Association
Canadian Nurses Association
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists
Collège des médecins du Québec
College of Family Physicians of Canada
College of Physicians and Surgeons of Alberta
Council on Medical Education
Federation of Medical Licensing Authorities of Canada
Medical Council of Canada
National Association of Pharmacy Regulatory Authorities
National Specialty Societies
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Lindsay Nicolle	Chair, Advisory Committee to Centre for Infectious Disease Prevention and Control
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Milton Tenenbein	Director, Emergency Services, University of Manitoba
John Turnbull	Faculty of Medicine, McMaster University
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James Wright	Department of Medicine, UBC Hospital Site, Vancouver Hospital

Working Group on System Issues
Working Group on Regulatory / Legal Issues
Working Group on Measurement / Evaluation
Working Group on Information / Communication

Information/Communication

Members:

John Millar (Co-chair)	Vice-President, Research and Population Health, Canadian Institute for Health Information
Bill Leslie (Co-chair)	Senior Advisor, Bureau of Licensed Products, Therapeutic Products Directorate, Health Products and Foods Branch, Health Canada
Michele Brennan	Quality Improvement Manager, Whitehorse General Hospital
Elizabeth Carlton	Senior Advisor, Legislation and Policy, Ontario Hospital Association
Hanif Chatur	Family Medicine resident, and Vice-President, Provincial Association of Internes and Residents - British Columbia (PAIR-BC)
Mary Ferguson-Pare	Vice-President, Nursing Services, University Health Network
Paula Hextall	Risk Manager, Regina Health District
Carol Kelly	Director, Insurance, Quebec Hospital Association
Anne McGuire	CEO, Annapolis Valley District Health Authority
Denis Morrice	President and CEO, The Arthritis Society (from February 2002)
Melanie Rantucci	Board member, Canadian Pharmacists Association
Mark Taylor	Deputy Head, Department of Surgery, St. Boniface General Hospital and University of Manitoba

Terms of reference:

To examine how improved communication among various players in the health-care system, including patients and the public, and across jurisdictions, can enhance the quality of patient safety.

External consultations:

Canadian Medical Association
Canadian Nurses Association
Canadian Healthcare Association
College of Family Physicians of Canada
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists

Ron Browne	CEO, Whitehorse General Hospital
John Gray	Executive Director, Canadian Medical Protective Association
Linda Hamilton	Manager, Professional Practice and Policy, College of Registered Nurses of Nova Scotia
Carolyn Moore	Executive Director, College of Registered Nurses of Nova Scotia
Supriya S. Sharma	Director, Marketed Biologicals and Biotechnology Products Division, Marketed Health Products Directorate, Health Canada.
Galt Wilson	Chair, Ethics Committee, College of Physicians and Surgeons of British Columbia
Lisa Crawford	Manager, Community Development, The Arthritis Society

Working Group on System Issues
Working Group on Regulatory/Legal Issues
Working Group on Measurement/Evaluation
Working Group on Education/Professional Development

Appendix B

ADMINISTRATIVE GROUP — PATIENT SAFETY

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Association of Canadian Academic Healthcare Organizations

Dr. John Gray
Executive Director and Chief Executive Officer
Canadian Medical Protective Association

Dr. Calvin Gutkin
Executive Director and Chief Executive Officer
College of Family Physicians of Canada

Ms. Elma Heidemann
Executive Director
Canadian Council on Health Services Accreditation

Mr. Jeff Poston
Executive Director
Canadian Pharmacists Association

Mr. Ian Shugart
Assistant Deputy Minister
Health Policy and Communications Branch
Health Canada

Mr. William Tholl
Secretary General and Chief Executive Officer
Canadian Medical Association

Terms of Reference:
To ensure appropriate and effective administrative support for the activities of the Steering Committee and five working groups. This will include management of the financial operations, provision of resources, the preparation of documents and reports, co-ordination and communication. The Administrative Group will report to the participating organizations. The group will not intervene in the activities of the Steering Committee or those of the working groups. The mandate of the Administrative Group will terminate with the activities of the National Steering Committee on Patient Safety on September 28, 2002.

Appendix C

PARTICIPATING ORGANIZATIONS AT THE 2001 CLOSED ROUNDTABLE ON PATIENT SAFETY

September 22nd, 2001

Federal Government
Health Canada

Provincial Governments
Alberta
Saskatchewan
Ontario
Québec
Nova Scotia

Territorial Governments
Northwest Territories
Nunavut

Health-care Organizations
Association of Canadian Academic Healthcare Organizations
Association of Canadian Medical Colleges
Canadian Association of Emergency Physicians
Canadian Association of Internes and Residents
Canadian College of Health Service Executives
Canadian Coordinating Office for Health Technology Assessment
Canadian Council on Health Services Accreditation
Canadian Healthcare Association
Canadian Institute for Health Information
Canadian Medical Association
Canadian Medical Protective Association
Canadian Nurses Association
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists
College of Family Physicians of Canada
College of Physicians and Surgeons of Alberta
College of Physicians and Surgeons of Manitoba
College of Physicians and Surgeons of New Brunswick
College of Physicians and Surgeons of Nova Scotia
College of Physicians and Surgeons of Saskatchewan
CQI Network
Federation of Medical Licensing Authorities of Canada
Institute for Clinical Evaluative Sciences
Institute for Safe Medication Practices Canada
Medical Council of Canada
The Royal College of Physicians and Surgeons of Canada

Appendix D

DRAFT MINI-GLOSSARY OF PATIENT-SAFETY TERMS
(For discussion purposes)

Defining terms related to patient safety is a significant challenge as different individuals, professions, organizations and cultures have assigned their own interpretations to the various words. However, developing a shared, comprehensive understanding of nomenclature is essential for co-ordinating effective local, regional and national activities in the area of patient safety. There is obviously not one right way to define these terms, but the following definitions attempt to capture the key aspects for a common understanding.

Terms are arranged alphabetically in the mini-glossary. In addition, each term is proceeded by an **'S*P*O'** icon, which relates each term to the "Structure, Process and/or Outcome" format, according to which letter(s) is/are bolded. (This format captures where, in the schema of events, attention needs to be directed for an understanding and correction of the problem.)

S*P*O

Active Failures

Actions or processes during the provision of direct patient care that fail to achieve their expected aims, for example, errors of omission or commission. While some active failures may contribute to patient injury, not all do.

S*P*O

Adverse Drug Reaction

Serious, undesired and/or unexpected reactions to a drug.

S*P*O

Adverse Effects (AEs)

Interchangeable with 'side effects', adverse effects result from drug treatment. AEs are the drug's secondary effects that are not intended for the patient. However, sometimes clinicians will use some or all of these known side effects to help in the treatment of a patient.

S*P*O

Adverse Event

Injury related to health-care management, rather than to an underlying disease process. An adverse event is an unplanned and undesired harmful occurrence, directly associated with care or services provided to a patient/client, such as an adverse reaction to a medication or a negative outcome of treatment. The occurrence may result from acts of commission (e.g., administration of the wrong medication) or omission (e.g., failure to institute the appropriate therapeutic intervention) and is related to problems in practice, products, procedures, and other aspects of the system.

S*P*O

Cause

An antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome, such as an action. A cause may also be remote, such as an underlying structural factor that influences the action, thus contributing to the outcome. Outcomes never have single causes.

S*P*O

Close Call (see also Near miss)

A situation in which the patient had a narrow escape from a serious complication.

S*P*O

Complication

A disease or injury consequent to another disease or injury and/or health-care intervention.

S*P*O

Contributing Factor *(interchangeable with Contributory Factor)*

An antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome.

S*P*O

Critical Incident

A type of incident in health care that involves the significant risk of loss of life, limb, or function. Critical incidents are considered 'critical' as they signal the need for immediate investigation and response, not only because of the potential or actual outcome for the patient, but also because of perceived problems with the process and underlying structure of care.

S*P*O

Error *(see also Unsafe Acts)*

Something that is or is not done, which is not intended, but which does not involve the breaking of a 'rule'. Human error can never be completely prevented, but many errors can be avoided, or trapped as they are made, or their effects can be treated and so mitigated.

S*P*O

Hazard

The major way in which death, injury or damage can occur. Hazards may be classified according to the amount of damage they may inflict (none, mild, moderate, severe) and by how frequently they may be encountered (never, rarely, sometimes, often).

S*P*O

Human Factors Engineering

A branch of engineering that specializes in designing efficient, human centred processes to improve reliability and safety.

S*P*O

Incident

An occurrence in which there is a problem with the process of care. If the incident leads to any harm, then the related injuries or complications may or may not be serious. If serious, the incident is 'critical.'

S*P*O

Lapse

A type of error that generally involves a failure of memory.

S*P*O

Latent Condition

The structural flaws in the system that contribute to error-producing factors.

S*P*O

Medical Error

A type of error that occurs in the context of the provision of health care.

S*P*O

Mistake

A type of error in which there is a failure with the mental processes involved in assessing information, developing plans, and judging the likely consequences of a planned action.

S*P*O

Multidisciplinary Case Review

An open discussion by the health-care team to identify the root causes of a critical incident and strategies to prevent a similar occurrence in the future. The proceedings are facilitated by trained personnel within a quality-improvement framework and opinions expressed during the course of the review are confidential.

S*P*O

Near Miss *(see also Close call)*

A situation in which the patient had a narrow escape from a serious complication.

S*P*O

Outcome

A product, result or effect. In health care, outcomes may be measured in a variety of ways, but tend to reflect the physical and psychological well-being of the patient, and associated costs.

S*P*O

Patient Safety

The state of continually working toward the avoidance, management and treatment of unsafe acts within the health-care system.

S*P*O

Preventable

A process or an outcome that is predictable, foreseeable, and capable of being forestalled. Not all incidents or adverse events are preventable, although the threshold of preventability changes with time and effort and is determined by the overall structure of the system.

S*P*O

Process

A course of action or proceeding, including what is done and how it is done. Examples of these interrelated activities within the health-care system include communication, problem-solving, decision-making, and conflict resolution.

S*P*O

Risk

The probability of danger, loss or injury within the health-care system.

S*P*O

Risk Management

Organizational activities designed to prevent patient injury or moderate the actual financial or organizational losses following an adverse event.

S*P*O

Root-Cause Analysis

A technique of systematic investigation of a critical incident to determine the contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and on developing recommendations for improvements to decrease the likelihood of a recurrence.

S*P*O

Slip

A type of error that relates to observable actions. A slip is commonly associated with a failure of attention or perception.

S*P*O

Structure

The supporting framework or essential parts and includes all elements of the health-care system that exist before any actions or activities take place.

S*P*O

Unsafe Acts

An error represents something that is or is not done, which is not intended, but which does not involve the breaking of a 'rule'. There are three types of errors: lapses, mistakes, and slips. A violation represents the intentional breaking of a rule or the intentional deviation from safe operating procedures or standards; violations can be positive, if used, for example, to prevent harm to a patient. Sabotage is a malevolent act with the intent of causing harm or damage.

S*P*O

System

Represents a set of interdependent elements interacting to achieve a common aim. Within the system there are components that can be classified in various ways, such as socio-geographic factors: national, provincial, organizational / institutional, health-care provider, and patient / client / family. Although the term is used to indicate both the entirety of health care and the smaller components, ideally 'system' should be reserved for use when describing the former. Alternatively, a modifier should be used to ensure clear understanding of the term, e.g., surveillance system.

Other Terms:

In addition, certain terms carry both a dictionary definition and specific societal values, which may or may not agree. For this reason, we recommend that the following terms generally not be used when discussing patient safety.

Accident

An occurrence that results in death or injury to one or more individuals and/or damage to equipment / facilities. However, the term carries the connotation that the event proceeded from some unknown cause, without foresight or expectation. This assumed link with the concept of 'bad luck' is the reason the term should not be used.

Blame

Assigning of culpability to one or more individuals after an error or adverse event. However, assigning blame does not recognize the complexity of the health-care system and the impact of latent conditions on the events in question. Furthermore, the result of assigning blame is personal shame, which, in the context of making errors, may contribute to a culture of fear of reprisal.

Fault

Denotes a wanting in moral character or a blameable imperfection. Fault often carries the pejorative connotation of blame or responsibility. For this reason, it is better not to use the word when referring to the actions of individuals in the context of patient-safety activities.

Negligence

Want of attention to what ought to be looked after; carelessness, disregard, or lack of ordinary care. However, negligence also carries a legal definition and an individual's actions can only be determined to be negligent by a court of law if they meet four specific requirements. Thus, this word should not be used when describing the actions of health-care providers, unless those actions have been determined to be negligent by the courts.

Recklessness

To act without regard for the consequences or danger, to act rashly or carelessly. The term reckless or recklessness is applicable to a health-care professional only within very narrow circumstances, such as professional regulatory reviews or other legal proceedings. Unfortunately, many individuals are tempted to use the term to explain or attribute blame following an adverse event. This term also should be reserved for the courts and / or professional regulatory proceedings.

Appendix E

THE FRAMEWORK MATRIX: SYSTEM ISSUES WORKING GROUP

	STRUCTURE →	PROCESS →	OUTCOME
Socio-geographic COMPONENTS	**Rules & regulations** **Policy & procedures** (including methods of proactive and reactive evaluation of the system) **Administration** (including management authority) **Funding** **Culture** (including static and dynamic aspects) **Environment** (including sites, space, ventilation, light, heat, ergonomics) **Equipment** (including number, design, maintenance, availability, spare parts, consumables) **Personnel / Staffing** - Individuals (including numbers, training, experience, competence) - Teams (including composition, standard and emergency operating procedures) **Population/Patients/Clients/Families** (including numbers, sex, culture, characteristics)	**Tasks performed** **Specific methods** followed (including treatment spectrum; communication; problem-solving; decision-making; conflict resolution; reporting where possible of errors, near misses, occasions where someone 'saved the day'; and disclosure to patients/clients/families, staff and relevant authorities of these events)	**Positive/negative final results** (including death, disease, disability, discomfort, dissatisfaction and dollars), with disclosure to patients / clients / families, staff and relevant authorities of these outcomes **On-going systematic audit & evaluation** of outcome, relating back to structural and procedural indicators and to both internal and external benchmarks (including self-evaluation and peer review of individuals and team debriefing and evaluation) **Episodic reporting & investigation** of adverse outcomes **Development & implementation of recommendations** for improvement **Feedback** to involved parties **On-going review**
Federal			
Provincial/ Territorial			
Organizational/ Institutional			
Personnel			
Patients			

Please see examples on next page

Example: Application of the Patient Safety Matrix to the proactive review of drug safety

The following is an example of how the matrix might apply in practice to the proactive review of drug safety at the federal / provincial / territorial levels; at organizational / institutional levels, as well as at the levels of the patient / doctor / nurse / pharmacist. The safety of a drug relates to adverse drug events, of which there are two types: non- preventable and potentially preventable. Non- preventable ADEs are serious, undesired and/ or unexpected reactions to a drug. They are non- preventable and are known as Adverse Drug Reactions (or ADRs).

These include toxic or allergic reactions in patients without apparent risk factors. Potentially preventable ADEs result from medication errors that lead to patient harm. Not all medication errors cause harm (because of error trapping and mitigation). When they do, they are related to unsafe acts and to latent conditions in the system, and are potentially preventable through system improvement.

	STRUCTURE →	PROCESS →	OUTCOME
Federal / Provincial/ Territorial levels	**REVIEW** **Policies & procedures** - drug licensing - drug marketing drug prescribing - follow-up - alerts (professional; public) - drug recall **Drug** pharmacological characteristics name (chemical, generic, trade) - appearance, labelling and packaging indications - contra indications adverse drug events (type, severity, frequency, duration) - warnings - storage (e.g., refrigeration) - administration characteristics (dosing, route, equipment, timing) **Information about drug** regulatory agencies (Canada, USA, Europe, Australasia) - pharmaceutical companies - adverse drug event databases reporting agencies (Canada, USA) **Information about population** numbers - ages - sex - cultural factors Co-morbidities (e.g., pregnancy) - allergies - historical & current drug use	**CONSIDER** **Marketing activities** - pharmaceutical organizations (e.g., detail pharmaceutical representatives, media and advertising agents) - special interest groups (e.g., Arthritis Society) **Prescribing activities** different medical specialties - other licensed prescribers (dentists, chiropractors, etc.) **Dispensing activities** - by pharmacists **Drug-acquiring activities by patients** - from pharmacies from other sources, including illegal internet shopping **Potential drug errors** prescribing phase - interpreting phase - dispensing phase administering/taking phase - monitoring phase	**EVALUATE** **Results** - Outcome #1 – therapeutic effect of treatment **Safety** - Outcome #2 – undesirable results of treatment or Adverse Drug Events **Costs** Outcome #3 – cost of treatment including costs of side effects
Organizational / Institutional levels	**REVIEW** **Reviewers** - Pharmacy & Therapeutics (P & T) Committee Specialty Departments (e.g., Anesthesia, Infectious Diseases) - Pharmacy & Nursing Liaison Committee - MAC **Drug** - pharmacological characteristics name (chemical, generic, trade) appearance, labeling & packaging - indications - contra indications adverse drug events (type, severity, frequency, duration) - warnings - storage (e.g., refrigeration) - administration characteristics (dosing, route, equipment, timing) **Patient** numbers - ages - sex - cultural factors co-morbidities, including pregnancy - allergies - other drugs	**CONSIDER** **Drug safety** - perform Failure Mode Effect Analysis (FMEA) on new drug to be considered as formulary items **Potential drug errors** prescribing phase - interpreting phase - dispensing phase - administering/taking phase monitoring phase	**EVALUATE POTENTIAL OUTCOMES** **Results** - Outcome #1 – therapeutic effect of treatment **Safety** Outcome #2 – undesirable results of treatment or adverse drug events **Costs** - Outcome #3 – cost of treatment, including costs of side effects **Drug removed from formulary** - cost savings - alerts to prescribers about lack of drug availability changes to computerized drug order sets - alerts to specific patients about lack of drug availability (as needed) **New drug added to formulary** - costs - alerts to prescribers about new drug availability changes to computerized drug order sets - alerts to specific patients about new drug availability (as needed)

Personnel (doctor / nurse / pharmacist) and patient levels	REVIEW	CONSIDER	EVALUATE POTENTIAL OUTCOMES
	Patient age - sex - cultural factors co morbidities, including pregnancy allergies - other drugs **Drug** - pharmacological characteristics - name (chemical, generic, trade) labeling & packaging - indications - contraindications adverse drug events (type, severity, frequency, duration) warnings - storage (e.g., need for refrigeration) - administration characteristics (dosing, route, equipment, timing) **Drug information sources** - health care professional (MD, Pharmacist, RN, other) non-professional (family, friend, colleague) - internet, library - disease association other	**Indication** on-label - off-label **Administration characteristics** - dosing route equipment - timing **Potential drug errors** - prescribing phase - interpreting phase dispensing phase - administering/taking phase - monitoring phase	**Results** Outcome #1 – therapeutic effect of treatment (condition for which drug is prescribed: improved, no change, worsened) **Safety** - Outcome #2 – undesirable results of treatment or adverse drug events (delirium, fraud, record, report) **Costs** - Outcome #3 – cost of treatment, including costs of side effects **Drug disposition** Outcome #4 continue taking versus discontinue drug

Example: Application of the Patient Safety Matrix to the reactive review of a single adverse outcome – death of a patient

The following is an example of how the matrix might apply in practice to the reactive review of the death of a patient. Investigation shows that the patient's death was related to a medication error. Underlying contributory factors included similar labeling of the two drugs involved, as well as problems with drug storage. Recommendations from the investigation included the development and implementation of guidelines, to decrease the probability of a recurrence of the same or similar events.

	STRUCTURE ►	PROCESS ►	OUTCOME
Reactive loop	N/A ◄	N/A ◄	**Patient dies**
	Mechanism for notification of family ◄ defined in Policies and Procedures	**Task:** notification of family ◄ **Methods:** as detailed in Policies and procedures (includes facts about immediate pre-mortem events and plan for investigation)	**Family notified**
	Mechanism for filing of report of death ◄ defined in Policies and Procedures, including notification of Administration	**Task:** file reports of death with relevant committees / parties ◄ **Methods:** includes alerting them for follow-up report on investigation of death	**Report of death filed** (Coroner / Medical Examiner, institutional / organizational death review committee, provincial / national death database)
	Mechanism for the investigation of death ◄ defined in Policies and Procedures	**Task:** investigation of death ◄ **Methods:** review of process for presence of unsafe acts, review of structure for presence / contribution of latent conditions	**Death investigated** (Results of review: intravenous bolus epinephrine in error, contributing to MI leading to death; epi label similar to glycopyrrolate; drug in wrong drawer, anesthesiologist alone)
	Mechanism for dissemination of investigation report defined in Policies and Procedures, including acceptance of responsibility for follow-up by Administration ◄	**Task:** dissemination of investigation results ◄ **Methods:** special safety alert to all disciplines internally / external independent safety organization, as well as government drug safety monitoring agencies; patient-safety bulletins/newsletters	**Report of investigation results** disseminated (to family, institutional/organizational/provincial/ national health care safety organization / agencies)
	Task Force for development and implementation of improvements, including new policies/procedures and guidelines, and on-going surveillance against recurrence defined in Policies and Procedures, including timeline for response by appropriate individuals / departments / institutions / organizations / provinces / geographic regions / federal agencies ◄	**Task:** development and implementation of improvements including new guidelines and on-going surveillance against recurrence, including rewriting of Policies & Procedures, where necessary ◄ **Methods:** steps to ensure inclusion of internal and external expertise	**Development and implementation of recommendations for improvements**

Appendix F

WORKING GROUP ON INFORMATION / COMMUNICATION
Action Plan

Goals	Messages/Actions	Product(s)	Target Audience(s)	Partners/ Lead Agencies	Dissemination (Role of I.T.)
1. **Communicate** with the Canadian public, health-care personnel, health institutions/ organizations, regulatory bodies **as to realistic expectations of the risks and benefits inherent in the health-care system**	• Statement of problem/issue and why addressing it now • Meta-analysis of existing data/information (literature review) on medical errors • Characterize patient safety as systems issue and identify barriers to and opportunities for change • Overview of initiatives to promote safety in other jurisdictions (i.e. who's doing what?) • Estimate of incidence of adverse events in Canada and discussion of existing efforts to ensure patient safety • Outline proposed strategies to enhance patient safety in Canada and identify opportunities for stakeholders to work collaboratively • Invite commentary from readers and suggestions for ways to improve system	• National Report on Patient Safety (nature of Backgrounder or Discussion Paper)	• Public • Health-care personnel • Regulatory colleges • Health organizations/ facilities	• CIHR • Health Canada (pursuant to mandate of health promotion and health protection) • Consumer groups	• Published by partners • Publicly available on-line • Widely disseminated
2. **Communicate** with the public **as to personal measures** they can adopt to reduce the potential for problems with the provision of care and any resultant adverse outcomes	• Statement of problem • Identify current methods to reduce adverse events and promote patient safety • Outline rights and responsibilities of patients in the health-care setting • Highlight known methods of reducing risk and encourage patients to take an active role in their care • Customize for specific patient populations • Invite commentary from readers/suggestions for ways to improve system	• Pamphlet • Public Service Announcement (PSA)	• Public	• Health Canada (under mandate of health promotion) • Provincial/territorial ministries of health • Consumer groups	• Availability to public in physician offices, hospitals, LTC facilities and community agencies • Dissemination to patient rights' organizations and patient advocacy groups • Distribution to disease-specific advocacy organizations • Availability on-line
3. **Communicate** with the Canadian public and health-care personnel **strategies to improve the safety of health care** in various health-care settings	• Data must be gathered on all near misses and incidents and their outcomes and contributory factors (where apparent) in all health-care settings from large institutions to patient's home. • Data gathered (in 1st bullet) must be analysed for contributing factors including environmental, technical, personal, etc. • Data gathered and analyzed must be communicated to all levels of the health-care system and to all settings with recommendations on changes that should be instituted to prevent adverse events. • Government regulators and health professional regulatory bodies to consider information (in 3rd bullet) to determine if regulatory interventions are needed or to issue standards of practice and cautions • All institutions and individual health-care personnel have responsibility for being aware of above information and acting on recommended changes. • Producers of health-care products identified in data (in 1st bullet) need to be informed that products can contribute to errors and changes may be recommended • Communication mechanisms must be established so that patient data is transferred between settings in a timely and efficient manner, while recognizing need for assurance of patient confidentiality • Invite commentary from readers and suggestions for ways to improve system	1. National database of all near misses and incidents and their outcomes and causes (where apparent) in all health-care settings from large institutions to patient's home. 2. Research conducted by national database organizers with input from a research advisory committee to identify research goals. 3. Regular reports of data, analysis and recommendations 4. Regulations or standards of practices 5. Include requirement in regulations/ standards of practice that institutions and individual health-care personnel have responsibility for being aware of above information and acting on recommended changes. 6. Reports developed (in no. 3) that involve health-care products to be distributed to producers. 7. Seamless care framework that outlines mechanisms and policies to ensure patient data is shared across all health-care settings; communication mechanisms including paper and electronic where possible	1, 2 & 3 - To be accessed for input and reporting by national and provincial organizations and governments, professional organizations, institutions, teams of health-care personnel and patients 4 & 5- National and provincial organizations and governments, professional organizations, institutions, teams of health-care personnel and patients 5 & 6 - Health-care product producers, e.g. pharmaceutical industry 5 & 6 - Health-care personnel and institutions and organizations, e.g. hospitals, clinics, individual practitioners	1. National and provincial governments and health professional organizations (associations and/or colleges), CIHI 2. Health research centres e.g. ICES, universities 3. Educational institutions for undergraduate and graduate programs 4. Governments and health professional regulatory bodies 5. Input from representatives of health-care product producers 6. Professional and institutional regulators and organizations and patient groups, e.g. consumer associations	• Publications (journals, newsletters) and websites of partners and lead agencies (National and provincial governments and health professional organizations, CIHI, CMPA) • Reports developed and sent by mail directly to producers. • Electronic communication means preferably, and paper documents where necessary. Smart Cards (carried by patient)

[1] Definition of health-care personnel: includes, but is not limited to, physicians, nurses, pharmacists, and other medical and support personnel involved in the delivery of health care.

4. **Communicate** with local, regional, provincial, territorial, national organizations, and educational and regulatory bodies' **about best practices** with respect to the management of the best provision of care, including the management of adverse events (through avoiding, trapping and treating)	• Develop standards, data bank/clearing house of good/best practice approaches to patient safety and reduction of adverse events • Concept of good/best practice needs to be imbedded in accreditation standards (CCHSA, RCPSC, etc.) • Best practice is interdisciplinary, team oriented, and collaborative • Encourage appropriate research to develop standards where they don't exist • Invite commentary from readers and suggestions for ways to improve system	1. Questionnaire (survey re best practice, novel approaches in order to begin to build data bank) 2. Possible creation of link/ collaboration with Cochrane Library 3. Creation of website (e.g. - hosted by CHA), staffed and resourced 4. Joint statement development by medical/legal/ insurer groups	1. Professional associations, regulatory bodies 2. Schools: medicine/allied health 3. Accrediting bodies 4. Barristers' societies/insurers (discussion of "no fault" approach)	1. Health science centres/educational institutions 2. CIHI 3. National health research agencies (e.g. CIHR) 4. Professional and regulatory bodies	• Need discussion/debate on timing of public dissemination until database/consensus initiatives well underway
5. **Develop strategies to** guide health-care personnel, institutions/ organizations, provinces and jurisdictions to **improve communication and information sharing** to reduce the potential for adverse events	1. Recommend that HC teams be included in educational and clinical forums such as morbid/mortality rounds, CE, etc. 2. Develop culture of learning and sharing through shared educational opportunities as above 3. Encourage sharing of patient data through secure means 4. Clarify that all health-care personnel have patient confidentiality as part of their professional codes and ensure that it is maintained 5. Standard formats for electronic exchange of information must be developed and supported by health-care personnel groups and computer software developers	1 & 2 - Communiqué to institutions and CE providers, health-care personnel associations, pharmaceutical companies, educational institutions 3 - Develop guidelines for inter-professional communication 4 & 5 - Include in guidelines in number 3	1 & 2 - Institutions and CE providers, health-care personnel associations, pharmaceutical companies, educational institutions 3, 4 & 5 - Health professionals, health-care personnel associations 4 - Governments developing privacy legislation 5 - Electronic communication developers, software developers	1. Educational institutions 3. CMPA	• Mail, journals, articles, conferences
6. **Develop standards, guidelines and policies in relation to appropriate disclosure** of adverse outcomes and any contributory factors within the health-care system, and **communicate this with the Canadian public,** health-care personnel, regulatory authorities and the legal profession	• Develop policy guidelines on disclosure of adverse events including policy on responsibility and disclosure • Include national standards on adverse-event recognition/reporting in policy guidelines in previous bullet • Include national and/or institutional standard on debriefing members of HC team of an adverse event (in policy guidelines in first bullet)	• Policy guideline booklet • Plan for full disclosure in accreditation standards	• Health-care personnel managers	• Health-care personnel and regulatory authorities • CCAPP • CCHSA • CMPA	
7. Develop strategies to **facilitate communications** among health-care personnel **when adverse events occur,** and with patients and families when a patient suffers an adverse outcome	• Include in all health-care personnel curriculum training on how to recognize, record, report and disclose adverse events. What is appropriate when an adverse event has occurred? • Develop national guidelines on adverse events communication that includes health-care teams and patients • Develop national guidelines to clarify a pro-reporting, no-fault process for health-care team personnel involved in adverse events • Provide information on safeguards to limit litigation, e.g. regarding recording of events • Develop scenarios for health-care personnel to use in training programs	• Develop curriculum objectives and send to all health-care personnel faculties and training facilities • Guidelines on adverse-event communication and a brochure detailing them • Guidelines and brochure detailing pro-reporting, no-fault process for health-care team personnel involved in adverse events • Include scenarios for health-care personnel to be used in training programs and include them in communication guidelines and brochures mentioned in previous two bullets	• Health-care personnel, educators • All health-care personnel and regulatory bodies • Regulatory bodies, employers, institutions and ultimately health-care personnel	• Health-care personnel, educators, organizations, e.g Association of Faculties of Pharmacy in Canada (AFPC) • Health-care personnel, associations involved in CE • Regulatory bodies • Health-care personnel, associations and regulatory bodies	• Through partners and directly to educational institutions • Regulatory bodies, directly to health-care personnel conference programs • Health-care personnel and associations, regulatory bodies, directly to health-care personnel

Appendix G

NATIONAL / INTERNATIONAL SUMMARY OF KEY INITIATIVES IN PATIENT SAFETY

National

Health Canada

Health Canada is responsible for funding the research of the Canadian Institutes of Health Research[1] (CIHR) and the Canadian Institute for Health Information[2] (CIHI) and other studies related to patient safety. For example, Health Canada recently awarded a contract to review the feasibility of establishing a national incident-tracking and reporting system for medications. Health Canada has also recently sponsored a national survey to gather information on the prevention of 'error' in health-care delivery and the extent to which organizations are reporting and addressing incidents.

The Canadian Institutes of Health Research and the Canadian Institute for Health Information

CIHR and CIHI have awarded a jointly funded research study to examine the extent of adverse events in Canadian acute-care hospitals and the availability of data that could be used to support continuing monitoring to reduce these events. The results of this study, the first of its kind in Canada, are expected to be released to the public in 2004.

Canadian Council on Health Services Accreditation (CCHSA)

The CCHSA is a national, independent, non-profit organization whose role is to objectively review the care and quality of services provided by a specific health-care organization. The CCHSA surveyors compare the findings obtained within the accreditation process to national standards. The assessment deals with all forms of risk that may occur within a health-care organization, but most particularly with clinical risk. Requirements for the measurement and management of risk may be found within the national accreditation standards. CCHSA is participating in national collaboratives on patient safety/error and is considering modifying the standards to reflect a greater focus on these issues.

Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP)

In the fall of 2000, an invitational workshop was co-hosted by the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) to address a number of key questions related to medication incident reporting and prevention. One of the outcomes of the workshop was the recommendation to establish a coalition of stakeholders - Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP). The Coalition was formed in February 2001 with the mandate to develop options, in the form of a business plan, for a comprehensive, viable,

[1] The Canadian Institutes of Health Research (CIHR) is Canada's premier federal agency for health research. Its objective is the creation of knowledge and its translation into improved health for Canadians, more effective health services and products, and a strengthened Canadian health-care system.

[2] The Canadian Institute for Health Information (CIHI) is an independent, non-profit organization that provides accurate and timely information needed to develop health policies, manage the Canadian health system effectively and create public awareness of the factors affecting good health.

sustainable and affordable medication-incident reporting and prevention system for Canadians. The desired outcome is a program that manages the risks inherent in medication use and moves toward a goal of risk prevention. Members of the Coalition include representatives from consumers, medicine, nursing, pharmacy, healthcare associations, information management, governments, and the pharmaceutical industry.

Sierra Systems Inc. was selected through a Request for Proposal process to assist with development of the report. Consultations with over 50 national and international stakeholders were undertaken during the development of the report. The report was released to Coalition members and external stakeholders on July 24, 2002. A copy is available.

Canadian Healthcare Association (CHA)

The CHA is a federation of provincial and territorial hospital and health organizations across Canada. Through its members, it represents a broad continuum of care, including acute care, home and community care, long-term care, public health, mental health, palliative care, addiction services, children, youth and family services, housing services, and professional and licensing bodies. The organization is a recognized national leader in advocating for a coordinated and effective response to "medical errors".

The CHA has initially identified the following categories of system issues (a more comprehensive policy brief to be issued in the near future):

- Cultural Barriers (promoting a "culture of safety" that encourages openness and objective analysis of error)
- Adoption of a "Systems" Approach (recognizing that most errors occur as a result of a sequence of failures in the complex processes of care)
- Reports of error (need to develop and implement comprehensive reporting standards and enforcement mechanisms related to 'medical errors')
- Governance and Leadership (a co-ordinated and effective response to medical errors in Canada is required)

The Institute for Safe Medication Practices (ISMP Canada)

The Institute for Safe Medication Practices (ISMP Canada) is an independent Canadian non-profit agency established for the collection and analysis of 'medication error' reports and the development of recommendations for the enhancement of patient safety. Like its sister organization, the ISMP in the US, ISMP Canada strives to promote safe-medication practices throughout health care communities in the country.

Specific goals include:

- To review medication errors submitted by practitioners to ISMP Canada and to make recommendations to reduce the probability that such errors will happen again
- To publish and disseminate information to the health-care community and its practitioners through efficient electronic means in order to promote safe medication use and strategies for reduction of error-induced injury
- To participate in co-operative programs with professional organizations in Canada in providing education about adverse drug events and their prevention
- To act as consultants to institutions and other health-care settings on medication use
- To develop educational and quality-improvement assessment tools for health-care professionals and institutions
- To establish and maintain a strong partnership with ISMP in the US, and the other national and provincial patient-safety organizations
- To provide educational programs for university and health-professional constituents

ISMP Canada has a variety of instruments for improving patient safety, including:

- Distribution of the ISMP Newsletter (provides alerts on identified drug errors such as those related to labelling and packaging problems)
- A Medication Safety Self-Assessment (a tool designed to help organizations self-

assess the safety of medication practices, identify opportunities for improvement, and compare the results with the aggregate experience of demographically-similar hospitals)
- A medication-error reporting and analysis software program (Analyse-err). The two components to the program are an objective factual reporting section and a root-causes analysis exercise (in use at several Canadian hospitals)

Further information may be obtained from the ISMP Web Site: http://www.ismp-canada.org

International

UNITED STATES

The Institute of Medicine Report (IOM)

The impetus for the United States to focus its attention on preventable medical errors began with the release of *To Err is Human: Building a Safer Health System* in 1999 - a report by the Institute of Medicine.

The IOM is a private, non-governmental organization created to advise the US federal government on scientific and technical matters. It reviewed major US studies of adverse events and medication errors, and from this analysis, estimated that between 44,000 and 98,000 people die in hospitals each year as a result of medical errors in that country. Even using the lower estimate would make medical errors the eighth leading cause of death in the US — above motor-vehicle accidents, breast cancer and AIDS. The study estimated that about 7,000 people per year die from medication errors alone. The report suggested a variety of strategies to improve patient safety, including implementation of safer medication-use systems and a national reporting system for medical errors.

Three months after the publication of the IOM report, an interagency federal government group, the Quality Interagency Coordination Task Force (QuIC) released its response, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*. This report, requested by the American President, provides an inventory of on-going federal actions to reduce adverse medical events and recommendations for more than 100 actions to be undertaken by federal agencies.

In January 2001, the Agency for Healthcare Research and Quality (AHRQ) commissioned the Stanford University Evidence-Based Practice Centre to review scientific literature regarding safety improvement. The report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, provides an extensive appraisal of the evidence on best safety practices for the delivery of health care.

In March 2001, the IOM released a second and final report, *Crossing the Quality Chasm: A New Health System for the 21st* Century. This report, building on the IOM's first report, provides bold recommendations to redesign the American health-care system, including specific direction for policy makers, health-care leaders, clinicians, regulators, purchasers and others. This comprehensive report includes:

- A set of performance expectations for the 21st century health-care system
- A set of 10 new rules to guide patient-clinician relationships
- An organizational framework to better align payment and accountability with quality improvements
- Key steps to promote evidence-based practice and strengthen clinical-information systems

The latest IOM report recognizes that health care is a complex system; IOM identifies practices that impeded quality care and explores how system approaches can be used to implement change.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The Joint Commission evaluates and accredits nearly 18,000 health-care organizations and programs in the United States. An independent, not-for-profit organization, JCAHO is the predominant standard-setting and accrediting body for health care in the United States. Since 1951, JCAHO has developed state-of-the-art, professionally-based standards and evaluated the compliance of health-care organizations against these benchmarks. Their mission is to continuously improve the safety and quality of care provided to the public

through the provision of health-care accreditation and related services that support performance improvement in health-care organizations.

This organization undertook root-cause analysis in 64 cases of surgical and post-operative adverse events and identified the following 8 root causes:

- Poor communications among caregivers
- Failure to follow established procedure
- Necessary personnel not available when needed
- Pre-op assessment incomplete
- Deficiencies in credentialing and privileging
- Inadequate supervision of house staff
- Inconsistent post-op monitoring procedures
- Failure to question inappropriate orders.

The National Patient Safety Foundation (NPSF)

The NPSF seeks to be a catalyst and a force for improving patient safety. They have four primary objectives within this process:

- Raise awareness
- Build a knowledge base
- Create a forum for sharing knowledge
- Facilitate the implementation of practices that improve patient safety

Over the past several years, NPSF has become known for its work in facilitating dialogue and co-operation on patient-safety issues; work on building a knowledge base has proceeded in full force. An example is the NPSF Clearinghouse, which aims to grow into the most comprehensive collection of patient-safety literature in the world. The Foundation also strives to develop the patient's role in improving safety in health care.

Further details may be found at the web site: *http://www.npsf.org*

Institute for Healthcare Improvement (IHI)

The Institute for Healthcare Improvement is a non-profit organization that supports integrative and collaborative efforts to improve health-care systems in the United States and Canada. IHI has produced a series of documents titled the *Breakthrough Series*, with each publication focusing on improvement in a single area of health care. For each document, 20 to 40 health organizations are brought together to study the latest information on improving a special clinical or operational area and to learn effective means to apply that information for rapid improvement. This guide includes IHI's well-recognized Plan-Do-Study-Act (PDSA) model for accelerating improvement and a step-by-step guide for reducing ADEs while addressing the barriers to change.

Further details may be found at the web site: *http://www.ihi.org*

UNITED KINGDOM

In 2000, the National Health Service (NHS) published An Organization with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS. The authors reported that at least 400 patients died or were seriously injured and that nearly 10,000 people were reported to have experienced serious adverse reactions to drugs (not all of which are preventable) in 1999. The report estimates that adverse events occur in approximately 10% of patient admissions in the U.K. This report recommends the creation of a new national system for reporting and analyzing adverse health-care events to ensure that lessons are identified and learned. Additionally, the recommendations put forth in this report support the analysis of adverse events at the local level for the purpose of improving care outcomes. Development of a strategy to build local capability for analysis is integral within the nation-wide implementation plan.

The NHS has produced a number of other relevant reports. They include *Building a Safer NHS for Patients, Doing Less Harm - Key Requirements for Health Care Providers, and Measurement and Monitoring of Surgical Adverse Events.*

Information on the reports and activities of the NHS can be found online at: *http://www.doh.gov.uk*

AUSTRALIA

In 1994, the Quality in Australian Health Care Study was commissioned by the Commonwealth Department of Health to determine the extent of adverse events (AEs) in Australian hospitals. A review of hospital medical records was undertaken to estimate patient

injury that occurred in health-care settings. This study was modelled on the Harvard Medical Practice Study in the United States.

The results of this study were based on the review of 14,179 admissions to 28 hospitals in two states. The review process involved initial screening by Registered Nurses using standard and strict criteria followed by an independent review and documentation by two, or, in cases of disagreement, three medical officers. The data revealed that, of 16.6% of admissions attributable to AEs, 51% were deemed preventable. In 77.1% of the cases, the disability had resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died (Wilson et al.,1995). Available online in the Medical Journal of Australia: *http://www.mja.com.au/*

The Australian Council for Safety and Quality in Health Care was established in January 2000 to facilitate and co-ordinate national action in safety in health care. The Council prepared its first report in July 2000 that sought funding for a five-year national work plan to improve safety and quality in the Australian health-care system. In February 2001, the Council produced a National Action Plan identifying the next steps in addressing national patient safety. The four priorities identified in its first year action plan included:

- Using data and information better throughout the system to support safer patient care
- Strengthening mechanisms to ensure safer clinical and organizational environments
- Actively promoting opportunities for consumer feedback and participation
- Redesigning of systems and processes of care to promote a strong culture of reliability and safety

Since then, the Council has established a website for promotion of its activities and feedback, surveyed health-care professionals on barriers to, and opportunities for, the provision of safer care, hosted a consumer conference and workshop, and produced two national reports on patient safety. In September 2001, the Council collaborated with the British Medical Journal and the Institute of Healthcare Improvement (USA) to organize the 1st Asia-Pacific Forum on Quality Improvement in Health Care.

Publications of the Australian Council for Safety and Quality in Health Care are available online at: *http://www.safetyandquality.org*

NEW ZEALAND

In March 2001, Hellen Cull, QC, released a report titled *Review of Processes Concerning Adverse Medical Events* that reviews current processes for reporting and investigation of adverse incidents undertaken by the following New Zealand agencies:

- The Health and Disability Commissioner
- The Medical Council of New Zealand
- The Medical Practitioners Disciplinary Tribunal
- The ACC Medical Misadventure Unit

Helen Cull, QC, identifies lessons that can be learned from this review. She recommends legislative and procedural changes that could ensure that adverse medical outcomes are identified and that appropriate, timely remedial action is taken. This information is intended to support the development of legislation, to improve the framework for the occupational regulation of health professionals, including processes for the reporting and investigation of adverse incidents.

Information on this report can be found at the New Zealand Ministry of Health website: *http://www.moh.govt.nz*

Tab 16

The Oncologist®
Breast Cancer

Commentary: Hormone Receptor Testing in Breast Cancer: A Distress Signal from Canada

D. Craig Allred

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Recent events in Canada underscore substantial problems with estrogen receptor (ER) testing by immunohistochemistry (IHC) in breast cancer [1, 2]. In 2005, a woman there was diagnosed with invasive lobular carcinoma. Her tumor was tested for ER expression by IHC in a laboratory managed by Eastern Health, the provincial health care provider in Newfoundland and Labrador. The results were negative, which is unusual for this type of tumor, so her physicians had it retested in another laboratory. The new IHC results came back positive, and the discrepancy led Eastern Health to investigate the accuracy of testing in Newfoundland and Labrador. Eventually, over 2,000 originally ER-negative cases were retested in another laboratory in Ontario, and nearly 40% were found to be ER-positive. An official inquiry was convened in July 2007, to determine the scope and causes of the problem, and to develop policies to prevent it from happening in the future (Commission of Inquiry on Hormone Receptor Testing at http://www.cihrt.nl.ca/transcripts.html). The conclusions of this inquiry are still forthcoming.

In current clinical practice, ER testing is mandatory in all newly diagnosed breast cancers, and accurate results are critical in determining the use of adjuvant hormonal therapy. This type of therapy significantly improves the outcome of many patients with ER-positive tumors, but it is ineffective with ER-negative disease. For this reason, most of the erroneous ER-negative patients in Newfoundland and Labrador were not treated with hormonal therapy, and some were almost certainly harmed because of it. This tragic outcome was avoidable and raises several urgent questions that should concern all of us: How did it happen? Is it happening elsewhere? What is being done to prevent it?

There are many well-known problems associated with measuring proteins by IHC, particularly proteins requiring quantified results such as ER [3, 4]. Some problems involve preanalytical issues unrelated to IHC itself, such as delayed or inadequate fixation of tissue, allowing proteins to degrade. Others are analytical in nature, such as the use of diverse reagents with unequal sensitivities [5–8], or antigen-retrieval procedures that inadequately re-expose proteins masked during fixation [4]. Most IHC assays rely on enzymatic detection systems with very rapid kinetics that are difficult to control,

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and it is very challenging to quantify results in an accurate and reproducible manner [9]. Postanalytical events may also contribute in the sense that tumors with very low levels of receptors (e.g., 1%–10% positive cells) may respond to hormonal therapy [6, 7, 10], and some laboratories use arbitrary definitions of positive that are too high (e.g., >10% positive cells). Fastidious oversight by highly experienced and knowledgeable personnel is required to recognize, resolve, and avoid these problems, and some or all of them may have contributed to the debacle in Canada.

Unfortunately, the problem with ER testing by IHC is not restricted to Newfoundland and Labrador. Perhaps the best evidence for this comes from the United Kingdom National External Quality Assessment Service (NEQAS). This organization has conducted and published the results of several studies on the accuracy and reproducibility of evaluating ER by IHC based on proficiency testing of 150 laboratories in 26 countries worldwide [4, 11–14]. The results identified error rates in some laboratories rivaling those in Newfoundland and Labrador, as well as the major technical problems causing them. The U.S. does not participate in NEQAS, and information regarding the accuracy of ER testing in this country is hard to find. Although many laboratories in the U.S. participate in proficiency testing offered by the College of American Pathologists (CAP), many do not, and the evaluation of ER by the CAP is less comprehensive than that of the NEQAS, so detailed results are not available. However, there is compelling anecdotal evidence suggesting that problems in the U.S. are also substantial. For example, in a recent large international clinical trial comparing hormonal therapies in receptor-positive breast cancer, a subset of >100 patients was enrolled with ER-negative/progesterone receptor (PgR)-positive tumors based on local laboratory results from several countries, including the U.S., who was a major contributor to the trial [15]. Repeat testing in an expert central laboratory revealed a 69% false-negative rate for ER in this subset of patients. Furthermore, there was a 44% false-negative rate for PgR in the group of >1,200 ER-positive/PgR-negative patients enrolled based on local laboratory results, so the problem is larger than ER alone. While far from being scientific, the false-negative rate of IHC testing for both receptors in my consulting practice over the past 10 years is about 30%, which is similar to that of other experienced consulting pathologists I have spoken with on this issue.

Given the critical need for accurate ER and PgR results in all patients with breast cancer, and the widespread difficulty obtaining them, it is clear that something must be done to remedy the problem. On one hand, it should be relatively easy to resolve because several comprehensively validated IHC methods have been published for other laboratories to emulate [5–7, 10, 16, 17]. On the other hand, it is remarkably difficult to persuade laboratories on a global scale to adopt the same methods, or to rigorously standardize and validate their own. A few years ago, a similar widely publicized predicament regarding human epidermal growth factor receptor (HER)-2 testing in breast cancer led to the development of rigorous guidelines by the CAP and the American Society of Clinical Oncology (ASCO) [18], and laboratories in the U.S. must soon comply with these guidelines to maintain CAP accreditation. The CAP and ASCO are also aware of the need to improve ER and PgR testing, and they are in the process of developing enforceable guidelines for these biomarkers as well. However, CAP accreditation is currently not required in the U.S. for laboratories to conduct these tests, and most laboratories are not CAP accredited. The situation is similar in other countries and it will take considerable resources, education, and persistence to achieve universal compliance in the use of assays that are comprehensively standardized and validated in an equivalent manner.

Ultimately, however, it is unrealistic to expect that even perfect tests for ER and PgR alone, by IHC or any other methods, will be sufficiently powerful to predict the response of all breast cancer patients to hormonal therapy because the biology involved is so complex. New more powerful predictors are needed, and they will most likely be based on multiple biomarkers. In this regard, there are many promising new approaches on the horizon at varying stages of development and validation, including oncotype DX® (Genomic Health, Inc., Redwood City, CA, http://www.genomichealth.com) [19, 20], the *HOXB13/IL17BR* gene ratio [21–23], and estrogen-regulated gene signatures determined by microarrays [24], to name a few. Hopefully, these and other approaches will lead to significant improvements in predicting response to hormonal therapies, and it will be important for them to avoid making the same mistakes concerning proficiency and standardization that have plagued ER, PgR, and HER-2 testing by IHC.

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Commentary: Hormone Receptor Testing in Breast Cancer: A Distress Signal from Canada

D. Craig Allred

Oncologist 2008;13;1134-1136; originally published online Nov 5, 2008;
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Tab 17

182 N.B.R. (2d) 341, 463 A.P.R. 341

1996 CarswellNB 554

Doyle v. **Green**

Region 2 **Hospital** Corporation (Defendant / Appellant) and Maurice Augustine Doyle (Plaintiff / Respondent) and Dr. David **Green** (Defendant / Defendant) and New Brunswick Healthcare Association (Intervenor) and New Brunswick Medical Society (Intervenor)

New Brunswick Court of Appeal

Hoyt C.J.N.B., Ryan and Turnbull JJ.A.

Heard: June 19, 1996
Judgment: November 25, 1996
Docket: 69/96/CA

Proceedings: Reversing in part (1996), 46 C.P.C. (3d) 52, 175 N.B.R. (2d) 125, 446 A.P.R. 125 (Q.B.)

Counsel: *John P. Barry, Q.C.*, and *Connie F. Morrissey*, for appellant.

Douglas L. Smith, for respondent.

Paulette C. Garnett, Q.C., for Dr. Green.

David T. Hashey, Q.C., by written submission, for intervenor New Brunswick Healthcare Association.

John D. Townsend, by written submission, for intervenor New Brunswick Medical Society.

Subject: Civil Practice and Procedure

Practice --- Discovery -- Discovery of documents -- Privileged document -- Miscellaneous privileges.

Practice -- Discovery -- Discovery of documents -- Privileged document -- Statutory privilege -- Plaintiff in malpractice action seeking disclosure of documents generated in proceedings before **hospital** committee -- **Hospital** claiming that documents privileged as study or research having as dominant purpose medical education or improvement of **hospital** practice -- Committee formed to investigate common disasters among patients -- Committee's dominant purpose not being education or improvement of **hospital** practice -- Privilege not applying to facts uncovered in investigation -- Evidence Act, R.S.N.B. 1973, c. E-11, s. 43.3(2)(b).

Following surgery for the repair of an inguinal hernia, the plaintiff suffered an infection which resulted in paralysis of his lower extremities. The plaintiff brought a medical negligence action against the **hospital** and its anaesthetist. The plaintiff alleged that the anaesthetist was negligent in the administration and handling of the anaesthetic, and was not competent or qualified to act as an anaesthetist. The plaintiff alleged that the anaesthetist had a severe personal substance abuse addiction which impaired his ability to use reasonable standards while acting as an anaesthetist. The plaintiff referred to the anesthesiologist's earlier arrest by the State of Connecticut Drug Control for writing false prescriptions for personal use, and to investigations by drug enforcement agencies in Canada and the United States. The plaintiff noted that following the plaintiff's surgery, the physician had been suspended by Health and Welfare Canada from writing prescriptions. The plaintiff alleged that the **hospital** was negligent in holding out that the physician was a specialist in anaethesiology, in continuing to grant **hospital** privileges to the anaesthetist, and in employing staff that it knew or ought to have known did not follow established procedures in reducing the risk of infection in an operating room.

In its affidavit of documents, the **hospital** claimed privilege for numerous documents, including documents resulting from its own investigations, other doctors' opinions in relation to the episode, and documents relating to complaints, recommendations, or incidents prior to the date of the plaintiff's admission into **hospital**. In addition, the anaesthesiologist claimed privilege with respect to a document purporting to be a consent order from the State of Conneticut, and recommendation letters containing opinions. The plaintiff applied for an order that all the documents be produced.

The application was allowed. The **hospital** appealed.

Held:

The appeal was allowed in part.

The conditions necessary to establish privilege at common law are that the communications originated in confidence that they would not be disclosed; that the confidentiality was essential to the maintenance of the relation between the parties; that the relation was one which ought to be sedulously fostered; and that the injury that would inure to the relation by disclosure was greater than the benefit gained for the correct disposal of litigation. Section 43.3(2)(b) of the *Evidence Act* (N.B.) specifies privilege for any document made by a **hospital** or **hospital** committee, prepared exclusively for the purpose of a study, research, or program, the dominant purpose of which is medical education or the improvement of **hospital** care or practice. However, the use of the words "exclusively" and "dominant purpose" are intended to limit the exclusionary privilege.

The documents relating to post-surgical infections, recommendations, and complaints against the anaesthesiologist, and incident reports involving him, failed the exclusive and dominant purpose limits in s. 43.3(2)(b). The recommendation letters were addressed "to whom it may concern," and thus lost common law privilege, because they did not orginate in confidence that they would not be disclosed. The remaining documents arose from problems sustained by the plaintiff and other patients at the **hospital**. They related specifically or incidentally to investigations launched by **hospital** authorities. Some of the documents were produced by **hospital** committees, and might be called a study directed at medical education or improvement in **hospital** care or practice. However, that was not their dominant purpose. The dominant purpose for the creation of the committees was a response to apparent common disasters involving certain patients. The documents did not attract protection under s. 43.3(2)(b). In addition, the investigation results did not meet the four common law privilege requirements. Even if the committee reports orginated in confidence that they would not be disclosed, confidentiality was essential,

and the **hospital** community would sedulously foster such a relation, the communications failed the balance test. The **hospital** authorities had a substantial interest in launching the investigations, and they had a public and even fiduciary duty to do so. The balance of interests between the **hospital** and the plaintiff favoured the plaintiff, even in cases where the announced creation of the committee was identified as relating to care and practice.

The document from the State of Conneticut purporting to be a consent order concerning a stay of the suspension of the anaesthesiologist's licence to practice in that state, and his probation for five years, stated that the order was not subject to reconsideration in any forum. The document was not privileged under the common law, nor under the Act.

The documents disclosing opinion evaluations of the anaesthesiologist from various doctors were privileged under the common law as peer evaluations. The appeal should be allowed in respect of those documents, and they should be excluded from production.

Cases considered:

Bainbridge v. Crawshaw, [1993] N.B.J. 618 (Q.B.) [unreported] -- *considered*

Basse v. Toronto Star Newspapers Ltd. (1985), 1 C.P.C. (2d) 105 (Ont. Master) -- *considered*

Bergwitz v. Fast (1980), 18 B.C.L.R. 368, 108 D.L.R. (3d) 732 (C.A.) -- *referred to*

F. v. Psychiatrist (1984), 54 B.C.L.R. 319 (S.C.) -- *considered*

*Finley v. University **Hospital** Board*, 14 C.P.C. (2d) 87, [1987] 2 W.W.R. 40, 33 D.L.R. (4th) 200, 53 Sask. R. 124 (Q.B.) [corrected at [1987] 2 W.W.R. 40 at 54, 33 D.L.R. (4th) 200 at 213 (Sask. Q.B.), leave to appeal to C.A. granted (1986), 14 C.P.C. (2d) 87n (Sask. C.A.)] -- *considered*

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R. v. Fosty, [1991] 6 W.W.R. 673, 8 C.R. (4th) 368, 130 N.R. 161, 75 Man. R. (2d) 112, 6 W.A.C. 112, 7 C.R.R. (2d) 108, (sub nom. *R. v. Gruenke)* 67 C.C.C. (3d) 289, [1991] 3 S.C.R. 263 -- *applied*

Skender v. Barker (1985), 67 B.C.L.R. 263 (Master) -- *considered*

Slavutych v. Baker, [1976] 1 S.C.R. 254, [1975] 4 W.W.R. 620, 38 C.R.N.S. 306, 75 C.L.L.C. 14,263, 55 D.L.R. (3d) 224 -- *applied*

*Smith v. Royal Columbian **Hospital*** (1981), 29 B.C.L.R. 99, 123 D.L.R. (3d) 723 (S.C.) -- *considered*

Statutes considered:

Evidence Act, R.S.N.B. 1973, c. E-11

s. 43.3considered

s. 43.3(2)(a)considered

s. 43.3(2)(b)considered

APPEAL by defendant in negligence action from judgment reported at (1996), 46 C.P.C. (3d) 52, 175 N.B.R. (2d) 125, 446 A.P.R. 125 (Q.B.), granting plaintiff's application for disclosure of documents claimed as priv- ileged.

The judgment of the court was delivered by *Ryan J.A.*:

1 On February 16, 1994, the respondent, Maurice A. Doyle, entered the Charlotte County **Hospital** at St. Stephen, New Brunswick for a hernia operation. Normally, this is an uncomplicated elective surgical procedure which he underwent. He promptly grew very ill and is now a paraplegic. He commenced action against the Region 2 **Hospital** Corporation and the anaesthetist, Dr. David Green, alleging negligence. Mr. Doyle claims negligence against Dr. Green in the provision of medical treatment and negligence against the **Hospital** Corporation in allowing Dr. Green to practise in its facilities.

2 Mr. Doyle seeks disclosure of certain records retained by the **Hospital** Corporation. To this end he successfully applied to a judge of the Court of Queen's Bench for an Order that the Corporation produce the documents for his examination. The **Hospital** Corporation and Dr. Green object to the production of these documents although the corporation has provided Mr. Doyle with many documents to which no objection has been taken by the corporation. The production of some of these latter documents were objected to by Dr. Green. Nevertheless, they were produced by the corporation.

3 On March 22, 1996, a Justice of this Court gave leave to the **Hospital** Corporation to appeal the interlocutory decision of Turnbull J. and on May 21, 1996 a panel of this Court, Hoyt C.J.N.B., Rice and Turnbull JJ.A. granted standing to the New Brunswick Healthcare Association and the New Brunswick Medical Association to file written submissions on the appeal. Various affidavits in support of their applications were received as evidence on the appeal. At the same hearing, Dr. Green was granted status in the appeal of the **Hospital** Corporation with the right to file a written submission and to make oral representation on the hearing of the appeal.

4 The position taken by the Healthcare and Medical Associations was one of principle in protecting patient records and confidentiality of proceedings within the **hospital** administration in order to facilitate candour and fullness of reporting among professionals and personnel. Their goal is, in the long term, the protection of the public.

5 The matter before the Court of Queen's Bench is reflected in the motion judge's description of the facts as follows:

> An affidavit of documents has been filed by the **Hospital** Corporation. One hundred and twenty-seven items are objected to being produced. One is a document prepared for the **Hospital's** insurers in relation to this litigation. One category relates to Dr. Green's qualifications and his annual extension of privileges. The other documents are all investigations and opinions in relation to this particular episode, or alleged breeches of **hospital** rules and regulations prior to February 1994.
>
> As one can imagine the senior staff of Region 2 **Hospital** Corporation immediately conducted a thorough investigation. It obtained reports on air quality control in the operating room, climate control reports for the drugs, and took swabs from various persons who may have been in contact with the four infected patients. Two doctors attended at the Charlotte County **Hospital** and found a bottle of Diprivan

and a syringe still in the O.R. This led to further investigations and reports, both at the laboratory of the Federal Department of Health and with the nursing staff as to any practice they had observed by Dr. Green in handling the anaesthetic agent. A learned report was received from the manufacturers of Diprivan on its properties and proper use and storage. There never was a formal hearing as such. No formal reports of committees were prepared or circulated.

There are two affidavits from doctors on staff at Region 2 **Hospital** Corporation in opposition to the application, in addition to Dr. Simon's affidavit attached to the affidavit of documents. Dr. Simon objected to production on the general grounds of physician/patient privilege, solicitor/client, some on the grounds of section 43.3(2)(a) of the *Evidence Act*, some of the 43.3(2)(b) of the *Evidence Act* and some of the common law principles of *Slavutych v. Baker* (1975) 55 D.L.R. (3d) 224 (S.C.C.). He did not specify which ground applied to which document.

Dr. David Beaudin is the Chairman of the Medical Quality and Resource Management Committee for Region 2 **Hospital** Corporation and that Committee has a number of different investigative committees to investigate, monitor and improve **hospital** care. One of the committees is a Peer **Review** Program and he has had a discussion with at least one physician who initially refused to participate in the program because of his concerns that comments and criticisms might become public.

A further affidavit in opposition to the application is filed by Dr. Mohan Iype, the Chief of Staff of the defendant Region 2 **Hospital** Corporation. He is also the Chairman of the Medical Advisory Committee and sets forth the names of various committees which are collectively known as Quality Assurance and Risk Management.

The Medical Advisory Committee acts in an advisory capacity to the Board of Trustees and to administration. It has set up various committees in the Charlotte County **Hospital** and other **hospitals** under its aegis to assist in carrying out its duties. I do not think anything hinges on naming the various committees and their functions. All do investigative work and monitor, maintain and seek improvements in **hospital** care.

The Order to Produce

6 The judge hearing the motion, Turnbull J., examined each of the 127 documents to which the parties objected either as being privileged under the protective umbrella of statutory provisions in the *Evidence Act*, R.S.N.B. 1973, c.E-11 or under the common law as set out in *Slavutych v. Baker*, [1976] 1 S.C.R. 254.

The Common Law Rule

7 In *Slavutych* the Supreme Court of Canada, *in obiter*, referred to the common law protection afforded to confidential communications as set out in Vol. 8 of *Wigmore on Evidence*, 3rd ed. (McNaughton Revision, 1961), para 2285. Spence J., at page 260, approved the reference from *Wigmore* as outlining four fundamental conditions necessary to the establishment of a privilege against the disclosure of communications:

(1) The communications must originate in a *confidence* that they will not be disclosed.

(2) The element of *confidentiality must be essential* to the full and satisfactory maintenance of the relation between the parties.

> (3) The *relation* must be one which in the opinion of the community ought to be sedulously *fostered.*
>
> (4) The *injury* that would inure to the relation by the disclosure of the communications must be *greater than the benefit* thereby gained for the correct disposal of litigation. [Italics in original]

8 The four conditions identified by Wigmore have been applied, or at least considered, in almost every Canadian jurisdiction and were again referred to by the Supreme Court of Canada in *R. v. Fosty*, [1991] 3 S.C.R. 263. Chief Justice Lamer, in adding potential to the extent of their range said at 289-90:

> ... This approach is consistent with the approach taken by this Court in *Slavutych v. Baker, supra*, and is, in my view, consistent with a principled approach to the question which properly takes into account the particular circumstances of each case. This is not to say that the Wigmore criteria are now "carved in stone", but rather that these considerations provide a general framework within which policy considerations and the requirements of fact-finding can be weighed and balanced on the basis of their relative importance in the particular case before the court. Nor does this preclude the identification of a new class on a principled basis.

See also *Bergwitz v. Fast* (1980), 108 D.L.R. (3d) 732 (B.C. C.A.) at 737-38 dealing with the fourth condition under *Wigmore; Smith v. Royal Columbian* ***Hospital*** (1981), 123 D.L.R. (3d) 723 (B.C. S.C.) according privilege and distinguishing *Bergwitz; Finley v. University* ***Hospital*** *Board* (1987), 33 D.L.R. (4th) 200 (Sask. Q.B.), balancing the respective interests in favour of the public; *F. v. Psychiatrist* (1984), 54 B.C.L.R. 319 (S.C.), disclosure not limited to reports; *Merrill Lynch, Royal Securities Ltd. / Ltée v. Granove* (1985), 35 Man. R. (2d) 194 (C.A.) employees' statements to investigators had to be produced; *Basse v. Toronto Star Newspapers Ltd.* (1985) 1 C.P.C. (2d) 105 (Ont. Master), production ordered of internal police reports; and *Skender v. Barker* (1985), 67 B.C.L.R. 263 (Master), letters to and from Law Society ordered produced.

9 As did the judge of first instance, I have reviewed each of the contested documents. I will deal with them on the basis of the two divisions under which they have been presented to us, the first ones as being privileged under the common law. Counsel for the **Hospital** Corporation claim common law privilege on items numbered 10 to 22. Item number 10 contains five letters or memos to Dr. Green concerning missing 1986 charts belonging to the **hospital**. There is no common law privilege in relation to these documents.

10 Items 11 to 20 and 22 to 26 are opinion evaluations of Dr. Green from various doctors. They are privileged under the common law as peer evaluations.

11 Item 21 is a letter to Dr. Green about the missing charts referred to in item 10. It is misdescribed in the affidavit of documents and is not privileged at common law. Dr. Green's counsel claims it should be excluded under s. 43.3(2)(b) of the *Evidence Act*. I will deal with that argument in the next section.

The Evidence Act

12 The *Evidence Act*, R.S.N.B. 1973, c. E-11 was amended in 1987 by adding s.43.3 to extend a privilege to certain **hospital** information and documents. Prior to that time, any protection came from the common law as mentioned in *Slavutych*, see Mr. Justice Freedman's comments in (1954) 32 C.B.R. 1.

13 The amendment to the *Evidence A ct* of New Brunswick defines "legal proceeding" and "witness" in the context of a **hospital** setting relating to evidence. It excuses a witness from providing certain information and re-

cords. It reads as follows:

43.3(1) In this section

"legal proceeding" means a proceeding in any court, including a proceeding for the imposition of punishment by fine, penalty or imprisonment to enforce an Act of the Legislature or a regulation made under that Act;

"witness" includes a person who, in connection with, or in the course of, a legal proceeding, is called upon to provide information, to answer, orally or in writing, a question or to produce a document, whether under oath or not.

43.3(2) A witness, whether a party to a legal proceeding or not, is excused from

(a) providing any information as to any proceeding before a committee established by a **hospital** to conduct any study, research or program for the purpose of medical education or improvement in medical or **hospital** care or practice, and

(b) producing any document made by a **hospital** or by a committee established by the **hospital**, prepared exclusively for the purpose of being used in the course of, or arising out of, any study, research or program, the dominant purpose of which is medical education or improvement in medical or **hospital** care or practice.

43.3(3) Subsection (2) does not apply to

(a) records maintained by **hospitals** as required by the *Public **Hospitals** Act* or the regulations, or

(b) medical records maintained by attending physicians pertaining to a patient.

43.3(4) A committee referred to in subsection (2) does not include a medical advisory committee exercising its functions respecting surgical and other privileges of the medical staff.

43.3(5) Notwithstanding that a witness

(a) is or has been a member of,

(b) has participated in the activities of, or

(c) has prepared a document for or has provided information to,

a committee referred to in subsection (2), that witness is not, subject to subsection (2), excused from answering any question or producing any document that that witness is otherwise bound to answer or produce.

14 Turnbull J. interpreted s.43.3 as follows and I agree, essentially, with his conclusion:

... In section 43.3(2)(a) privilege is extended to any information as to any proceeding before a committee. It is what went on or who expressed what opinions in the proceeding before the appropriate body that is privileged.

> I am of the opinion that subsection 43.3(2)(b) amends the law stated in the *Bergwitz* and *Finley* cases (supra) to the extent that committee reports (documents) the dominant purpose for which is medical improvement or education are also privileged. If they were not it would be fairly easy to glean approbation if any changes were instituted. It is not difficult to guess that the committee found fault in the *Bergwitz* case. Such reports prepared by the **hospital** or the appropriate committee are privileged if the dominant purpose is educational or to improve **hospital** care. The subsections are to be interpreted in their ordinary grammatical sense and not in a broad sense urged by counsel for the **Hospital** Corporation. I believe that subsection 43.3(5) must be read in conjunction with subsection 43.3(2) and only makes sense if 43.3(2)(a) and (b) receive their grammatical interpretation. A person who has been a member of the investigating committee or has prepared documents is not prohibited from giving his own opinion at a trial nor is a person who was on the fact finding team excused from producing any document unless it would be otherwise privileged by 43.3(2)(a) or (b) or at common law. I believe that subsection 43.3(3) has been added for an abundance of clarification and subsection 43.3(4) makes it clear that when the Medical Advisory Committee is exercising its function respecting privileges of medical staff this committee will not be shielded by privilege pursuant to subsection 43.3(2) but that committee in exercising that function will still be guided by the common law as set out in *Slavutych*, as regards documents before it.

15 Counsel for the **hospital** corporation advance the proposition that certain information in documents 46, 48, 51, 53, 54, 57, 64, 69, 74, 78, 79, 81, 82, 83 and 84 fall under the privilege accorded under s.43.3(2)(a). As well, they argue that document 65 comes under (a) as well as (b) and ought to be excluded from production.

16 Under s.43.3(2)(a) a witness is excused from providing information as to any proceeding before a committee established by a **hospital** for certain purposes. I do not see how the documents objected to would fall under (a). If they are to be excluded, it would have to be on the basis of the wording in (b).

17 In reviewing documents 23 to 43 and 44 to 85 it is important to note two qualifying words in s. 43.3(2)(b): "exclusively" and "dominant purpose". These words are intended to limit the exclusionary privilege to documents generated by a **hospital** or committee. A **hospital** or **hospital** committee cannot be required to produce a document prepared exclusively for the purpose of being used in the course of, or arising out of, any study, research or program, the dominant purpose of which is medical education or improvement in medical or **hospital** care or practice.

18 Tracking closely the footsteps of the motions judge, I conclude that although certain aspects of the matters dealt with in committees related to improvements in care the documents did not come into existence exclusively or for any dominant purpose relating to any study, research or program.

19 Item 27 is a letter of complaint about Dr. Green's tardiness in arriving at the operating room; item 28 reminds Dr. Green of protocol; item 29 relates to his unavailability by beeper; item 30 refers to the admission of a patient admitted but not seen by him; item 31 asks for a response to five incidents; item 32 refers to two patients admitted by the doctor but not seen by him; item 33 alleges neglect; item 34 is a complaint from two residents from Deer Island; item 35 is a response from Dr. Green to a complaint from an extra-mural nurse; item 36 refers to the doctor's response to a page call; item 37 relates to an emergency; item 38 relates to his reappointment to active staff; items 39 and 40 refer to Dr. Green's completion of Workers' Compensation files; items 41 and 42 are letters of recommendation addressed to whom it may concern, and item 43 is a letter to Dr. Green concerning an offer of a contract for anaesthesia services. All these documents fail the exclusivity and dominant purpose

limits in (b). This applies to items 10 and 21 objected to by Dr. Green's counsel as well.

20 Counsel for Dr. Green claims that items 41, 42 and 132 are privileged at common law. The problem is that although they are matters of opinion, they are addressed "to whom it may concern". As a result they have lost the protective covering of confidentiality as originating in a confidence that they will not be disclosed.

21 The documents listed as items 44 to 85 contain three items which do not relate specifically or incidentally to investigations carried out by the **hospital** concerning Dr. Green and the use of certain drugs in the Charlotte County **Hospital** around the time of Mr. Doyle's admission and operation. Item 46 is an operating room schedule; item 51 is an article concerning post surgical infections and item 84 is a memo that Dr. Green has agreed to follow Dr. Davies' directives. None of these is privileged either at common law as confidential or under the exclusive and dominant purpose test under s. 43.3(2)(b).

Investigations

22 The other 39 documents arose as a result of the resultant problems sustained by Mr. Doyle and others at the Charlotte County **Hospital**. They relate specifically or incidentally to investigations launched by **hospital** authorities in response to an obvious crisis situation. The **hospital** authorities are public servants of a public institution. It is their legal responsibility to thoroughly investigate and, if possible, determine the cause of any complaint precipitating the crisis.

23 Undoubtedly some of the results in some of the documents were produced by a committee or committees established by the **hospital** and might well be called a study directed at medical education or improvement in medical **hospital** care or practice. These ingredients are essentials under s. 43.3(2)(b). What is missing are the two integral features of having been prepared "exclusively" and for the "dominant purpose" of medical education or improvement in care or practice.

24 The dominant purpose for the creation of the committees was a response to apparent common disasters to certain patients. The documents cannot be given protection under (2)(b).

25 As well, in my opinion, these important results cannot be screened from scrutiny under the common law. The investigation results cannot survive scrutiny of the four common law requirements developed by *Wigmore* and referred to in *Slavutych* and *Fosty* by the Supreme Court of Canada. Even if one were to accept, which I do not, an argument that the first three requirements had been met, (1) that the communications in the committees' reports originated in a *confidence* that they would not be disclosed, (2) that *confidentially* was essential and (3) that the **hospital** community would sedulously foster such a relation, the argument dismally fails the balance test.

26 In this case, the **hospital** authorities undoubtedly had a substantial interest in promptly launching their investigation into what went wrong at the Charlotte County **Hospital**. In fact, it was their public duty, even their fiduciary duty, to do so. In balancing the respective interests of the **hospital** community and that of the litigant, I conclude in favour of the litigant. Even in cases where the announced creation of the committee was identified as relating to care and practice, I would favour disclosure of any parts of a report relating to particular incidents relating to litigation or potential litigation unless circumstances existed showing that confidentiality, or some other crucial aspect, was essential under public policy. Disclosure should be ordered in cases where the matter of the complaint under **review** is the subject of the litigation. See *Bergwitz v. Fast* and *Finley v. University* ***Hospital*** *Board* and see *Smith v. Royal Columbian* ***Hospital*** for a distinguishable contrary view. As well, I would con-

fine the decision in *Bainbridge v. Crawshaw*, [1993] N.B.J. No. 618 (QL) (Q.B.) to the unique circumstances of that case.

27 One item remains to be considered, number 109, a document from the State of Connecticut purporting to be a consent order signed by David J.M. Green, M.D. and concerning the suspension of his licence to practice medicine in that state for five years, a stay of the suspension and his probation for five years. The document, further states that the consent order is not subject to reconsideration, collateral attack, or judicial **review** under any form or in any forum. The document is not privileged under the common law as contended by Dr. Green's counsel nor under the *Evidence Act* as contended by counsel for the **hospital** corporation.

The Intervenors

28 The two intervenors, the Healthcare Association and the Medical Society have brought serious arguments before the court in relation to the overall principles supporting privilege in **hospital** matters. They contend that it is important that the balance between individual recovery rights and the protection of patient care in general must tip towards the latter. They point out that much information is already available through other **hospital** records relating directly to the patient. They evidence great concern over the general issue of producing documents which arise in the **review** process conducted internally in **hospitals** through a series of committees principally made up of medical practitioners and other health care personnel.

29 Their argument is that if protection of what goes on in these committees is not available, then the process will not function properly. I appreciate the concerns of the medical profession and **hospital** administrations in their difficult and oft times trying efforts to perfect and improve health care. To this end, I think that they are correct when they implore the courts to be cautious in balancing rights and protections. I have taken their concerns into account in arriving at the conclusions which I have in this appeal.

Conclusion

30 I would allow the appeal in part and exclude various peer evaluations, items 11-20 and 22-26, as privileged under the common law. The appeal with respect to the vast majority of items objected to is dismissed. In view of the mixed success on the appeal, I would award costs in favour of the respondent, who was largely successful in his defence of the appeal, in the sum of $1,200.00 jointly and severally against the Region 2 **Hospital** Corporation and Dr. David Green.

Appeal allowed in part.

END OF DOCUMENT

Tab 18

HEALTH CARE AT THE CROSSROADS:

Strategies for Improving the Medical Liability System and Preventing Patient Injury

Joint Commission
on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

HEALTH CARE AT THE CROSSROADS:

Strategies for Improving the Medical Liability System and Preventing Patient Injury

Joint Commission
on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

Joint Commission Public Policy Initiative

This white paper is a product of the Joint Commission's Public Policy Initiative. Launched in 2001, this initiative seeks to address broad issues that have the potential to seriously undermine the provision of safe, high-quality health care and, indeed, the health of the American people. These are issues that demand the attention and engagement of multiple publics if successful resolution is to be achieved.

For each of the identified public policy issues, the Joint Commission already has relevant state-of-the-art standards in place. However, simple application of these standards, and other unidimensional efforts, will leave this country far short of its health care goals and objectives. Thus, this paper does not describe new Joint Commission requirements for health care organizations, nor even suggest that new requirements will be forthcoming in the future.

Rather, the Joint Commission has devised a public policy action plan that involves the gathering of information and multiple perspectives on the issue; formulation of comprehensive solutions; and assignment of accountabilities for these solutions. The execution of this plan includes the convening of roundtable discussions and national symposia, the issuance of this white paper, and active pursuit of the suggested recommendations.

This paper is a call to action for those who influence, develop or carry out policies that will lead the way to resolution of the issue. This is specifically in furtherance of the Joint Commission's stated mission to improve the safety and quality of health care provided to the public.

Table of Contents

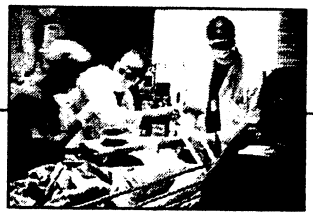
INTRODUCTION

Increasingly the subject of newspaper headlines and even physician picket lines, the current "medical liability crisis" is beginning to rally policymakers to become serious about reforms to the current tort system. Efforts to stem the rise in liability insurance premiums have most commonly taken the form of seeking caps on non-economic damages awarded in medical liability cases. Indeed, in several states that have implemented such caps, liability insurance premiums have increased less than in states without caps.[1] But capping damages on the back end of litigation does not address all of the factors that lead to litigation on the front end. At a time of growing awareness and acknowledgement of medical error – and active efforts to address this problem -- the effectiveness of the tort system itself in deterring negligence, compensating patients, and exacting corrective justice is being called into question.

There is in fact a fundamental dissonance between the medical liability system and the patient safety movement. The latter depends on the transparency of information on which to base improvement; the former drives such information underground. As a result, neither patients nor health care providers are well served by the current medical liability system. This is seemingly not a real "system," but rather a patchwork of disjointed and inconsistent decisions that has limited ability to inform the development of improved health care practices.[2]

Several studies have, with remarkable consistency, revealed the inconsistency of the medical liability system in determining negligence and compensating patients. The Harvard Medical Practice study found that two percent of negligent injuries resulted in claims, and only 17 percent of claims appeared to involve negligent injury.[3] Subsequent studies conducted in Colorado and Utah found similar results.[4] Few injured patients receive compensation through the medical liability system, and those who do receive highly variable recompense, even for injuries that appear to be quite similar.

It is estimated that at least $28 billion is spent each year on the inter-related combination of medical liability litigation and defensive medicine.[5] The latter involves the excessive ordering of non-essential tests and treatments solely for risk management purposes. In a country in which escalating health care costs and diminishing health care access are top-of-mind public concerns,[6] these costs are increasingly indefensible, especially in the absence of evidence that such expenditures improve patient safety and health outcomes.



AMONG THE SPECIFIC ISSUES ADDRESSED BY THE ROUNDTABLE WAS THE EXTENT TO WHICH THE CURRENT MEDICAL LIABILITY SYSTEM UNDERMINES OR SUPPORTS PATIENT SAFETY, AND IF, INDEED, IT UNDERMINES PATIENT SAFETY, ARE EFFECTIVE REMEDIAL ACTIONS POSSIBLE?

INTRODUCTION

On average, a medical liability case takes three to five years to come to closure.[7] Closed claims provide valuable data for researchers to mine, but because of the lengthy elapse of time, opportunities for swift intervention to address unsafe practices are often lost. Cases that reach settlement in the intervening years are typically cloaked by "gag clauses" that require complainants' silence, and squelch efforts to elucidate and ameliorate the factors that lead to injury.

The core of the Joint Commission's mission is to continuously improve the safety and quality of care provided to the public. In pursuit of its mission, the Joint Commission has, over the past decade, redrawn its accreditation standards to more sharply focus on patient safety. In addition, it has, since 1996, operated a national voluntary adverse event reporting database, and in recent years, has used this database to develop and incorporate into its accreditation process a series of concrete, setting-specific National Patient Safety Goals and Requirements. Among Joint Commission standards is a requirement that health care organizations, through the responsible physician, disclose unexpected outcomes and adverse events to their patients. The ability of health care organizations to comply with this standard and others, as well as to report adverse events to the Joint Commission's database, is severely undermined by the medical liability system. The liability system supports a "wall of silence"[8] -- discouraging disclosure and inhibiting efforts to create cultures of safety inside health care organizations and among practitioners.

Creating cultures of safety within health care and improving quality and access -- indeed, making health care truly better -- requires that legal and medical institutions work together.[9] In order to frame the complex factors and issues that need to be addressed in order to accomplish such alignment, the Joint Commission convened an expert Roundtable. Among the principal specific issues addressed by the Roundtable were the extent to which the current medical liability system undermines or supports patient safety, and if, indeed, it undermines patient safety, are effective remedial actions possible? Further, if the aforementioned dissonance is serious and real, what short-term steps should be taken to moderate the negative impacts of the system? And finally, what potential long-term alternatives to the current tort system should be considered and how might they best be pursued? This white paper represents a culmination of these discussions. The many recommendations contained herein are all actionable and should be pursued, in no small measure, to better serve the common good.

THERE IS IN FACT A FUNDAMENTAL DISSONANCE BETWEEN THE MEDICAL LIABILITY SYSTEM AND THE PATIENT SAFETY MOVEMENT. THE LATTER DEPENDS ON THE TRANSPARENCY OF INFORMATION ON WHICH TO BASE IMPROVEMENT; THE FORMER DRIVES SUCH INFORMATION UNDERGROUND.

Executive Summary

Recommendation I. Pursue Patient Safety Initiatives that Prevent Medical Injury

When the Institute of Medicine released its landmark report, *To Err Is Human,*[10] the frequent occurrence of medical error went public. Now, five years after the IOM report, error remains ubiquitous in health care delivery. To be sure, activities and initiatives aimed at improving patient safety have been and continue to be pursued. However, there are obstacles within health care organizations that stymie improvement – most notably, lack of will, resources and knowledge.

The axiom, "you learn from your mistakes" is too little honored in health care. Near-miss and error reporting is an essential component of safety programs across safety-conscious industries. Within health care, though, many physicians are often reluctant to engage in patient safety activities and be open about errors because they believe they are being asked to do so without adequate assurances of legal protection.[11] The stifling specter of litigation results in the under-reporting of adverse events by physicians and avoidance of open communications with patients about error.[12]

The IOM report suggests that 90 percent of medical errors are the result of failed systems and procedures that are poorly designed to accommodate the complexity of health care delivery. If properly designed, these systems and procedures could better prevent inevitable human errors from reaching patients. But understanding the root causes of errors requires their divulgence in the first place. In sharp contrast to the systems-based orientation of the patient safety movement, tort law targets individual physicians.[13]

I.A Strengthen Oversight and Accountability Mechanisms to Better Ensure the Competencies of Physicians and Nurses

As the IOM reports make clear, multiple broken systems can be identified in the majority of cases in which a serious adverse event has occurred. However, there remains today too little effort to unveil the specific contributory factors to such occurrences. That said, a systems-based approach to quality improvement does not preclude individual accountability. Accountability mechanisms – licensure, certification, and peer review – also need to be strengthened to ensure an optimally qualified health care workforce. The tort system should not be the net to snare incompetent physicians, and it cannot be effective, when it is cast so wide.

Executive Summary

The American Board of Medical Specialties (ABMS) is now in the process of implementing encompassing new requirements for the maintenance of board certification for the 24 medical specialties it represents. These requirements would eventually apply to over 90 percent of practicing physicians. Following suit, the Federation of State Medical Boards is also pursuing an agenda for the maintenance of physician licensure.

While the legal system is often maligned by physicians, some physicians do not hesitate to use it to stave off loss of hospital privileges and licensure. Going forward, to avoid the quagmire in which hospitals often find themselves when they attempt to curtail or remove privileges, these institutions need to be thorough and deliberate in their initial granting of privileges, to consider granting new privileges for shorter periods of time, and to apply objective measures of performance before renewing privileges. This approach would be synchronous with the movement of certification boards to grant time-limited board certification, and to undertake rigorous competency assessment on a continuing basis.

Administrative and clinical leadership must also take greater initiative to ensure the competency of their nurses. Nurse staffing shortages have made the hiring of new nurses a priority, but newly graduated nurses typically receive far too little training before assuming clinical responsibilities, and the monitoring of clinical performance is uneven at best. The growing use of external staffing agencies to fill staffing gaps only makes this problem worse.

I.B Allow health care researcher access to open liability claims to permit early identification of problematic trends in clinical care

One of health care's principal patient safety success stories is anesthesiology. The American Society of Anesthesiologists uses case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project – created in 1985 -- contains 6,448 closed insurance claims. Analyses of these claims have, for example, revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.

Closed claims data analysis is the one way in which the current medical liability system helps to inform improvements in care delivery. However, reliance on closed claims for information related to error and injury is cumbersome at best. It may take years for an insurance or malpractice claim to close. These are years in which potentially vital information on substandard practices remains unknown. Providing patient safety researchers with access to open claims, now protected from external examination, could vastly improve efforts aimed at identifying worrisome patterns in care and designing appropriate safety interventions.

EXECUTIVE SUMMARY

I.C ENCOURAGE APPROPRIATE ADHERENCE TO CLINICAL GUIDELINES TO IMPROVE QUALITY AND REDUCE LIABILITY RISK

Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance.[14] In court, clinical guidelines are increasingly invoked to prove or disprove deviations from the standard of care. But there is a more significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to clinical guidelines can have a significant role in reducing legal risk.[15] The study, which focused on obstetrical patients, found a six-fold increase in risk of litigation for cases in which there was a deviation from relevant clinical guidelines.[16] Further, one-third of all obstetric claims analyzed in the study were linked to non-compliant care.[17]

I.D SUPPORT TEAMWORK DEVELOPMENT THROUGH TEAM TRAINING, "CREW RESOURCE MANAGEMENT," AND HIGH-PERFORMING MICROSYSTEM MODELING

Teamwork -- indeed, team training -- has been identified by patient safety experts as an essential factor in reducing the risk of medical error. In aviation, "Crew Resource Management" (CRM) is the methodology used to guide team development among pilots, flight attendants and other crew. In this context, predefined roles and responsibilities for various scenarios help to assure the safety of every flight. Consistently applying such an approach to health care delivery could increase the timeliness and accuracy of communications – breakdowns of which are commonly implicated sources of serious adverse events. This could also help to enlist clinicians and support staff in committing to a common goal – safe and effective care – in the often high-pressure and chaotic environments of health care. Unfortunately, health care professionals are not educated and trained to work as teams or even team members. Recreating the culture of health care delivery to value team-based care must begin at the earliest point of intervention -- health care professional education -- and be continuously reinforced in practice.

Clinical units that successfully foster strong team-based approaches to health care delivery do exist. In their research, Nelson, Batalden *et al* identified high-performing, front-line clinical units called microsystems.[18] A microsystem is further defined as a small group of people who regularly work together to provide care to discrete sub-populations of patients, and share business and clinical aims, linked processes, and a common information environment.[19] Microsystems are often embedded in larger organizations – the "macrosystem."

High-performing microsystems produce superior outcomes and cost-effective care, and at the same time, provide positive and attractive working environments.[20] These units are also characterized by the high value placed on patient safety, as well as compliance with policies and other requirements.

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I.E Continue to leverage patient safety initiatives through regulatory and other quality oversight bodies

A study recently published in *Health Affairs* by Devers *et al* concludes that the major driver for hospital patient safety initiatives is Joint Commission requirements.[21] The majority of hospitals surveyed as part of the study explicitly noted that they were working to meet Joint Commission requirements – developing better processes for reporting, analyzing, and preventing sentinel events; meeting patient safety standards, including acknowledgement of leadership's accountability for patient safety and the creation of a non-punitive culture; and meeting the specific National Patient Safety Goals.[22]

In the Devers *et al* study, the description of hospital patient safety initiatives also highlights the influence of other third parties in driving patient safety improvements. The Leapfrog Group was frequently mentioned by study participants, particularly with regard to its influence in driving the adoption of Computerized Physician Order Entry (CPOE) systems.

I.F Encourage the adoption of information and simulation technology by building the evidence-base of their impacts on patient safety, and pursue proposals to offset implementation costs

In its *Crossing the Quality Chasm* report, The Institute of Medicine underscores the importance of information technology as a key factor in meeting several of its quality aims. Since then, the momentum toward widespread adoption of information technology has accelerated. Leading proponents include the National Alliance on Healthcare Information Technology, the Markle Foundation's Connecting for Health initiative, and now the Department of Health and Human Services itself, with the appointment of a national coordinator for IT initiatives last year.

I.G Leverage the creation of cultures of patient safety in health care organizations

The pressures on health care leaders today are great. Increasing costs, increasing demand for services, and unfavorable reimbursement policies mean that patient "throughput" – the time in which patients move into, through, and out of the health care setting – must be accelerated to maintain revenues. This acceleration of the care process heightens the risk of medical error, and compromises effective patient-practitioner communications.[23] Yet, in this environment, a culture of patient safety must be created and emulated from the top down. This responsibility lies both with individual health care organizations and practitioners, and with those who set health care policy in this country.

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I.H Establish a federal leadership locus for advocacy of patient safety and health care quality

Until this country both elevates the importance of quality and safety problems and engages in a coordinated approach to solutions, it will be difficult to make significant strides in addressing the foundational patient safety problems that persist today. Creation of an Office of Health Care Quality in the Department of Health and Human Services could provide a powerful platform for setting priorities and direction for improving patient safety and health care quality. Such an office could also coordinate and enhance the efforts of established private and public sector bodies already engaged in patient safety and quality improvement activities.

I.I Pursue "pay-for-performance" strategies that provide incentives to focus on improvements in patient safety and health care quality

New public and private sector payer initiatives designed to "pay for performance" may provide a new opportunity to align incentives for increasing safety and improving quality and patient outcomes. In 2003, CMS launched a demonstration project in partnership with Premier Inc. to test the effectiveness of paying hospitals more for better performance according to selected measures. In 2005, a new demonstration project was initiated for large medical group practices. Small but symbolically significant bonuses are to be based on results in the management of specific clinical conditions and procedures. The pay-for-performance concept essentially envisions rewards for desired behaviors and outcomes.

Recommendation II. Promote Open Communication Between Patients and Practitioners

Lack of disclosure and communication is the most prominent complaint of patients, and their families, who together have become victims of medical error or negligence. Years of expensive and wounding litigation often ensue when families are sometimes only seeking answers.

II.A Involve health care consumers as active members of the health care team

Health care consumers are playing an important role in the patient safety movement – as educated advocates for change based on their own experiences. When individuals' stories reach the right audience, listeners pay heed. Health care consumers can specifically help to prevent adverse events by being active, informed, and involved members of the health care team.

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For patients and family members, the physical and emotional devastation of medical error cannot be easily overcome. What they want most out of their ordeal is honest and open dialogue about what went wrong, and a "legacy" – having their experience serve as a lesson for prevention in the future.[24] Seldom are such communications and assurances forthcoming.

II.B ENCOURAGE OPEN COMMUNICATION BETWEEN PRACTITIONERS AND PATIENTS WHEN AN ADVERSE EVENT OCCURS

An unintended consequence of the tort system is that it inspires suppression of the very information necessary to build safer systems of health care delivery. When it comes to acknowledging and reporting medical error, there is too often silence between practitioners and patients; practitioners and their peers; practitioners and the organizations in which they practice; and health care organizations and oversight agencies.

One of the basic principles of patient safety is to talk to and listen to patients.[25] Several elements are fundamental to any disclosure effort. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology.[26]

The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients, and to their family members when appropriate. A recent study confirms that many hospitals – half of those surveyed -- are reluctant to comply with this standard for fear of medical liability suits.[27] If disclosure is taken a step further to the offer of an apology, hospitals and physicians are even more likely to gravitate to traditional "defend and deny" behaviors. But there is increasing awareness that openness has the potential to heal, rather than harm, the physician-patient relationship. A growing number of hospitals, doctors and insurers are coming around to the idea that apologies may save money by reducing error-related payouts and the frequency of litigation.[28]

II.C PURSUE LEGISLATION THAT PROTECTS DISCLOSURE AND APOLOGY FROM BEING USED AS EVIDENCE AGAINST PRACTITIONERS IN LITIGATION

Today, some prominent medical centers have adopted policies that urge doctors to disclose their mistakes and to apologize.[29] Insurers, too, are increasingly urging apologies.[30] And, a growing number of states are passing laws that protect an apology from being used against a doctor in court.[31] More such protections will be needed in order for most caregivers and organizations to feel comfortable with apologies, despite the ethical imperatives underlying such disclosure.

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II.D ENCOURAGE NON-PUNITIVE REPORTING OF ERRORS TO THIRD PARTIES THAT PROMOTES SHARING OF INFORMATION AND DATA ANALYSIS AS THE BASIS FOR DEVELOPING SAFETY IMPROVEMENT STRATEGIES

Few caregivers and health care organizations voluntarily break through the wall of silence to report life-threatening medical errors beyond the walls of their institutions. The Joint Commission has had a voluntary reporting system since 1996, but its Sentinel Event Database receives only about 400 new reports of events each year – well below the 44,000 to 98,000 medical error-related deaths estimated by the IOM to occur each year.

A number of states now have mandatory error reporting systems of various types.[32] One of the most active, the New York State Patient Occurrence Report and Tracking Systems (NYPORTS), logged approximately 30,000 reports in 2003.[33] A new reporting system in Pennsylvania captures reports of near-misses as well as actual errors. Reporting systems can capture enormous volumes of data, but without the requisite resources to analyze the data and translate it into useful information, their potential is far from being fully realized. Other types of external reporting systems include voluntary reporting systems tailored to specific health care segments and medical specialty-based reporting systems.[34]

There remains a substantial lack of clarity as to whether error analyses reported to a third-party, such as a state agency or the Joint Commission, are afforded legal privilege protections. This lack of certainty of protection continues to hamper reporting efforts that could otherwise yield essential information for making breakthrough improvements in health care safety.

II.E ENACT FEDERAL PATIENT SAFETY LEGISLATION THAT PROVIDES LEGAL PROTECTION FOR INFORMATION REPORTED TO DESIGNATED PATIENT SAFETY ORGANIZATIONS

Patient safety legislation – under consideration by the Congress for several years and currently pending reintroduction in the current Congress – proposes legal protection for information reported to any Patient Safety Organization, as defined in the legislation. Passage of patient safety legislation of this nature would provide the cornerstone for effective reporting systems that assure confidentiality and encourage the sharing of lessons learned from the analyses of adverse events.

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Recommendation III. Create an Injury Compensation System that is Patient-Centered and Serves the Common Good

Only a small percentage (2-3 percent) of patients who are injured through medical negligence ever pursue litigation, and even fewer ever receive compensation for their injuries.[35] Those who are awarded compensation wait an average of five years to receive it.[36] Clearly, the current tort system falls short in compensating injured patients. As for exacting justice, there is often little correlation between court findings of negligence and actual negligence.[37] And rather than deterring negligence, there is a common refrain among physicians that the current tort system "keeps us from doing things that we, as good professionals, would naturally do."[38]

A central question is how the medical liability system can be restructured to actively encourage physicians and other health care professionals to participate in patient safety improvement activities.[39] The goal of any such restructuring should be to reduce litigation by decreasing patient injury, by encouraging open communication and disclosure among patients and providers, and by assuring prompt and fair compensation when safety systems fail.

III.A Conduct demonstration projects of alternatives to the medical liability system that promote patient safety and transparency, and provide swift compensation to injured patients

Numerous proposals have been suggested for improving the medical liability system over the past several years. These proposals center on three broad approaches: 1) creation of alternative mechanisms for compensating injured patients, such as through early settlement offers; 2) resolving disputes through a so-called "no-fault" administrative system or through health courts; and 3) shifting liability from individuals to organizations.[40] Though these approaches are distinct, they are not in conflict. One could imagine an injury resolution system that incorporates the characteristics of all three.

Inherent in any alternative to the current tort system must be a high priority for disclosure -- an acknowledgement of the error or injury, an apology, and assurances that steps will be taken to avoid such an error in the future.

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A 2003 IOM report calls for demonstration projects to test the feasibility and effectiveness of alternative injury compensation systems that are patient-centered and focused on safety.[41] Such demonstration projects are needed to begin the process of mitigating the periodic medical liability crises that, aside from economic factors, result from the delivery of unsafe care, unreliable adjudication of claims, and unfair compensation for injured patients.

III.B Encourage Continued Development of Mediation and Early-Offer Initiatives

Some states and liability insurance companies are already pursuing reforms to reduce reliance on litigation as a means to resolve injury claims.

In 2002, Pennsylvania became the first state to require hospitals to disclose, in writing, adverse events to patients or their families.[42] Nevada and Florida have since followed Pennsylvania's lead.[43] Pennsylvania is also the site of a Pew-sponsored demonstration project that encourages mediated dispute resolution.[44] As part of this model, physicians are encouraged to disclose adverse events to their patients and to apologize.[45] Patients or their families are provided with an early and fair offer of compensation, and the opportunity for mediation to resolve disputes.[46] It is too soon to know the full ramifications of the Pew-sponsored project, but early indications are that it has been successful in mitigating litigation.[47]

COPIC Insurance Company, a physician-owned liability insurer in Colorado, initiated its "3Rs" (respect, respond and resolve) program in 2000. Under this program, each insured physician is encouraged to communicate openly with the patient if an adverse event occurs, and to offer an apology when warranted.[48] COPIC pays for patient expenses, and also reimburses for lost wages.[49] Importantly, patients are not asked to waive their rights to litigation.[50] Since its inception, none of the cases addressed through the 3Rs program has gone to litigation.[51]

Comprehensive medical liability reform is the long-term solution for resolving the issues inherent in today's system, but there are actions that can be taken in the intermediate term that would bring greater integrity and transparency to the process.

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III.C Prohibit confidential settlements — so-called "gag clauses" — that prevent learning from events that lead to litigation

Medical liability claims are often settled before they reach trial, or before the trial ends in judgment. Terms of these settlements typically include a "gag clause" that requires the confidential sequestering of all information related to the case. Such confidential settlement offers may encourage quick resolution, but this is achieved at the cost of forever barring access to potentially important information that could be used to improve the quality and safety of care.

III.D Redesign or replace the National Practitioner Data Bank

Physicians named in medical liability judgments and settlements, as well as disciplinary actions, are reported to the National Practitioner Data Bank (NPDB). The primary reason for the existence of the NPDB is to permit hospitals and licensing boards to track physician performance issues. Since its inception, questions have continued to be raised about the validity and reliability of the NPDB.[52] A 2000 GAO report cited a multitude of NPDB problems, including underreporting of disciplinary actions, which, the report states, is a far better expression of physician competence than medical liability claims.[53] In fact, medical liability claims data constitute 80 percent of the information contained in the NPDB.[54] The information the data bank contains is also characterized in the GAO report as substantially incomplete – lacking, for example, any information as to whether the standard of care was considered when a claim was settled or adjudicated[55]

There is a need for a centralized information or sources that reliably capture important inputs about the performance of physicians and other practitioners, but other options than the NPDB exist. For instance, the Federation of State Medical Boards (FSMB) regularly makes information on disciplinary actions taken against physicians publicly available. It has now been five years since the release of the GAO report critical of the NPDB, and no substantial progress has been made to implement its recommendations. Given the relative ineffectiveness of the NPDB, it either needs to be substantially redesigned or its responsibilities need to be reassigned to other more reliable information repositories.

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III.E Advocate for court-appointed, independent expert witnesses to mitigate bias in expert witness testimony

Accountability for health care professional competency lies with the individual and his or her licensing and certification boards, and employers. This accountability should increasingly extend to the conduct of physicians who act as expert witnesses in medical liability cases. As many who have participated in a medical liability case can attest, expert opinion is subject to substantial potential bias when that opinion is paid for by either the defendant or the plaintiff in a case.[56] According to the Federation of State Medical Boards, expert witnesses who give false or misleading testimony are subject to disciplinary action.[57] In the long term, court-appointed experts that are independent of either plaintiffs or defendants are more likely to provide objective support to the litigation process.

Conclusion

It is clearly time to actively explore and test alternatives to the medical liability system. The goal of such alternatives is not to legally prescribe "blame-free" cultures. Rather, the goal is to stimulate the creation of "just cultures," that is, health care environments that foster learning – including learning from mistakes – but that also emphasize individual accountability for misconduct. Inherent in any viable alternative for addressing medical liability claims should be the potential for fairly compensating greater numbers of injured patients, while allowing health care practitioners and providers the opportunity to reveal error, learn from such errors, and ensure that they are not repeated.

Redesigning the medical liability system will necessarily be a long-term endeavor. Meanwhile, more and continued efforts aimed at fostering transparency among provider organizations, practitioners, and patients; seeking alternatives to litigation; leveraging the development of patient safety cultures; treating health care providers fairly; and honoring patients are both noble goals and practical necessities that must be actively pursued.

INHERENT IN ANY VIABLE ALTERNATIVE FOR ADDRESSING MEDICAL LIABILITY CLAIMS SHOULD BE THE POTENTIAL FOR COMPENSATING GREATER NUMBERS OF INJURED PATIENTS, WHILE ALLOWING HEALTH CARE PROVIDERS THE OPPORTUNITY TO REVEAL ERROR, LEARN FROM SUCH ERRORS, AND ENSURE THAT THEY ARE NOT REPEATED.

I. Pursue Patient Safety Initiatives that Prevent Medical Injury

Five Years Hence

When the Institute of Medicine released its landmark report, *To Err Is Human,*[58] the frequent occurrence of medical error went public. Now, five years after the IOM report, error remains ubiquitous in health care delivery. To be sure, activities and initiatives aimed at improving patient safety have been and continue to be pursued. The health care industry has embraced the safety efforts of other industries, such as aviation and manufacturing, though it has not yet been able to emulate the successes realized in these industries. There are obstacles within health care organizations that stymie improvement – most notably, lack of will, resources and knowledge. These can be overcome with hard work and commitment, or, in the words of Paul O'Neill, "when safety becomes a precondition for all other priorities." But the medical liability system provides a far more formidable obstacle to meeting patient safety improvement goals than the obstacles that exist within health care organizations.

The axiom, "you learn from your mistakes" is too little honored in health care. Near-miss and error reporting is an essential component of safety programs across safety-conscious industries. Within health care, though, many physicians are often reluctant to engage in patient safety activities and be open about errors because they believe they are being asked to do so without adequate assurances of legal protection.[59] The stifling specter of litigation results in the under-reporting of adverse events by physicians and avoidance of open communications with patients about error.[60]

The IOM report suggests that 90 percent of medical errors are the result of failed systems and procedures that are poorly designed to accommodate the complexity of health care delivery. If properly designed, these systems and procedures could better prevent inevitable human errors from reaching patients. But understanding the root causes of errors requires their divulgence in the first place. In sharp contrast to the systems-based orientation of the patient safety movement, tort law targets individual physicians.[61]

Taking Account

All doctors, even the nation's best doctors, make mistakes.[62] Despite its high-tech progress, health care delivery remains very much a human endeavor. Statistics suggest the strong likelihood that every surgeon will be named in a suit during his or her career.[63] The tort system's blunt weapon seems ill-suited when it is potentially directed at every person practicing medicine. As the IOM reports make clear, multiple broken systems can be identified in the majority of cases in which a serious adverse event has occurred. However, there remains today too little effort to unveil the specific contributory factors to such occurrences. That said, a systems-based approach to quality improvement does not preclude individual accountability. Accountability mechanisms – licensure, certification, and peer review – also need to be strengthened to ensure an optimally qualified health care workforce. The tort system should not be the net to snare incompetent physicians, and it cannot be effective, when it is cast so wide.

The American Board of Medical Specialties (ABMS) is now in the process of implementing encompassing new requirements for the maintenance of board certification for the 24 medical specialties it represents. Specialty boards already must provide recertification programs and time-limited certificates.[64] Additionally, physicians will be expected to continuously meet core competency requirements respecting patient care, medical knowledge, practice-based learning and improvement, interpersonal and communications skills, professionalism, and systems-based practice.[65] These requirements would eventually apply to over 90 percent of practicing physicians.

Following suit, the Federation of State Medical Boards is also pursuing an agenda for the maintenance of physician licensure. But efforts to strengthen the stringency of medical licensure requirements are not necessarily embraced by the field of medicine. In 2004, the Federation of State Medical Boards instituted a clinical and communication skills assessment as a requirement of physician licensure. This change was met with a firestorm of resistance, despite its potential benefits for physicians and the public, mainly on the grounds that such skills assessment should be the responsibility of medical schools and not tied to licensure. Physicians are most often sued, not for bad care, but for inept communication. Physicians who communicate poorly with patients and families, and who otherwise have a bad "bedside manner," are sued more often than physicians who communicate effectively.[66]

While the legal system is often maligned by physicians, some physicians do not hesitate to use it to stave off loss of hospital privileges and licensure. Hospitals and state medical boards that pursue the removal of a physician's right to practice often find themselves in the middle of intense legal battles. These legal maneuvers consume hospital and medical board resources. And, for hospitals, the drain on resources, plus the loss of income the physician otherwise generates, can stifle motivation to take action.

Going forward, to avoid the quagmire in which hospitals often find themselves when they attempt to curtail or remove privileges, these institutions need to be thorough and deliberate in their initial granting of privileges, to consider granting new privileges for shorter periods of time, and to apply objective measures of performance before renewing privileges. This approach would be synchronous with the movement of certification boards to grant time-limited board certification, and to undertake rigorous competency assessment on a continuing basis.

THE AXIOM, "YOU LEARN FROM YOUR MISTAKES" IS TOO LITTLE HONORED IN HEALTH CARE. NEAR-MISS AND ERROR REPORTING IS AN ESSENTIAL COMPONENT OF SAFETY PROGRAMS ACROSS SAFETY-CONSCIOUS INDUSTRIES.

Administrative and clinical leaders must also take greater initiative to ensure the competency of their nurses. Nurse staffing shortages have made the hiring of new nurses a priority, but newly graduated nurses typically receive far too little training before assuming clinical responsibilities, and the monitoring of clinical performance is uneven at best. The growing use of external staffing agencies to fill the staffing gaps only makes this problem worse. According to Joint Commission data, insufficient staffing has been implicated in 24 percent of reported sentinel events; inadequate orientation and training has been identified in 58 percent of these occurrences. Conversely, several studies have shown the positive impacts on quality and outcomes when nurse staffing is optimized – fewer complications, fewer adverse events and lower mortality.[67]

Revelations

One of health care's principal patient safety success stories is anesthesiology. In the 1980s, in the midst of a separate medical liability crisis, the rate of anesthesia-related deaths was one in 10,000; 6,000 people per year who had undergone anesthesia died or suffered brain damage, and anesthesiologists' liability insurance premiums had sharply escalated.[68] Following a national news magazine broadcast which pilloried the field for these outcomes, the American Society of Anesthesiologists (ASA) decided to seize the opportunity presented by the crisis to improve anesthesiology safety.

It started with the hiring of a systems engineer. Through close scientific examination of 359 anesthesia errors, every aspect of anesthesia care – equipment, practices, and caregivers – was analyzed. Eventually, with the commitment of leadership and resources towards the task, the many system failures revealed by the study were re-engineered, and anesthesia-related death rates fell to one in more than 200,000 cases.[69]

The ASA continues to use case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project – created in 1985 -- contains 6,448 closed insurance claims. Analyses of these claims have, for example, recently revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.

Closed claims data analysis is the one way in which the current medical liability system helps to inform improvements in care delivery. However, reliance on closed claims for information related to error and injury is cumbersome at best. It may take years for an insurance or medical liability claim to close. These are years in which potentially vital information on substandard practices remains unknown. Providing patient safety researchers with access to open claims, now protected from external examination, could vastly improve efforts aimed at identifying worrisome patterns in care and designing appropriate safety interventions.

In addition to anesthesiology's early work in identifying the human factors and system failures that cause error, anesthesiology has also promoted reliance on standards and guidelines to support optimal anesthesiology care. Anesthesiology has also been at the forefront in the use of patient simulation for research, training and performance assessment. With simulation, no patients are at risk for exposure to novice caregivers or unproven technologies.[70]

Anesthesiology is still far from perfect. But, its "institutionalization of safety,"[71] continues to serve the field well as it tackles the continuing threats to patient safety that are endemic to modern medicine.

Paths to Protection

Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance.[72] In court, clinical guidelines are increasingly invoked to prove or disprove deviations from the standard of care. But there is a more significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to clinical guidelines can have a significant role in reducing legal risk.[73] The study, which focused on obstetrical patients, found a six-fold increase in risk of litigation for cases in which there was a deviation from relevant clinical guidelines.[74] Further, one-third of all obstetric claims analyzed in the study were linked to non-compliant care.[75]

Some clinicians have not embraced clinical guidelines on the grounds that they intrude on the physician's autonomy, and discourage the appropriate individualization of care that would best serve particular patient needs. However, the demonstrated impact of clinical guideline adherence on reducing liability exposure provides ample incentive for physicians to rethink the autonomy proposition. Clinical guideline adherence is also an increasingly important factor in the defense of medical liability cases. The Maine, Florida and Kentucky legislatures have experimented with legislation that establishes clinical guideline adherence as an affirmative defense in medical liability litigation.[76]

Team Players

Teamwork -- indeed, team training -- has been identified by patient safety experts as an essential factor in reducing the risk of medical error. In aviation, "Crew Resource Management" (CRM) is the methodology used to guide team development among pilots, flight attendants and other crew. In this context, predefined roles and responsibilities for various scenarios help to assure the safety of every flight. Consistently applying such an approach to health care delivery could increase the timeliness and accuracy of communications – breakdowns of which are commonly implicated sources of serious adverse events. This could also help to enlist clinicians and support staff in committing to a common goal – safe and effective care – in the often high-pressure and chaotic environments of health care delivery. Unfortunately, health care professionals are not educated and trained to work as teams or even team members. Recreating the culture of health care delivery to value team-based care must begin at the earliest point of intervention -- health care professional education -- and be continuously reinforced in practice.

Clinical units that successfully foster strong team-based approaches to health care delivery do exist. In their research, Nelson, Batalden *et al* identified high-performing, front-line clinical units called microsystems.[77] A microsystem is further defined as a small group of people who regularly work together to provide care to discrete sub-populations of patients, and share business and clinical aims, linked processes, and a common information environment. Microsystems are often embedded in larger organizations – the "macrosystem."[78]

The high-performing microsystems identified in this study produce superior outcomes and cost-effective care, and at the same time, provide positive and attractive working environments.[79] These units are also characterized by the high value placed on patient safety, as well as compliance with policies and other requirements. The clinical units studied were involved in different types of care – rehabilitation, orthopedic oncology, hospice care, family medicine, and emergency care, that was provided in a variety of settings, including hospitals, nursing homes, clinics and even the home.[80] Across this continuum, the microsystems had nine common characteristics that interacted to contribute to their success. These included leadership, culture, organization support, patient focus, staff focus, interdependence of the care team, information and information technology, process improvement, and performance patterns.[81]

If microsystems are the "building blocks"[82] of the macro-organization, potential promise lies in replicating the characteristics of those that are high performing to create high-performing, safe health care environments. In fact, Nelson, Batalden *et al*, write, "A seamless, patient-centered, high-quality, safe and efficient health system cannot be realized without this transformation of the essential building blocks that combine to form the care continuum."[83]

Peer Pressure

A study recently published in *Health Affairs* by Devers *et al* concludes that the major driver for hospital patient safety initiatives is Joint Commission requirements.[84] The majority of hospitals surveyed as part of the study explicitly noted that they were working to meet Joint Commission requirements – developing better processes for reporting, analyzing, and preventing sentinel events; meeting patient safety standards, including acknowledgement of leadership's accountability for patient safety and the creation of a non-punitive culture; and meeting the specific National Patient Safety Goals.[85]

RECREATING THE CULTURE OF HEALTH CARE DELIVERY TO VALUE TEAM-BASED CARE MUST BEGIN AT THE EARLIEST POINT OF INTERVENTION -- HEALTH CARE PROFESSIONAL EDUCATION -- AND BE CONTINUOUSLY REINFORCED IN PRACTICE.

More than half of the Joint Commission's accreditation standards for hospitals are directly related to patient safety. These include standards relating to infection control, medication use, and surgery and anesthesia, among others. In addition to standards, the Joint Commission also annually issues, and requires compliance with, its National Patient Safety Goals. These goals are formulated by an expert panel comprising a variety of clinicians, management experts, and national leaders in patient safety, and set forth specific requirements for improving the safety of care delivery. The goals address fundamental performance issues such as surgical site marking, patient identification, and communications among caregivers that can result in error, including the use of abbreviations in medical orders and the use of verbal orders.

To address wrong-site, wrong-person, wrong-procedure surgery, the Joint Commission has taken that particular safety goal a step further by issuing the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery.™ The Universal Protocol calls for a pre-operative verification process; marking of the operative site; taking a 'time out' immediately before starting the procedure; and adapting the requirements to non-operating room settings, including the bedside where procedures are also performed.

The Joint Commission's Sentinel Event Policy requires organizations that experience a sentinel event to complete a thorough and credible root cause analysis, implement improvements to reduce risk, and monitor the effectiveness of those improvements.

The root cause analysis is expected to drill down to underlying organization systems and processes to identify opportunities for redesign that could reduce the likelihood of failure in the future. Health care organizations are encouraged to report sentinel events and root cause analysis findings to the Joint Commission to permit trend analysis, and to identify lessons learned and patient safety solutions that can be disseminated to accredited organizations.

Since 1996, more than 2500 sentinel events have been reviewed by the Joint Commission. Among these, patient suicide, operative/post-operative complications, wrong-site surgery, medication error, and delay in treatment are the most common types of sentinel events that have been reported. The top five contributory factors to sentinel events include communication issues, inadequate orientation and training of staff, incomplete or inaccurate patient assessments, staffing levels, and unavailability of patient information.

In the Devers *et al* study, the description of hospital patient safety initiatives also highlights the influence of other third parties in driving patient safety improvements. The Leapfrog Group was frequently mentioned by study participants, particularly with regard to its influence in driving the adoption of Computerized Physician Order Entry (CPOE) systems. In fact, information technology implementation – specifically including electronic medical records (EMRs) --is expected to have major positive impacts on patient safety.

The Joint Commission and other standard setters, and third-party review organizations clearly must work to assure that their standards, other requirements, and review mechanisms are continuously updated to optimize their impact in driving patient safety improvement.

Man vs. Machine

Where human error is inevitable, health care is now, finally, turning to automation. Much of the delay in widespread deployment of health care information technology has been the failure of its proponents to make the value proposition. The benefits over costs = value equation, until recently, had not achieved the requisite level to create impetus for acquisition. Lack of standardization and integration, and the absence of significant drivers to make the investment – which is substantial – have long held back potential purchasers and users. Recently, the prospects for advancement and application of information technology have improved.

In its *Crossing the Quality Chasm* report, The Institute of Medicine underscores the importance of information technology as a key factor in meeting several of its quality aims. Since then, the momentum toward widespread adoption of information technology has accelerated. Leading proponents include the National Alliance on Healthcare Information Technology, the Markle Foundation's Connecting for Health initiative, and now the Department of Health and Human Services itself, with the appointment of a national coordinator for IT initiatives last year.

Information technology solutions have the potential to address many of the factors in health care delivery that have proven to be major risk points for error. Communications between caregivers, availability of patient information, medication prescribing and use, and adherence to clinical guidelines can all be improved through reliance on IT capabilities. However, even with the evidence-base for IT becoming well established, health care organizations and practitioners are still pondering over how to secure adequate funding to support appropriate and necessary IT purchases.

Despite their obvious patient safety benefits, EMRs and CPOE systems are often met with much resistance by clinical staff, particularly physicians. Some initial implementations of CPOE actually served to increase error because of poor systems design and inadequate user training. It is essential that physician support be mobilized to ensure successful IT adoption. Among the ways physician support can be gained is for organization leaders to reinforce their commitment to patient safety and patient safety solutions; involve physician leaders in choosing systems; identify champions to spur others to use them; and, most importantly, ensure that the systems support and enhance physician workflow.[86]

Financial and performance incentives could speed the adoption of IT. For instance, liability insurers could offer premium discounts to organization and individual users of CPOE and other IT solutions. And new pay-for-performance models could tie performance criteria such as reduced adverse drug events – a derivative of the use of CPOE – to incentive pay arrangements.

Top Down

The pressures on health care leaders today are great. Increasing costs, increasing demand for services, and unfavorable reimbursement policies mean that patient "throughput" – the time in which patients move into, through, and out of the health care setting – must be accelerated to maintain revenues. This acceleration of the care process heightens the risk of medical error, and compromises effective patient-practitioner communications.[87] Yet, in this environment, a culture of patient safety must be created and emulated from the top down. This responsibility lies both with individual health care organizations and practitioners, and with those who set health care policy in this country.

Where federal leadership and accountability for the quality of health care is lacking, the liability system is tapped to replace regulation.[88] State-based patient safety authorities have been established in such states as Massachusetts and Pennsylvania to support activities aimed at improving safety, and these are promising developments.

Despite the launching of a number of quality initiatives by the Department of Health and Human Services over the past few years, there is neither a focused approach to, nor advocacy for, health care quality and patient safety within the federal government. Until this country both elevates the importance of quality and safety problems and engages in a coordinated approach to solutions, it will be difficult to make significant strides in addressing the foundational patient safety problems that persist today. Creation of an Office of Health Care Quality in the Department of Health and Human Services could provide a powerful platform for setting priorities and direction for improving patient safety and health care quality. Such an office could also coordinate and enhance the efforts of established private and public sector bodies already engaged in patient safety and quality improvement activities.

New public and private sector payer initiatives designed to "pay for performance" may provide a new opportunity to align incentives for increasing safety and improving quality and patient outcomes. In 2003, CMS launched a demonstration project in partnership with Premier Inc. to test the effectiveness of paying hospitals more for better performance according to selected measures. In 2005, a new demonstration project was initiated for large medical group practices. Small but symbolically significant bonuses are to be based on results in the management of specific clinical conditions and procedures. The pay-for-performance concept essentially envisions rewards for desired behaviors and outcomes.

Other than selected CMS demonstration projects, hospitals and physicians are generally paid the same federal dollar whether the level of care is truly exemplary or clearly substandard. This obviously offers little incentive for pursuing much needed improvements in the safety and quality of health care that is being delivered today. This is one of the most important foundational issues that enhanced federal leadership could and should address.

Recommendations to Pursue Patient Safety Initiatives that Prevent Medical Injury:

Tactics	Accountability
• Strengthen oversight and accountability mechanisms to better ensure the competencies of physicians and nurses	→ State medical boards, American Board of Medical Specialties, state nursing boards, health care provider organizations
• Allow health care researcher access to open liability claims to permit early identification of problematic trends in clinical care	→ insurers
• Encourage appropriate adherence to clinical guidelines to improve quality and reduce liability risk	→ medical staff leaders, medical professional societies, health care administrators, health care purchasers and payers
• Support teamwork development through team training, "Crew Resource Management," and high-performing microsystem modeling	→ health care educators, health care administrators, medical and nursing staff leaders, chiefs of medicine
• Continue to leverage patient safety initiatives through regulatory and other quality oversight bodies	→ accrediting, licensing and regulatory bodies, patient safety organizations, purchasers and payers
• Encourage the adoption of information and simulation technology by building the evidence-base of their impacts on patient safety, and pursue proposals to offset implementation costs	→ information technology task forces, i.e. Connecting for Health, DHHS Office of Information Technology, health care providers organizations and technology vendors
• Leverage the creation of cultures of patient safety in health care organizations	→ health care administrators, medical and nursing staff leaders
• Establish a federal leadership locus for advocacy of patient safety and health care quality	→ DHHS
• Pursue "pay-for-performance" strategies that provide incentives to focus on improvements in patient safety and health care quality	→ CMS and private-sector health care purchasers and payers

II. Promote Open Communication Between Patients and Practitioners

Patient Centeredness

"...we have had the unique opportunity to gain insight into the American health care system and its lenient oversight; the general disregard of the patient when a medical error occurs; the lack of quality-of-care standards; the lack of integrity and the code of silence, as the IOM put it, present at hospitals; the absence of accountability and consequences when medical error occur; the legal system and its distortion; and the general complexity of the system whose responsibility it is to ensure patient safety."[89] These words are Susan Sheridan's, a wife and mother whose newborn son suffered preventable, permanent and devastating injury and whose husband lost his life as a result of medical error. Ms. Sheridan, now a patient safety advocate, endured lengthy trials and dueling expert testimony, in her family's attempt to learn what went wrong. Unfortunately, her story is like that of many others who have been injured within the health care system.

Lack of disclosure and communication is the most prominent complaint of patients, and their families, who together have become victims of medical error or negligence. Years of expensive and wounding litigation often ensue when families are sometimes only seeking answers.

In seeking something good from tragedy, Ms. Sheridan has educated many about the continued occurrence of kernicterus, the condition that left her son severely disabled. Kernicterus results from untreated jaundice in newborns and is readily responsive to treatment if properly diagnosed. In part through her efforts, new guidelines for the diagnosis and treatment of children born with kernicterus were recently promulgated by the American Academy of Pediatrics.

In fact, health care consumers are playing an important role in the patient safety movement – as educated advocates for change based on their own experiences. When individuals' stories reach the right audiences, listeners pay heed. Health care consumers can specifically help to prevent adverse events by being active, informed and involved members of the health care team.

HEALTH CARE CONSUMERS CAN SPECIFICALLY HELP TO PREVENT ADVERSE EVENTS BY BEING ACTIVE, INFORMED AND INVOLVED MEMBERS OF THE HEALTH CARE TEAM.

Sound of Silence

For patients and family members, the physical and emotional devastation of medical error cannot be easily overcome. What they want most out of their ordeal is honest and open dialogue about what went wrong, and a "legacy" – having their experience serve as a lesson for prevention in the future.[90] Seldom are such communications and assurances forthcoming.

In their book, *Wall of Silence,* authors Rosemary Gibson and Janardan Prasad Singh describe the ways in which information on medical error is kept under cover. An unintended consequence of the tort system is that it inspires suppression of the very information necessary to build safer systems of health care delivery. When it comes to acknowledging and reporting medical error, according to Gibson and Singh, there is too often silence between practitioners and patients; practitioners and their peers; practitioners and the organizations in which they practice; and health care organizations and oversight agencies.

In addition to the fear of litigation, the wall of silence is amplified by the fears of physicians and health care organizations about the loss of reputation, accreditation or licensure, and income. The wall of silence severely undermines efforts to create a culture of safety within health care organizations and across the health care system. Indeed, patients will not be safe until caregivers feel safe to talk about and act on medical error.

So Transparent

One of the basic principles of patient safety is to talk to and listen to patients.[91] Several elements are fundamental to any disclosure effort. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology.[92]

The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients, and to their family members when appropriate. A recent study confirms that many hospitals – half of those surveyed -- are reluctant to comply with this standard for fear of medical liability suits.[93] If disclosure is taken a step further to the offer of an apology, hospitals and physicians are even more likely to gravitate to traditional "defend and deny" behaviors. But there is increasing awareness that openness has the potential to heal, rather than harm, the physician-patient relationship. A growing number of hospitals, doctors and insurers are coming around to the idea that apologies may save money by reducing error-related payouts and the frequency of litigation.[94]

YEARS OF EXPENSIVE AND WOUNDING LITIGATION OFTEN ENSUE WHEN FAMILIES ARE SOMETIMES ONLY SEEKING ANSWERS.

Charles Utley, a patient who, after surgery, was left with a surgical sponge festering in a body cavity, decided not to pursue litigation because his doctor and the hospital administrator took responsibility and apologized to him.[95] "They honored me as a human being," he said.[96] In turn, Mr. Utley settled for less compensation for his injuries than he could have potentially been awarded if the case had been adjudicated.[97]

The VA Medical Center in Lexington, Kentucky has an established "apology policy" that has helped it to reduce levels of litigation; however, the relevancy of this approach to private sector health care institutions -- where the prospects of suits are much greater -- has been questioned. Nevertheless, now prominent medical centers, such as the Dana-Farber Cancer Institute and Johns Hopkins Hospital, have policies that urge doctors to disclose their mistakes and to apologize.[98] Insurers, too, are increasingly urging apologies.[99] And, increasingly, states, such as Colorado and Oregon, are passing laws that protect an apology from being used against a doctor in court.[100] More such protections will be needed in order for most caregivers and organizations to feel comfortable with apologies, despite the ethical imperatives underlying such disclosure.

Only the Brave

Few caregivers and health care organizations voluntarily break through the wall of silence to report life-threatening medical errors beyond the walls of their institutions. The Joint Commission has had a voluntary reporting system since 1996, but its Sentinel Event Database receives only about 400 new reports of events each year – well below the 44,000 to 98,000 medical error-related deaths estimated by the IOM to occur each year.

The Joint Commission requires organizations reporting a sentinel event – defined as an unexpected occurrence involving death or permanent loss of function – to conduct an analysis to determine the underlying causes of such events. Root cause analysis and risk reduction information from the Sentinel Event Database form the basis for *Sentinel Event Alerts* – error prevention advice that is regularly disseminated to the health care field.

A number of states now have mandatory error reporting systems of various types.[101] One of the most active, the New York State Patient Occurrence Report and Tracking Systems (NYPORTS), logged approximately 30,000 reports in 2003.[102] A new reporting system in Pennsylvania captures reports of near-misses as well as actual errors.

WHEN IT COMES TO ACKNOWLEDGING AND REPORTING MEDICAL ERROR, THERE IS TOO OFTEN SILENCE BETWEEN PRACTITIONERS AND PATIENTS; PRACTITIONERS AND THEIR PEERS; PRACTITIONERS AND THE ORGANIZATIONS IN WHICH THEY PRACTICE; AND HEALTH CARE ORGANIZATIONS AND OVERSIGHT AGENCIES.

Reporting systems can capture enormous volumes of data, but without the requisite resources to analyze and translate data into useful information, their potential is far from being fully realized.

Other types of external reporting systems include reporting systems tailored to specific health care segments, such as the Veterans Administration's (VA) nascent Patient Safety Reporting System, and medical specialty-based reporting systems.[103] One such specialty-based system developed by the Neonatal Intensive Care Quality (NICQ) Collaborative and sponsored by the Vermont Oxford Network, encourages Internet-based, anonymous, voluntary reporting by health care professionals working in neonatal intensive care units (NICU). The system has logged 1230 reports in a 27-month study period that have identified a broad range of errors.[104] Reported information is analyzed by a team of experts who provide feedback and recommendations to participating NICUs.[105] The robust participation in the system is attributed to the natural allegiance participants have to their medical specialty peers and their confidence in expert opinion leaders.[106]

There remains a substantial lack of clarity as to whether error analyses reported to a third-party, such as a state agency or the Joint Commission, are afforded legal privilege protections. This lack of certainty of protection continues to hamper reporting efforts that could otherwise yield essential information for making breakthrough improvements in health care safety.

Patient safety legislation – under consideration by the Congress for several years and currently pending reintroduction in the current Congress – proposes legal protection for information reported to any Patient Safety Organization, as defined in the legislation. Passage of patient safety legislation of this nature would provide the cornerstone for effective reporting systems that assure confidentiality and encourage the sharing of lessons learned from the analyses of adverse events.

Fly Safely

Many safety experts point to the reporting model used by the Federal Aviation Administration (FAA). The Aviation Safety Reporting System (ASRS) was developed by the FAA to "increase the flow of information regarding actual or potential deficiencies in the aviation system."[107] The launch of the ASRS was prompted by a plane crash near Dulles Airport in 1974. Some of the reasons for the crash – poorly defined altitude markers at Dulles and unclear instructions from air control – were widely known (in the case of the markers) and bound to be repeated (unclear instructions).[108]

The ASRS captures "near miss" reports (actual airline events typically do not go unnoticed) and is administered by a third-party, NASA, for two reasons. First, an airline industry employee is more likely to report an error resulting in a near-miss to someone outside of his or her "chain of command," and second, NASA has the resources to analyze the incoming data and disseminate lessons learned.

Reporting is mandatory, confidential and protected – no punishment is meted out for those who report a near miss within ten days of its occurrence, but failure to report removes such immunity. And since there has never been a breach of confidentiality, trust in the system among flight and ground crews is high.

The ASRS has five traits that have made it "the linchpin" of modern aviation's impressive safety record – ease of reporting, confidentiality, third-party administration, timely analysis and feedback, and regulatory action.[109] These traits, applied to a medical error reporting system, could help health care achieve a similarly impressive safety record.

RECOMMENDATIONS TO PROMOTE OPEN COMMUNICATION BETWEEN PATIENTS AND PRACTITIONERS:

TACTICS	ACCOUNTABILITY
• Involve health care consumers as active members of the health care team	→ health care practitioners and provider organizations
• Encourage open communication between practitioners and patients when an adverse event occurs	→ health care administrators, risk managers, clinical leaders, liability insurers
• Pursue legislation that protects disclosure and apology from being used as evidence against practitioners in litigation	→ health care organizations and practitioners, trade and professional organizations
• Encourage non-punitive reporting of errors to third parties that promotes sharing of information and data analysis as the basis for developing safety improvement strategies	→ health care organizations and medical and nursing staff leaders, oversight and regulatory bodies
• Enact federal patient safety legislation that provides legal protection for information reported to designated patient safety organizations	→ U.S. Congress

III. Create an Injury Compensation System that is Patient-Centered and Serves the Common Good

If It's Broken...

Only a small percentage (2-3 percent) of patients who are injured through medical negligence ever pursue litigation, and even fewer ever receive compensation for their injuries.[110] Those who are awarded compensation wait an average of five years to receive it.[111] Clearly, the current tort system falls short in compensating injured patients. As for exacting justice, there is often little correlation between court findings of negligence and actual negligence.[112] And rather than deterring negligence, there is a common refrain among physicians that the current tort system "keeps us from doing things that we, as good professionals, would naturally do."[113]

A central question is how the medical liability system can be restructured to actively encourage physicians and other health care professionals to participate in patient safety improvement activities.[114] The goal of any such restructuring should be to reduce litigation by decreasing patient injury, by encouraging open communication and disclosure among patients and providers, and by assuring prompt and fair compensation when safety systems fail. Reform proposals, such as caps on non-economic damages, while important temporizing measures, are unlikely to accomplish these objectives by themselves. Rather, according to Columbia Law Professor William Sage, "patient safety may be the trigger that finally propels ideas such as accelerated compensation for clearly avoidable events, less adversarial forms of dispute resolution, non-judicial compensation mechanisms, encouragement of private contracting, and assumption of legal responsibility by medical institutions from the academic literature into the real world."[115]

...Fix It

Numerous proposals have been suggested for improving the medical liability system. These proposals center on three broad approaches: 1) creation of alternative mechanisms for compensating injured patients, such as through early settlement offers; 2) resolving disputes through a so-called "no-fault" administrative system or through health courts; and 3) shifting liability from individuals to organizations.[116] Though these approaches are distinct, they are not in conflict. One could imagine an injury resolution system that incorporates the characteristics of all three.

An administrative system approach -- similar to the mechanisms generally in use today to address worker's compensation claims – would eliminate negligence as the basis for compensation and provides for a no-trial, administrative resolution process.[117] However, because the term "no-fault" implies the absence of responsibility for injury or untoward outcomes, "strict liability" may be a more appropriate and accurate term.[118]

In the design of an administrative system, proponents have proposed that compensation be based on determination of avoidability, rather than on negligence.[119] Such preventable events could be defined through Avoidable Classes of Events (ACEs) categories that are expert-based and can be used to trigger an early offer of compensation.[120]

Safety experts and systems engineers have demonstrated that non-punitive approaches encourage the detection of errors, and improvement, which, according to the IOM, "...suggests that resolving malpractice cases without a determination of fault will help rather than harm quality." An administrative approach also makes sense in light of the poor track record of the tort system in consistently determining negligence.

An early settlement – or compensation offer – can be an important component of a strict liability model, as it is for many mediation programs that institutions rely on as an alternative dispute resolution mechanism. Early-offer programs meet the needs of patients, providers and practitioners for swift resolution of claims. Compensation values could be based on a fee schedule that has predetermined rates based on the avoidable event and its concomitant injury. Such fee schedules would essentially eliminate the random variability of award judgments. The predictability of pay-outs could also help to stabilize insurance premium rates, although it is likely that more patients would rightly receive compensation under such a model.[121]

While there is no designation of negligence under a strict liability approach, designation of responsibility is one of its key features. If there were a shift to enterprise liability, the health care organization would have a new and strong incentive to foster a culture of patient safety, and to identify and redesign vulnerable systems. Experience-rating the enterprise's liability premiums could further induce greater investments in improving patient safety.

Another way in which to foster cultures of patient safety and accountability would be to require individual physicians or provider organizations to "earn" their way into alternative dispute resolution systems. The bases for earning into the system could include the meeting of specified standards and other performance thresholds. Given the leadership of the Centers for Medicare and Medicaid Services (CMS) in developing pay-for-performance quality improvement models, the agency could become the lead sponsor of an "earn-in" model for alternative dispute resolution.[122]

A CENTRAL QUESTION IS HOW THE MEDICAL LIABILITY SYSTEM CAN BE RESTRUCTURED TO ACTIVELY ENCOURAGE PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS TO PARTICIPATE IN PATIENT SAFETY IMPROVEMENT ACTIVITIES.

Access to alternative dispute resolution, and potentially, medical liability insurance subsidies, could be closely tied with pay-for-performance and other measurement-based performance monitoring initiatives.[123]

Based on the precedents of the U.S. Tax Court system and worker's compensation administrative law, the concept of specially appointed health courts is another potential alternative to the current tort system model. The Robert Wood Johnson Foundation recently awarded a grant to Common Good, a national bipartisan legal reform coalition, and the Harvard School of Public Health to design a prototype of the health court system.[124] In addition to specially designated health courts for resolving disputes, the concept incorporates reliance on expert guidelines for compensation of avoidable events.[125] For straightforward cases, an expedited process would allow injured patients to apply for compensation without the necessity of legal representation. Such individuals -- based on the application of malpractice standards (avoidable events) -- would receive awards based on a schedule of damages. For complex cases, a health court judge would hear arguments from lawyers, as well as testimony from court-appointed, independent experts. The health court judge – having special knowledge regarding the assessment of scientific evidence and medical practice -- would base rulings on determinations of the standard of care. Damages would be awarded based on the predetermined fee schedule. Under the health court system, all settlements and adjudications would be made publicly available.

Inherent in any alternative to the tort system must be a high priority for disclosure -- an acknowledgement of the error or injury, an apology, and assurances that steps will be taken to avoid such an error in the future.

A 2003 IOM report calls for demonstration projects to test the feasibility and effectiveness of alternative injury compensation systems that are patient-centered and focused on safety.[126] Such demonstration projects are needed to begin the process of mitigating the periodic medical liability crises that, aside from economic factors, result from the delivery of unsafe care, unreliable adjudication of claims, and unfair compensation for injured patients.

INHERENT IN ANY ALTERNATIVE TO TORT REFORM MUST BE A HIGH PRIORITY FOR DISCLOSURE -- AN ACKNOWLEDGEMENT OF THE ERROR OR INJURY, AN APOLOGY, AND ASSURANCES THAT STEPS WILL BE TAKEN TO AVOID SUCH AN ERROR IN THE FUTURE.

Taking Initiative

Absent action by the Federal government, some states and liability insurance companies are already pursuing – for better or worse -- reforms to reduce reliance on litigation as a means to resolve injury claims.

In the 2004 election, Florida voters adopted a proposition that limits lawyers' contingency fees in medical liability cases, and entitles patients to 70 percent of damages awarded that are $250,000 or less, and 90 percent for damages exceeding $250,000. Lawyers otherwise typically receive 30 to 40 percent of damages. However, Florida voters also passed a measure that expands public access to medical records and adverse event reports – essentially nullifying peer review protections in that state. Florida has also passed a ballot initiative mandating the revocation of physicians' licenses to practice medicine if they have received three or more adverse medical liability judgments, as opposed to settlements. There are substantial questions as to whether either or both of the latter two actions will constructively advance the patient safety agenda.

In Wyoming, voters last year defeated a proposal to cap non-economic damages on medical liability claims, but passed a measure to allow the use of alternative dispute resolution, including medical panel reviews of potential claims against providers and practitioners before they can be filed.

In 2002, Pennsylvania became the first state to require hospitals to disclose, in writing, adverse events to patients or their families.[127] Nevada and Florida have since followed Pennsylvania's lead.[128] Pennsylvania is also the site of a Pew-sponsored demonstration project that encourages mediated dispute resolution.[129] As part of this model, physicians are encouraged to disclose adverse events to their patients and to apologize.[130] Patients or their families are provided with an early and fair offer of compensation, and the opportunity for mediation to resolve disputes.[131] It is too soon to know the full ramifications of the Pew-sponsored project, but early indications are that it has been successful in mitigating litigation.[132]

COPIC Insurance Company, a physician-owned liability insurer in Colorado, initiated its "3Rs" (respect, respond and resolve) program in 2000. Under this program, each insured physician is encouraged to communicate openly with the patient if an adverse event occurs, and to offer an apology when warranted.[133] COPIC pays for patient expenses, and also reimburses lost wages.[134] Importantly, patients are not asked to waive their rights to litigation.[135] Since its inception, none of the cases addressed through the 3Rs program has gone to litigation.[136]

The Menu

The following tables outline the different alternatives for liability system reform and delineate the potential impact of each on deterring negligence and supporting engagement in patient safety activities, providing swift compensation to injured patients, supporting transparency in the patient-practitioner relationship, and addressing claims fairly.

TABLE 1: ALTERNATIVE SYSTEM REFORMS AND THEIR IMPACT

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE-EVENTS (ACEs)	MEDIATION-EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
DETERRENCE EFFECT — PATIENT SAFETY IMPACT	- supports creation of a just patient safety culture - encourages reporting of adverse events	- represents consensus on what constitutes an avoidable event - encourages prevention of avoidable events	- alternative dispute resolution mechanism to litigation can potentially "warm" reporting of adverse events	- more reliable judgments have the potential to send clearer messages for deterrence	- provides incentive for prioritization of enterprise-wide safety
SWIFT COMPENSATION	- no-trial, administrative process - compatible with "early offer" compensation system	- can trigger eligibility for early compensation offer	- provides prompt settlement and compensation	- swifter address of claims - could provide more reliable and standardized compensation	
OPEN DISCLOSURE	- removal of litigation threat supports open disclosure	- makes "avoidability" and therefore, eligibility for compensation, transparent to providers and patients alike	- offers non-judicial dispute resolution that encourages communication between parties		
CORRECTIVE JUSTICE	- provider is accountable for all avoidable medically related losses	- restitution can be sought in conventional tort system or alternative system - potential to compensate greater number of injured patients	- health care provider or organization is accountable - settlements are often sequestered	- provides the potential for more reliable and credible adjudication and restitution of claims - makes fault determinations	- holds enterprise accountable for the safety and quality of health care practice and practitioners

TABLE 2: AN OVERVIEW OF ALTERNATIVES

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE-EVENTS (ACEs)	MEDIATION-EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
KEY FEATURES	- eligibility based on avoidability rather than negligence - no trial, holds providers strictly responsible for medically related losses	- pre-determination of events that should not occur in quality health care delivery - triggers eligibility for compensation	- prompt, private settlement offers	- appointment of special expert courts to hear medical cases or administer compensation based on avoidable events	- shifts liability from individual provider to provider organization
PROS	- promotes prevention & transparency - widens eligibility for compensation - faster resolution of claims	- standardizes eligibility for compensation - quicker identification of meritorious cases	- can avoid litigation - lowers costs - swift & assured compensation for patients - promotes transparency	- could improve the reliability of judgments - quicker resolution of claims - provides public access to settlement and adjudication findings	- promotes institutional safety - potential to stabilize liability insurance fees
CONS	- perception that "no-fault" means "no accountability"	- comprehensive ACE list currently non-existent - development of the list requires an array of expert consensus	- intensifies pressure on patients to settle	- requires judges who have special knowledge or training	- legal provisions (Stark laws) may prohibit liability insurance coverage of non-employee physicians
COMPATIBILITY	- compatible with current system if based on "earn-in" model-providers meet criteria for admin. system; others are in conventional system	- a basis to determine eligibility for alternative and conventional compensation systems - can be paired with standardized compensation fee schedule	- used with current tort system - can be used with admin. systems, ACEs	- is paired with ACEs and standardized compensation schedule - adds trial option to an administrative system	- works with alternatives and current tort system
REAL-WORLD APPS.	- worker's compensation laws - Fla. & Va. injury-specific demonstrations		- Liability insurer models - Health plan models - Provider models	- Special court precedents – tax and patent courts -- and worker's compensation laws	- precedents in product liability law

Open the Black Box

While comprehensive medical liability reform is the long-term solution for resolving the issues inherent in today's system, there are actions that can be taken in the intermediate term that would bring greater integrity and transparency to the process.

Medical liability claims are often settled before they reach trial, or before the trial ends in judgment. Terms of these settlements typically include a "gag clause" that requires the confidential sequestering of all information related to the case. Such confidential settlement offers may encourage quick resolution, but this is achieved at the cost of forever barring access to potentially important information that could be used to improve the quality and safety of care. Such settlements are of course encouraged by insurers to save court costs, and physicians are often amenable because the gag clauses preclude the sharing of information that could be damaging to their reputations. But gag clauses are antithetical to patient-centeredness – they deprive injured patients the opportunity to provide a legacy, and they provide a disservice to the provider and practitioner communities by preventing learning.

Physicians named in medical liability judgments and settlements, as well as disciplinary actions, are reported to the National Practitioner Data Bank (NPDB). Information contained in the NPDB is only accessible to hospitals and other health care organizations, licensing boards, and professional societies. Individual practitioners can only access information about themselves. Medical liability insurers, advocacy groups and members of the general public cannot access the data bank. The NPDB was established through federal statute and is managed by the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS).

The primary reason for the existence of the NPDB is to permit hospitals and licensing boards to track physician performance issues. Since its inception, questions have continued to be raised about the validity and reliability of the NPDB.[137] A 2000 GAO report cited a multitude of NPDB problems, including underreporting of disciplinary actions, which, the report states, is a far better expression of physician competence than medical liability claims.[138] In fact, medical liability claims data constitute 80 percent of the information contained in the NPDB.[139]

WHILE COMPREHENSIVE MEDICAL LIABILITY REFORM IS THE LONG-TERM SOLUTION FOR RESOLVING THE ISSUES INHERENT IN TODAY'S SYSTEM, THERE ARE ACTIONS THAT CAN BE TAKEN IN THE INTERMEDIATE TERM TO BRING MORE INTEGRITY AND TRANSPARENCY TO THE PROCESS.

The information the data bank contains is also characterized in the GAO report as substantially incomplete -- lacking, for example, any information as to whether the standard of care was considered when a claim was settled or adjudicated.[140]

Because of its operational unsoundness, the NPDB represents a significant threat to physicians concerned about their reputations and ability to practice medicine. As previously discussed, medical liability judgments and settlements do not necessarily reflect medical negligence. Settlements, in particular, are often business decisions made by insurers who consider the potential cost of trial to outweigh the benefit of fighting a claim, without regard to the merits of the claim. The NPDB is also philosophically dissonant with patient safety theory – all errors and actions it contains are tracked and related to individuals. It provides no information about, or insights into, related systems failures. And finally, its access limitations are antithetical to the goal of transparency in the patient-physician relationship.

There is a need for a centralized information source or sources that can reliably capture important inputs about the performance of physicians and other health care practitioners, but options other than the NPDB exist. For instance, the Federation of State Medical Boards (FSMB) regularly makes information on disciplinary actions taken against physicians publicly available. It has now been five years since the release of the GAO report critical of the NPDB, and no substantial progress has been made to implement its recommendations.

Given the relative ineffectiveness of the NPDB, it either needs to be substantially redesigned or its responsibilities need to be reassigned to other more reliable information repositories.

Accountability for health care professional competency lies with the individual and his or her licensing and certification boards, and employers. This accountability should extend to the conduct of physicians who act as expert witnesses in medical liability cases. As many who have participated in a medical liability case can attest, expert opinion is subject to substantial potential bias when that opinion is paid for by either the defendant or the plaintiff in a case.[141]

According to the Federation of State Medical Boards, expert witnesses who give false or misleading testimony are subject to disciplinary action.[142] In Massachusetts, the medical society has established a series of standards that require, among others, that experts who testify in court be state-licensed, board-certified, and actively practicing in the field in which they represent themselves as experts. More aggressive oversight of expert witnesses by state licensing boards and professional societies would be an important short term and continuing contribution to ensuring more ethical expert testimony. In the long term, court-appointed experts that are independent of either plaintiffs or defendants are more likely to provide objective support to the litigation process.

RECOMMENDATIONS TO CREATE AN INJURY COMPENSATION SYSTEM THAT IS PATIENT-CENTERED AND SERVES THE COMMON GOOD:

TACTICS	ACCOUNTABILITY
• Conduct demonstration projects of alternatives to the medical liability system that promote patient safety and transparency, and provide swift compensation to injured patients	→ CMS, state-based initiatives
• Encourage continued development of mediation and early-offer initiatives	→ liability insurers, health care organizations, health plans
• Prohibit confidential settlements – so-called "gag clauses" – that prevent learning from events that lead to litigation	→ legal system
• Redesign or replace the National Practitioner Data Bank	→ DHHS Health Resources and Services Administration
• Advocate for court-appointed, independent expert witnesses to mitigate bias in expert witness testimony	→ medical professional societies, state medical boards

Conclusion

The current national tort reform discussion affords an opportunity to extend the focus on caps on non-economic damages to pursue fundamental, far-reaching changes to the health care system that would benefit patients, providers, practitioners, and the general public. But these significant benefits can only be achieved if the debate is informed by the voices of those who understand the inverse relationship between the impacts of the current medical liability system and efforts to improve patient safety. Instituting a federal cap on non-economic damages, while having the potential to slow the rise in liability premiums, will not alter the fundamental unfairness to patients and physicians and the deleterious impact on patient safety that are inherent in the existing tort system.

Now, five years after the seminal Institute of Medicine (IOM) report on patient safety, *To Err is Human*, too little progress has been made in identifying, learning from, and ameliorating medical error. While there are multiple reasons for this disappointing progress, no one can deny that the vulnerabilities for practitioners and provider organizations created by the medical liability system – fear of litigation, loss of liability coverage, and professional reprisals among them – are driving underground information vital for learning and solution development.

It is clearly time to actively explore and test alternatives to the medical liability system. The goal of such alternatives is not to legally prescribe "blame-free" cultures, but rather, to stimulate the creation of "just cultures." "Just cultures" foster learning – including learning from mistakes – but also emphasize individual accountability for misconduct. Inherent in any viable alternative for addressing medical liability claims should be the potential for fairly compensating greater numbers of injured patients, while allowing health care practitioners and providers the opportunity to reveal error, learn from such errors, and ensure that they are not repeated.

It is now two years since the IOM released another relevant report -- *Fostering Rapid Advances in Health Care.*[143] In addressing the medical liability system, the report calls for demonstration projects of alternatives for resolving medical liability claims. To date,

IT IS CLEARLY TIME TO ACTIVELY EXPLORE AND TEST ALTERNATIVES TO THE MEDICAL LIABILITY SYSTEM.

no such demonstration projects have been initiated. This lapse is increasingly unacceptable in the face of the emergence of the medical liability system's problems as a pressing public policy issue. Both the federal and state governments need to put this issue at the top of their public policy "to do" lists.

Redesigning the medical liability system will necessarily be a long-term endeavor. Meanwhile, more and continued efforts aimed at fostering transparency among provider organizations, practitioners, and patients; seeking alternatives to litigation; leveraging the development of patient safety cultures; treating health care providers fairly; and honoring patients are both noble goals and practical necessities that must be actively pursued.

The ultimate goal is to make health care as safe as it can be, while also assuring appropriate redress for patients when it is warranted. Such public policy would truly serve the common good.

A Vision for Tort Resolution & Injury Prevention:

- All health care organizations acculturate patient safety – making it a precondition of all other priorities – with the goal of reducing incidences of malpractice.
- When a medical error occurs, the injured patient is promptly informed of the error and receives an apology, and analysis of the error informs the prevention of such error in the future.
- An early offer of compensation for losses is promptly provided to the patient.
- If a claim of injury remains in dispute, an alternative dispute mechanism is employed to bring the claim to a swift, fair and efficient resolution.

ACKNOWLEDGEMENTS

The Joint Commission sincerely thanks the Roundtable members for providing their time and expertise in the development of this report.

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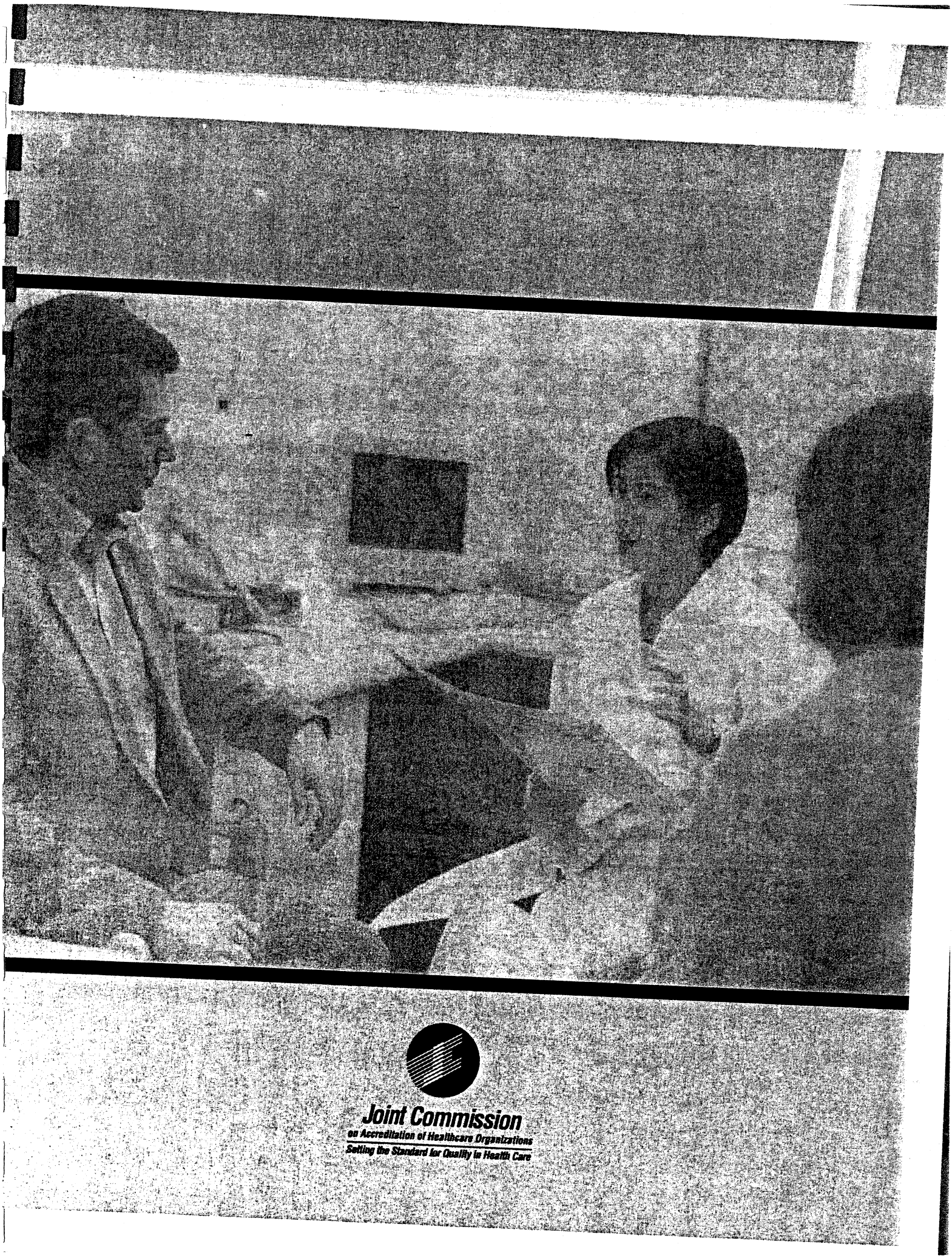
HEALTH CARE AT THE CROSSROADS:

STRATEGIES FOR IMPROVING THE MEDICAL LIABILITY SYSTEM AND PREVENTING PATIENT INJURY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Tab 19

Patient Safety Law: From Silos to Systems

Appendix 2: Country Reports THE UNITED STATES OF AMERICA

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The United States of America

The United States of America is a Federal Republic. The country's population is approximately 294 million.

Health Care System Context

Law

The United States uses a common-law system but has law at the federal and state level.

Health

The foundation of the health care in the United States is weighted towards private finance and the market – it focuses on the supply of services rather than the ability to access services. Health care is not regarded as a social right in the United States, nor is it considered a universal entitlement.[1] While in most other industrialized countries the principles of universality, public financing and administration and expenditure controls are integral parts of health care systems, the United States is an outlier where employer-based benefits are the norm and public insurance is extremely limited.[2]

Health Services Delivery

The Federal government directly subsidizes the costs of care for some population groups and indirectly subsidizes health care through tax deductions for private insurance plans. The distinction between private and public sectors in the U.S. is essentially based on population categories. Government involvement is limited to dual-tiered system of federal and state programs – Medicare and Medicaid. The Medicare and Medicaid programs were established by the federal government in 1965 to provide financial assistance to the elderly, disabled and the poor. Medicaid is a social assistance program based on a means test that provides hospital and physician care to persons eligible for federal welfare benefits. The program reimburses private providers for services rendered. It is primarily administered by the states, but is jointly funded by federal and state governments. Medicare covers the elderly or disabled who are eligible for social security benefits. Part A covers inpatient hospital care and is directly paid by the federal

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[1] Antonia Maioni, *Parting at the Crossroads* (Princeton, N.J.: Princeton University Press, 1998) at 8.
[2] *Ibid.*

government and financed by social security taxes on workers. Part B offers supplementary insurance for physician and outpatient services and involves deductibles and co-payments. Public expenditures on health care in the United States account for less than half of the total spending on health[3] (in 1997 46.7 percent of the national expenditure on health).[4] Only approximately 45 percent of the U.S. population is covered by publicly financed hospital insurance (based on 1997 figures)[5] and twenty-five percent have publicly funded medical coverage.[6] Of the Americans covered by private health insurance, 80 percent rely on benefits tied to employment.[7] An estimated 40 million Americans have no coverage – public or private – and that number increases each year. Millions more are 'under-insured' in that they may only be covered for hospital inpatient care, not physician services, outpatient care or pharmaceuticals. The Medicare and Medicaid programs are administered at the federal level by Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). Part of the federal Department of Health and Human Services, CMS is a major federal agency, employing over 4,000 employees and concentrating on policy development, health care research, budget preparation and analysis, enforcement of health care quality standards and legislative analysis and liaison. The federal Department of Veterans Affairs provides medical services for those who have served in the armed forces in the United States. The Veterans Health Administration administers the provision of health services for veterans. The Centers for Disease Control and Prevention are the public health arm of the federal government.

The federal government's funding role in the health system is not generally directed at funding service provision, rather, as Jacobs states, "the U.S. Government's first and most generous involvement in health care focused on expanding the supply of hospital-centered, technologically sophisticated health care."[8] This is so generally because when the health system first developed, both the federal and state governments were weak and had few resources.[9] The power vacuum meant that the health care system was dominated by private interests, by organized professional group(s), elite medical researchers and supporters of capitalism.[10] Suppliers dominated the system so there was powerful support for the state's activities to be extended to infrastructure support. The *Hill-Burton Hospital Construction Act 1946* committed the federal government to financially supporting hospital construction ($3.7 billion spent in 35 years). Medical research in particular currently is, and was, heavily funded by the federal government, with one congressman calling it "the best kind of health insurance."[11] Federal research funding

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[3] *Ibid.*
[4] Organisation for Economic Co-operation and Development, *OECD Health Data, 1998* (Paris:OECD, 1998).
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[8] L. Jacobs, "Politics of America's Supply State: Health Reform and Technology" (1995) 14:2 Health Aff. 143 at 144-145.
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[10] *Ibid.* at 43.
[11] *Ibid.* at 46.

agencies include the National Institutes of Health and the Agency for Health Care Research and Quality.

The United States' expenditure on health as a percentage of GDP is the highest amongst OECD countries – in 1995 the U.S. spent 14 percent of its GDP on health care.[12] This is due to the complex multi-payer system which increases administrative costs and to a rapid increase in health care costs and demand. Government tried to contain the costs of health care through encouraging private sector initiatives.[13] For example, the Nixon government passed *The Health Maintenance Organization Act 1973* to encourage the development of prepaid group plans that could restrain expenditure by hospitals and physicians and centralize health care delivery (known as HMO's). By 1995, managed care became a dominant part of the U.S. health system administered by HMO's. Managed care can be defined as "health plans that contract selectively with providers on a discounted basis and provide utilization management and quality assurance".[14] Basically, third-party funders contract with doctors on the terms of service delivery; patients no longer control usage and charging through individual encounters between them and a physician. Decisions about the provision of health care are therefore made by autonomous corporations and medical practitioners. Federal and state governments also directly regulate the private insurance market through micro-regulation of the provision of health care, using such tools as anti-trust regulation and competition law.

Performance

The Commonwealth Fund's International Working Group on Quality Indicators compares forty quality indicators from five countries: Australia, Canada, New Zealand, the United Kingdom and the United States.[15] Each country studied had different areas of good performance and weakness. The U.S. had the highest breast cancer survival rates and cervical screening rates were very high. Waiting times for elective surgery were the lowest. U.S. doctors were most likely to ask for the patient's opinion and to discuss the emotional burden of illness. Although decreasing in other countries, asthma mortality rates are increasing in the U.S. U.S. citizens reported trouble seeing doctors, particularly on nights and weekends and for same day appointments. They also reported the most financial barriers to care and the most coordination of care problems.

The World Health Organization examined the relative performance of health systems of member countries.[16] Overall health system attainment (this measures the level of health,

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[12] OECD, *supra* note 4.
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[14] J. Gabel, "Ten Ways HMOs Have Changed During the 1990's" (1997) 16:3 Health Aff. 134 at 144.
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[16] The World Health Organization, *The World Health Report 2000* (Geneva: The World Health Organization, 2004).

the distribution of health, the level of responsiveness, the distribution of responsiveness and the fairness of financial contribution) was one of the indicators measured. The report estimated that the U.S. ranked fifteen on the list (Canada 7, Australia 12, U.K. 9, Denmark 20 and N.Z. 26).[17] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. The U.S. ranked number 37 in the world (Canada 30, U.K. 18, Australia 32, Denmark 34, and New Zealand 41).[18] The responsiveness of health systems was also examined in regard to the level of responsiveness (defined as dignity, autonomy, confidentiality, prompt attention, quality of basic amenities, access to social support networks during care and the choice of care provider). The U.S. ranked one (U.K. 26-27 (with Qatar), Denmark 4, Canada 7-8, Australia 12-13, New Zealand 22-23). In terms of the distribution of responsiveness (in relation to disadvantaged groups), the U.S. ranked third, making it equal with 37 other countries including the U.K., N.Z., Canada, Denmark and Australia.

In 2000, the Institute of Medicine released its seminal text – *To Err is Human*.[19] In this report, it concludes that health care needs to move beyond blaming individuals for retrospective events and focus on preventing future errors by designing safety into the system. It made a number of recommendations - the following relate recommended changes to or use of law:

1) Congress should "establish a Center for Patient Safety within the Agency for Healthcare Research and Quality. This center should:
   - set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
   - develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

2) A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should:
   - designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
   - require all health care organizations to report standardized information on a defined list of adverse events;

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[17] Because of statistical uncertainty Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.

[18] Canada, Australia and Denmark are in the same range.

[19] Institute of Medicine, *To Err is Human: Building a Safer Health System,* (Washington, D.C.: National Academy Press, 2000) [To Err].

- provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and
- designate the Center for Patient Safety to:

  (a) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and

  (b) receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

3) The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:

- describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
- convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
- periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
- fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

4) Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed-by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

5) Performance standards and expectations for health care organizations should focus greater attention on patient safety.

- Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.
- Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

6) Performance standards and expectations for health professionals should focus greater attention on patient safety. Health professional licensing bodies should:

(a) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
(b) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

7) Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should:

(a) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
(b) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
(c) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;
(d) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and
(e) collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

8) The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre and post-marketing processes through the following actions:

• develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
• require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
• work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.[20]

The Institute of Medicine released *Crossing the Quality Chasm* in 2001.[21] The IOM concluded, "In its current form, habits, and environment, American health care is incapable of providing the public with the quality health care it expects and deserves."[22] It calls for improvements in six dimensions of health care performance: safety; effectiveness; patient-centeredness; timeliness; efficiency; and equity. It suggests that improvements cannot be made within the current U.S. healthcare system and advocates

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[20] *Ibid.* at 1-15.
[21] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington DC: National Academy Press & Institute of Medicine, 2001).
[22] *Ibid.* at 43.

for the redesign of the U.S. health care system at four levels: patients' experiences (level A); the small units of care delivery (microsystems) (level B); organizations that house and support microsystems (level C) and the environment of laws, rules, payment, accreditation and professional training that shape organizational action (level D).[23] The quality of actions at level B, C, D ought to be defined as the effects of those actions at level A. It endorsed the following statement on the purpose for the U.S. health care system suggested by the President's Advisory Committee: "the purpose of a health care system is to reduce continually the burden of illness, injury, and disability and to improve the health status and function of the people of the United States." The IOM suggested the following six "Aims for Improvement:"

- Safety – patients should be as safe in health care facilities as they are in their own homes.
- Effectiveness – the health care system should match care to science, avoiding both the overuse of ineffective care and the under-use of effective care.
- Patient-centeredness – health care should respect the patient's choices, culture, social context, and specific needs.
- Timeliness – care should continually reduce waiting times and delays for patients and care providers.
- Efficiency – the reduction of waste and the reduction of the total cost of care should be never-ending, including for example waste of supplies, equipment, space, capital, ideas and human spirit.
- Equity – the system should seek to close racial and ethnic gaps in health status.

Patient Safety

Key Statistics

A number of studies in the U.S. have identified significant patient safety related problems in U.S. hospitals. The earliest studies were the Harvard Medical Practice study conducted in 1991, which estimated an adverse event rate of 3.7 percent with a death or permanent disability rate of 0.7 percent.[24] Similar results were found in the course of another study conducted at the same time (Utah/Colorado study).[25] In 2000, the Institute of Medicine published a report entitled *To Err is Human,* which drew attention to the new emerging statistical reality that as many as 98,000 Americans die each year as a result of medical

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[23] See also, Donald Berwick, "A User's Manual for the IOM's 'Quality Chasm' Report" (2002) 21:3 Health Affairs 80.

[24] T.A. Brennan *et al.* "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 N. Engl. J. Med. 370 and L.L. Leape, T.A. Brennan, *et al.*, "The Nature of Adverse Events in Hospitalized Patients: Results from the Harvard Medical Practice Study II" (1991) 324:6 New Engl. J. Med 377.

[25] Eric Thomas, DM Studdert, Helen Burstin, *et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado* (2000) 38:3 Med. Care 261.

error.[26] A more recent (2004) study of the pediatric population in the United States suggests that medical errors are responsible for the deaths of nearly 4,500 children in the U.S. every year and cost more than $1 billion per year. Children less than one year old and those covered by Medicaid (i.e. the poor) were more likely to experience medical errors.[27] Another 2004 study by the same authors examined the impact of medical injuries and concluded that more than 30,000 patients died each year.[28]

Institutional Regulation

Institutional regulation occurs at both the federal and state level. In addition, the acceptance of private accreditation by certain federal and state regulators as a means of satisfying program participation or licensure requirements makes accreditation significant. For example, federal law allows institutions to be deemed as meeting the Conditions of Participation for Medicare if they are accredited by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), a non-profit organization that accredits over 15,000 healthcare facilities in the United States.[29] JCAHO sets standards against which health care facilities are accredited and recent initiatives include standards concerning wrong site, wrong procedure or wrong person surgery.[30] Their standards are widely followed, as meeting JCAHO requirements is one mechanism for facilities to qualify for Medicare.

At the federal level, the Centers for Medicare and Medicaid Services (CMS) administer the Medicare program and jointly administer the Medicaid program with states. Health care organizations seeking to participate in the programs must be certified as complying with the Conditions of Participation and Condition of Coverage requirements appropriate for their organization.[31] These conditions contain standards intended to "improve quality and protect the health and safety of beneficiaries."[32] Hospitals seeking to participate are required to meet standards pertaining to patient rights, quality improvement, staffing, infection control and numerous other areas of hospital operation.[33] In 2003, a new condition of participation was implemented using a performance improvement

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[26] Institute of Medicine, *To Err supra* note 19.

[27] M. Miller & C. Zhan, "Pediatric Patient Safety in Hospitals: A National Picture in 2000" (2004) 113:6 Pediatrics 1741. The study is not without its critics who charge that it grossly overstates the impact of medical errors because it included deaths that could not unequivocally be attributed to mistakes. Anne Harding, "Study Finds US Paediatric Medical Errors Kill 4500 Children a Year" (2004) 328:7454 BMJ 1458.

[28] C. Zhan & M. Miller, "Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization" 2003 290:14 JAMA 1868.

[29] Deemed Status for JCAHO accreditation is found in section 1865 of the *Social Security Act* and in regulations at 42 C.F.R. 488.5. Accredited hospitals will not be deemed to meet a condition of participation that CMS identifies as being higher or more precise than JCAHO's requirements.

[30] Scott Gottlieb, "United States Brings in New Rules to Prevent Surgical Errors" (2004) 329:7456 BMJ 13.

[31] For a list of rules and regulations governing each type of organization, see CMS, *Conditions of Participation, Conditions of Coverage Citations*" online: CMS < http://www.cms.hhs.gov/cop/1.asp>.

[32] *Ibid.*

[33] 42 C.F.R. § 482 (2003).

framework that requires hospitals to "develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program" or QAPI. [34] Designed to set a clear expectation that hospitals must take a proactive approach to improving their performance, this condition is a minimum requirement for hospitals to both systematically examine their quality and undertake ongoing improvement projects.[35] A hospital's QAPI program must:

- include an ongoing program that shows measurable improvement in relation to indicators for which there is evidence that it will improve health outcomes and reduce medical errors. Hospitals are required to measure, track and analyze quality indicators, including adverse patient events;
- incorporate quality indicator data. Data the hospital collects should be used for monitoring the effectiveness, safety and quality of services and identifying improvement strategies;
- set priorities for improvement activities, which involves focusing on high-risk, high volume areas that affect health outcomes and patient safety. These activities must involve tracking adverse patient events and medical errors, studying their causes, and implementing preventative actions and feedback and learning mechanisms throughout the hospital.
- include distinct performance improvement projects. The number and scope of the projects conducted by the hospital must be proportional to the scope and complexity of the hospital's operation and be similar in effort to projects conducted by CMS contracted quality improvement organizations (QIOs).

The regulation makes the hospital's governing body accountable for ensuring the ongoing program for patient safety and quality improvement is well defined, implemented, maintained and adequately funded.[36] Considerable discretion is given to hospitals to design their program in an effort to increase flexibility and reduce regulatory burden, while maintaining an appropriate level of accountability.[37] Compliance with the QAPI regulatory framework is assessed by state agency surveyors, who survey a certain number of hospitals each year to determine whether they are compliant with the applicable conditions of participation.[38] Hospitals are required to show through the use of objective data that improvements have occurred in relation to actual care outcomes or other performance indicators as a result of their QAPI program.[39] If the hospital is significantly non-compliant with the QAPI requirements, it may be terminated from the Medicare or Medicaid programs.[40]

In addition to the survey process, CMS uses the Quality Improvement Organization (QIO) program as a mechanism to ensure that medical care paid for under the Medicare

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[34] 42 C.F.R. § 482.21 (2003). The regulation was made under *Social Security Act* § 1861(e), 42 U.S.C. 1395x (2005).
[35] 68 Fed. Reg. 3435-3436 (Jan. 24, 2003)
[36] 42 C.F.R. § 482.21(e) (2003).
[37] 68 Fed. Reg. 3437 (Jan. 24, 2003).
[38] Surveys are conducted pursuant to *Social Security Act* §1864, 42 U.S.C. 1395aa (2005).
[39] 68 Fed. Reg. 3443 (Jan. 24, 2003).
[40] 68 Fed. Reg. 3436 (Jan. 24, 2003).

program is medically necessary and reasonable, is of a quality that meets professionally recognized standards of health care and is provided in the most economical setting.[41] Under the program, CMS contracts with 53 independent organizations (one for each state, territory and the District of Columbia) to monitor and improve the quality of care delivered to beneficiaries. Under the Act, the organization must be composed of a substantial number of physicians and have at least one individual who is a consumer representative on its governing body.[42] Each quality improvement organization (QIO) is governed by a three year contract, known as a Statement of Work (SOW), which outlines their responsibilities and is divided into tasks.[43]

Quality review mechanisms for Medicare have evolved over time and reflect CMS's "transition from a financing program to a value based purchaser of health care."[44] Utilization and Quality Control Peer Review Organizations (PROs) were created by Congress in 1982[45] to replace controversial professional standards review committees (PSROs).[46] Earlier contract cycles focused on individual case review and the reduction of inappropriate admissions to hospitals. By the early 1990s, an evolving awareness emerged among stakeholders that retrospective individual case analysis was an ineffective means of improving the overall quality of health care. Later contract cycles moved to a quality improvement approach and the primary activity of the PROs became collaboration with stakeholders to implement quality improvement projects in areas of clinical concern.[47] These projects typically focus on clinical care processes known to improve patient outcomes or specific preventative services and improvements in care are measured using national disease specific quality of care measures.[48] For example, one current measure of the quality of care involving pneumonia used by CMS is whether

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[41] Currently known as Quality Improvement Organizations (QIOs), these functions of utilization and quality control peer review organizations are set out in section 1154 of the *Social Security Act* § 1154, 42 U.S.C. § 1320c-3 (2005). Further information on what norms of care are to be applied by QIOs is contained in Social Security Act § 1154 (a)(6)(A).

[42] *Social Security Act* § 1152, 42 U.S.C. § 1320c-1 (2005).

[43] *Social Security Act* § 1153, 42 U.S.C. § 1320c-2 (2005).

[44] V. Bhatia *et al.* "Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement" (2000) 22:1 Health Care Finan. Rev. at 73.

[45] *Peer Review Improvement Act 1982,* Pub. L. No. 97-248, 96 Stat. 381(amending *Social Security Act*, Title XI Part B).

[46] PSROs were created in the 1970s to ensure quality care and to check rapidly rising Medicare hospital costs. They were widely viewed as a mechanism for controlling costs and medial practice, rather than improving quality of care and it is widely agreed they were unsuccessful in accomplishing either goal. Their reputation was as torpid watchdogs, lacking authority, and in many cases the desire to question doctors' decisions. See Bhatia *et al. supra* note 44 and Spencer Vibbert, *The Doctor Watchers* (Ground Rounds Press & Whittle Direct Press, 1991) at 15.

[47] It should be noted that while QIO activity has been focused on quality improvement, there are indications that in the 8th SOW there will be activities more directly focused on patient safety. A summary of the draft 8th SOW requires QIOs to work with select rural or low volume hospitals to implement a safety culture and redesign systems to address local patient safety issues. Centers for Medicare and Medicade, Services, Office of Clinical Standards and Quality, Quality Improvement Group, "Proposed Summary of Draft 8th Statement of Work: Task 1c2 Rural/Low Hospital" (2004) at 8, online: <www.ahqa.org/pub/uploads/8SOWExecSummaryv5.doc>

[48] CMS, *Statement of Work, Group Three Contracts* online: CMS <http://www.cms.hhs.gov/qio/2l.pdf>. Quality of care measures are defined in the SOW as "measures of how often these critical processes or services are performed or how often desired outcomes are achieved."

pneumonia patients at a hospital received their first dose of antibiotics within four hours of arrival.[49] Begun in 1999, the 6th Statement of Work (SOW) contract directed PROs to improve care in six clinical areas (AMI, heart failure, stroke, pneumonia, breast cancer and diabetes) that are major sources of mortality and morbidity for the Medicare population. Twenty-four process of care measures were developed in these areas and were based on scientific evidence and consensus that these processes can improve outcomes. A study that analyzed whether quality of care for Medicare beneficiaries had improved based on 22 of these indicators concluded that while care had improved, the data could not conclusively indicate the degree to which the improvements were tied to QIO's quality improvement efforts.[50] However, the study cites earlier evidence that suggests QIO interventions can lead to improvements, based on an analysis of a 1992 Cooperative Cardiovascular Project (CCP) implemented by PROs, where assistance given to providers to change care processes for AMI in four pilot states resulted in improved outcomes.[51] Under Section 109 (d) of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) , the Institute of Medicine (IOM) will conduct a study of the QIO program and its effectiveness and a report, including any legislative recommendations, is to be submitted to Congress no later than June 1, 2006.[52]

The MMA also has a provision that requires acute care hospitals to report a set of 10 hospital quality measures to CMS (through QIOs) in order to receive the full annual payment update from Medicare.[53] Eligible hospitals who fail to report on these indicators during the 2005-2007 fiscal period will have their annual payment update reduced by 0.4 percent. This statutory provision is intended to promote the public reporting of hospital quality data, which in turn is designed to help consumers make informed decisions about hospital care and to give hospitals incentives to improve their performance.[54] As of September 2004, 98.3 percent of eligible hospitals had satisfied the reporting requirements. As of April 2005, hospital performance data concerning the 10 measures, along with other measures voluntarily reported by hospitals through the Hospital Quality Alliance (HQA) project, is publicly available on the *Hospital Compare* website.[55]

Institutions are also regulated through state licensure laws, which set out minimum requirements for the institution's structure and operating processes in order for the facility to legally operate. Some states are incorporating patient safety into their hospital

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[49] These indicators are reportable to CMS under the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) initiative.

[50] Stephan Jencks, "Changes in Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001" (2003) 289:305 JAMA 312.

[51] Study limitations included the lack of a comparator group and the fact that the four states were not a random sub-sample of the country. See T. Marciniak *et al* "Improving the Quality of Care for Medicare Patients with Acute Myocardial Infarction" (1998) 279 JAMA 1351.

[52] *Medicare Prescription Drug Improvement and Modernization Act of 2003*, Pub. L. No. 108-173, 117 Stat. 2066.

[53] *Ibid.* at § 501(b).

[54] CMS, *Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) August 2005* online: CMS <http://www.cms.hhs.gov>; CMS, *Nearly All Eligible Hospitals are Reporting Quality of Care Data*, (2004) online: CMS <http://cms.hhs.gov>.

[55] See <www.hospitalcompare.hhs.gov>.

licensure laws. In order to be licensed in Florida, hospitals must have in place a patient safety plan, a patient safety officer and a patient safety committee, which will promote patient safety and help implement, review and evaluate the quality of the hospital's patient safety measures.[56] The hospital must also have in place an internal risk management program that includes an adverse incident reporting system, risk management education and training, and the development and implementation of procedures and systems to prevent wrong patient, wrong site, and wrong surgery procedure errors.[57] The law makes the hospital's governing board accountable for the internal risk management program. Nevada, New Jersey, and Washington have similar requirements. Other states have requirements for quality assurance or patient safety programs in specific facilities (in DC adult and pediatric trauma facilities, in Florida hospices and in Texas ambulatory surgical centers).

The quality of care in nursing homes has been a significant issue in the U.S. for more than thirty years. In 1986, the Institute of Medicine published a report that set out detailed recommendations for reforming the regulation of nursing homes.[58] The recommendations were largely accepted at the federal level and were enacted in the *Nursing Home Reform Act* as part of the *Omnibus Budget Reconciliation Act of 1987.* CMS is responsible for producing and maintaining federal regulations that all nursing homes interested in participating in Medicare and Medicaid must conform to (60 percent of the $90 billion spent in 1999 on nursing home care was borne by the states and federal government).[59] The state survey, licensing and certification agencies are responsible for surveying or inspecting nursing homes to check compliance with regulations, investigating complaints and reporting results to the CMS. State agencies and regional officers of CMS are responsible for taking enforcement action when deficiencies are identified. The Centers fund most costs of Medicare/Medicaid certification and oversees the performance of the state survey agencies. Nursing homes must also comply with state licensing requirements. In addition to the more general regulatory requirements set out in such statutes, some states have initiatives specifically aimed a safety in long-term care facilities. North Carolina, for example, has required that the Department of Health and Human Services contract with an entity to develop and implement a Medication Error Quality Initiative for nursing homes to analyze reports from each nursing home on the aggregate number of medication errors by type and cause.[60]

However, a number of bodies continue to publish reports that are critical of the regulation of nursing homes, including the Special Senate Committee on Aging, the U.S. General Accounting Office, and the Institute of Medicine, which revisited nursing home regulation and concluded that further reform is needed. The Clinton administration launched a nursing home initiative in 1998 aimed at improving the effectiveness of regulation.

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[56] Fla. Stat. § 395.1012 (2005).
[57] *Ibid.* at § 395.0197.
[58] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes* (Washington DC: National Academy Press, 1986).
[59] Kieran Walshe, "Regulating U.S. Nursing Homes: Are We Learning From Experience?" (2001) 20:6 Health Aff. 128.
[60] N.C. Gen. Stat. § 131E-128.5.

There is some evidence to suggest that the quality of care in nursing homes may have improved in the last ten to fifteen years and that some of these improvements may be attributed to regulation. For example, the rates of physical and chemical restraint have reduced, as have the rates of urinary incontinence and catheterization. Hospital admission rates have also decreased. However, pressure sore rates have not changed and malnutrition, dehydration and feeding problems remain common, while bowel incontinence has increased.[61]

Critics suggest that there should be further reforms. One camp argues that regulatory standards should be toughened and more aggressively enforced. There should be more frequent inspections, greater use of sanctions and penalties and more uniform and rigorous application of existing regulations. The other camp believes that the regulatory burden is too great. They suggest regulation should be simplified and focused on the small number of problem nursing homes and reoriented towards a partnership model. Critics also note that regulatory fragmentation is a critical issue in nursing home regulation. Federal responsibility is split between national and regional offices and there is evidence to suggest that this causes communication problems and reduces the effectiveness of regulation. Responsibility is also split between regional federal offices and state survey agencies and conflicts may arise for the state agencies, which are accountable to the federal agency and to the state government. Federal and state regulation run side by side and this may result in duplication, conflicts and confusion.[62] Critics also note that there must be a balance between accountability and independence. They note that nursing home regulation is often a highly politicized process, which may result in risk averse and cautious regulators. They also highlight the conflict between the state and federal governments' dual roles as funders and regulators, noting that any move to tighten regulations to improve quality results in pressure for the government to spend more on reimbursements.

Working Conditions Regulation

Union negotiations over work conditions for medical residents were not possible in the U.S. until 1999, when the National Labor Board overturned twenty years of precedent by recognizing that medical residents were employees and allowing them the right to collective bargaining.[63] However, very few resident groups have sought to exercise collective bargaining rights.

In 2001, the Public Citizen Health Research Group, the American Students Medical Association, the Committee of Interns and Residents and others petitioned the federal Occupational Safety and Health Administration to regulate the work hours of residents.

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[61] Walshe, *supra* note 59.
[62] Walshe, *supra* note 59.
[63] *Boston Medical Center Corporation v House Officers' Association/Committee of Interns and Residents* 330 N.L.R.B. 152 (1999).

The Administration rejected the petition on the grounds that the ACGME, a private sector agency, should be responsible for work hour restrictions.[64]

The working hours problem in relation to health providers has excited legislative interest in the United States. Two states, New York and Puerto Rico, have legislation limiting work hours, although similar legislation is being considered by a number of states including Massachusetts, Delaware, New Jersey, Pennsylvania and California.

In New York, legislation was enacted as the result of the death of Libby Zion in a New York hospital. [65] Her father claimed that his daughter died because of inadequate care from overworked and under-supervised medical house officers. A grand jury was convened and found problems with the system of residency training and physician staffing that routinely allowed resident-physicians to work more than 100 hours per week for thirty to forty continuous hour periods. The grand jury found that over-worked, sleep-deprived residents and lack of supervision were serious potential dangers for patients and that the method of training doctors was "counterproductive to providing quality medical care".[66] A committee was established in 1987 to review the grand jury's findings. It recommended that a resident's scheduled workweek should be limited to 80 hours averaged over a four week period. Residents should not be scheduled to work shifts exceeding 24 consecutive hours and residents should have at least one scheduled 24 hour period of non-working time per week.

In 1989, the recommendations became part of the *New York State Health Code,* as revision to section 405.[67] The legislation requires 24 hour supervision of acute care inpatient units by an experienced attending physician, 12 hour work limits for residents and attending physicians in emergency departments, work periods not exceeding 24 hours in other departments, scheduled work weeks for residents not exceeding an average of 80 hours per week over four weeks and at least one 24 hour non-working period per week and ancillary support for resident physicians. In addition, the legislation provided hospitals with $240 million (U.S.) a year for eight years to hire more ancillary staff and board certified physicians. Compliance was 'voluntary'.

The most significant problem with this legislation was that it was routinely ignored. In 1998, the New York State Department of Health conducted a four day unannounced investigation of 12 hospitals across New York State. All 12 were found to be flagrantly violating the resident working hour limits, although supervision was appropriate. Findings were that: 37% of residents were working more than 85 hours per week; 20% exceeded 95 hours per week; 60 percent of surgical residents exceeded 95 hours per week and 38% of residents worked in excess of 24 hours per week. Residents also reported

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[64] See Hal Lawrence, "The Impact of Residents' Work-Hour Restrictions" (2003) 3 Current Womens' Health Rep. 487.

[65] N.Y. Comp. Codes & Regs tit. 10, § 405.4 (2004).

[66]. Supreme Court of the State of New York, County of New York. Part 50. Report of the Fourth Grand Jury for the April/May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County. New York: Supreme Court of the State of New York; 1986: 50.

[67] N.Y. Comp. Codes & Regs tit. 10, § 405.4 (2004).

busy on-call time with limited rest.[68] In 2002, 66 percent of hospitals surveyed were not in compliance with the regulations. Fifty-six percent violated the 24 hour requirements, 34 percent violated the 80 hours per week requirements, 23 percent did not provide 24 hours off and 13 percent did not provide the required hours off between shifts.[69]

Puerto Rico recently passed an *Act to Regulate the Work Shifts of medical interns and residents in Puerto Rico*.[70] The Puerto Rican legislation dictates that resident work hours be limited to 80 hours a week, 24 hour shifts, and duties only every third night. Emergency Department shifts are limited to 12 hours, with exceptions from the Secretary of the Health Department of Puerto Rico allowing a maximum of 15 hours. Emergency Department shifts must be separated by at least 10 hours off, according to the Act, while all other shifts must be separated by 8 hours. Residents must also have one day off per week. The Act specifies no additional shift hours for non-patient duties (i.e. no additional hours for administration or learning) and moonlighting is prohibited once a resident reaches the maximum 80 hours for that week. Penalties for violations include a fine of up to $5,000 for programs and a fine of up to $200 for each resident. A committee established within the Health Department will handle complaints.

A House Committee of the United States Congress is considering the *Patient and Physician Safety and Protection Act of 2005*.[71] The 2005 Bill intends to reduce work hours and increase supervision of resident-physicians to ensure the safety of patients and the resident-physicians. The Preamble notes:

- Federal government spends $8 billion per year to train resident-physicians and therefore has an interest in assuring the safety of patients and residents
- Residents perform a significant amount of time performing activities not related to training
- The excessive numbers of hours worked by residents is inherently dangerous for patient care and for the lives of the residents
- The scientific literature has demonstrated that sleep deprivation of the magnitude seen in residency training programs leads to cognitive impairment
- A substantial body of research indicates that excessive hours worked by resident physicians leads to higher rates of medical error, motor vehicle accidents, depression and complications in pregnancy
- The medical community has not adequately addressed the problem
- The effects of sleep deprivation on resident physicians does not change between specialties
- The federal government has regulated the work hours of other industries when the safety of employees or the public is at risk

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[68] Rita Kwan & Robert Levy, *A Primer on Resident Work Hours: 5th Edition August 2004* (Reston VA: American Medical Student Association, 2004).
[69] Lawrence, *supra* note 64.
[70] *An Act to Regulate the Work Shifts of medical interns and residents in Puerto Rico* [2003] P.R. Laws 47. An English translation is available online at: American Student Medical Association <http://www.amsa.org/hp/rwh_pr.doc>.
[71] U.S. Bill H.R. 1228, *Patient and Physician Safety and Protection Act of 2005*, 109th Cong., 2005.

The Bill states that residents may work no more that a total of eighty hours per week and 24 hours per shift. There shall be at least ten hours between shifts, one full day off a week and one full weekend off a month. In an emergency department a resident shall work no more than 12 continuous hours and shall not be scheduled on call more often than every third night. A resident may file an anonymous complaint and a hospital may be fined up to $100,000 per program in any six month period. A person appointed by the Secretary of Health and Human Services anonymously surveys residents, conducts on site investigations, publicly discloses violations and reports to Congress. The Bill also allows the provision of extra funding to enable compliance.

The hours worked by nurses are also subject to attempted legislative intervention. A Committee of the U.S. Congress is currently examining the *Safe Nursing and Patient Care Act of 2005*.[72] The Bill intends to provide for patient protection by limiting the number of mandatory overtime hours a nurse may be required to work in Medicare funded facilities. The Preamble notes:

- The Federal Government has a substantial interest in assuring that delivery of health care services to patients in health care facilities is adequate and safe.
- The widespread practice of requiring nurses to work extended shifts and forego days off causes nurses to frequently provide care in a state of fatigue, contributing to medical errors and other consequences that compromise patient safety.
- Limitations on mandatory overtime will ensure that health care facilities throughout the country operate in a manner that safeguards public safety and guarantees the delivery of quality health care services and facilitates the retention and recruitment of nurses.

The Bill provides that a nurse should not be required to work more than any of the following: the scheduled work shift or duty period of the nurse; 12 hours in a 24-hour period; or 80 hours in a consecutive 14-day period. The Bill gives nurses the right to complain of violations free from retaliatory or discriminatory actions by providers. Providers who violate the provisions can receive a fine up to 10,000 and will have their names posted a DHHS website. The legislation also requires a study to determine the maximum length of time it is safe for a nurse to work.

The movement towards establishing legislated staffing levels for health care regimes is at its strongest in the U.S. After sustained lobbying by the Californian Nurses Association, California introduced comprehensive legislation in 1999[73] to establish minimum staffing levels in hospitals through the use of nurse to patient ratios to ensure quality patient care.[74] Reasons for the introduction of this legislation included California had one of the

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[72] U.S., Bill H.R. 791, *Safe Nursing and Patient Care Act of 2005*, 109th Cong., 2005.

[73] U.S., A.B. 394, *An Act to add Section 2725.3 to the Business and Professions Code, and to add Section 1276.4 to the Health and Safety Code, relating to health care*, 1999, Reg. Sess., Cal., 1999.

[74] Prior California law in 1976-1977 established nursing levels in acute hospitals requiring a minimum of one nurse per two patients in intensive care and coronary care units and that 50 percent of the nurses working these units be registered. Regulations from the 1990s require hospitals to develop and use patient

lowest nurse-to-patient ratios of any state in the U.S. (due to retrenchments caused by managed care and market based decisions) and studies linked the decline in nurse to patient ratios with an increase in the severity of the illnesses faced by patients. The ratios were implemented in stages, with the first stage being a 6:1 ratio in general medical-surgical units and moving to a 5:1 ratio in 2005. Programs could apply for a waiver to establish flexible staffing strategies or an exemption in the case of rural facilities.

In 2004, the Governor of California passed emergency regulations to suspend, for three years, the second stage of the program, while the Department of Health Services conducted a study of the effects of the law. He cited concerns from provider groups that hospitals would have to close or refuse to admit patients[75] if the new ratios were enforced. Provider groups were also concerned that the 6:1 ratio is actually the safe standard and that the state was trying to "raise the bar" by introducing the 5:1 ratio.[76] However, a Superior Court Judge in early March 2005 overturned the emergency regulations and ruled that California hospitals must comply with the newer, more stringent regulations.[77] The judge decided there was no emergency to justify use of such powers and that there was no substantial risk of harm if the ratio was lowered as scheduled.

The Californian legislation requires that the Department of Health Services establish minimum nurse-to-patient ratios for registered and licensed practical nurses in acute care hospitals, acute psychiatric hospitals and specialty hospitals. The legislation also prohibits unlicensed personal from performing certain procedures, including: the administration of medication; venipuncture; parental or tube feedings; inserting nasogastric tubes; inserting catheters; tracheal suctioning; assessment of patient condition; patient education; and moderate complexity laboratory tests. Enforcement of the ratios is weak – the Department inspects the hospital within two days if there is an immediate threat to the safety of patients and 70 days if it judges that there is no threat. If there is a violation the hospital must submit an action plan. The Department of Health Services has no power to impose fines or monetary penalties. Other mechanisms do exist. Medi-Cal (Medicaid) and Medicare require that hospitals comply with all laws and regulations and can audit and deny payment. It also increases an institution's medical malpractice risk if it is not in compliance with the law.

Legislation was also introduced in Hawaii, Tennessee, Missouri, and Iowa in 2004 requiring specific nurse-to-patient ratios in hospitals and/or other health care facilities. Connecticut legislation, introduced in 2004, calls for the Commissioner of Public Health to adopt regulations establishing minimum nurse-to-patient ratios. In 2004, Maine

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classification systems to measure the acuity of patients and determine nurse staffing needs for inpatient units on a shift-by-shift basis. Joanne Spetz, "California's Minimum Nurse-to-Patient Ratios: The First Few Months" (2004) 34:12 J. Nurs. Admin. 571.

[75] There are no reports of permanent reduced access to inpatient care from California directly attributable to the ratios, *Ibid.*

[76] Lynda Gledhill, "1-to-5 Nurse Patient Ratio Must be Met, Judge Says. Ruling on State's Hospitals is Upheld, Overriding Governor" *San Francisco Chronicle* (5 March 2004) B7.

[77] *Ibid.*

enacted legislation requiring minimum nurse to patient staffing ratios determined by a staffing system in which hospitals are required and held accountable for developing nurse staffing plans to respond to patient numbers and acuity and staff skill mix. Illinois, New York, Tennessee, Rhode Island, Pennsylvania, Michigan, and Massachusetts have introduced legislation requiring a combination of minimum nurse to patient ratios augmented by hospital based staffing systems.

Nurse-to-patient ratios are also on the agenda for Federal legislators in the U.S. The *Nurse Staffing Standards for Patient Safety and Quality Care Act 0f 2005*[78] is currently being considered by House committees.

Professional Regulation

The regulation of health practitioners occurs at the state level. All states require health practitioners to possess a license or certificate as a means of ensuring they are competent to practice.

Generally, state boards or professional bodies conduct licensing. These Boards in addition to controlling entry into the profession also protect the public by disciplining practitioners who are incompetent or who engage in unprofessional practice. Deriving their authority from state professional practice laws, some boards are independent self-regulatory bodies with full licensing and disciplinary powers, while others are part of larger state agencies, such as Departments of Health.

The Pew Health Professions Commission (a private research commission) noted in its work from 1989-1999 the conflict of interest in vesting professional boards with government authority. It suggested the development of an interdisciplinary oversight board to coordinate health professional regulation in each state.[79]

In Virginia, for example, a Board of Health Professions is established.[80] The Board is comprised of one member from each regulatory body and five members appointed by the governor. Its role as set out in statute is to:

> 1. To evaluate the need for coordination among the health regulatory boards and their staffs and report its findings and recommendations to the Director and the boards;
> 2. To evaluate all health care professions and occupations in the Commonwealth, including those regulated and those not regulated by other provisions of this title, to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed. Whenever the Board determines that the

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[78] U.S., Bill H.R. 1222, To amend the Public Health Service Act to establish direct care registered nurse-to-patient staffing ratio requirements in hospitals, and for other purposes, 109th Cong., 2005.
[79] The Pew Health Professions Commission, online: Future Health <http://www.futurehealth.ucsf.edu/compubs.html>
[80] *Department of Health Professions,* Va. Code Ann. tit. 54.1 § 54.1-2500 (1988).

public interest requires that a health care profession or occupation which is not regulated by law should be regulated, the Board shall recommend to the General Assembly a regulatory system to establish the appropriate degree of regulation;
3. To review and comment on the budget for the Department [Department of Health Professions];
4. To provide a means of citizen access to the Department;
5. To provide a means of publicizing the policies and programs of the Department in order to educate the public and elicit public support for Department activities;
6. To monitor the policies and activities of the Department, serve as a forum for resolving conflicts among the health regulatory boards and between the health regulatory boards and the Department and have access to departmental information;
7. To advise the Governor, the General Assembly and the Director on matters relating to the regulation or deregulation of health care professions and occupations;
8. To make bylaws for the government of the Board of Health Professions and the proper fulfillment of its duties under this chapter;
9. To promote the development of standards to evaluate the competency of the professions and occupations represented on the Board;
10. To review and comment, as it deems appropriate, on all regulations promulgated or proposed for issuance by the health regulatory boards under the auspices of the Department. At least one member of the relevant board shall be invited to be present during any comments by the Board on proposed board regulations;
11. To review periodically the investigatory, disciplinary and enforcement processes of the Department and the individual boards to ensure the protection of the public and the fair and equitable treatment of health professionals;
12. To examine scope of practice conflicts involving regulated and unregulated professions and advise the health regulatory boards and the General Assembly of the nature and degree of such conflicts;
13. To receive, review, and forward to the appropriate health regulatory board any departmental investigative reports relating to complaints of violations by practitioners of Chapter 24.1 (§ 54.1-2410 et seq.) of this subtitle;
14. To determine compliance with and violations of and grant exceptions to the prohibitions set forth in Chapter 24.1 of this subtitle; and
15. To take appropriate actions against entities, other than practitioners, for violations of Chapter 24.1 of this subtitle.[81]

The Department of Health Professions, receives all complaints about registered health professions and records them, monitors the operations of the state boards in response to complaints, assists them perform their functions, establishes a health professional intervention program and a prescription monitoring program. It also performs other functions. Beneath the Department, Boards of Medicine, Nursing and so on operate.[82]

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[81] *Ibid.*
[82] *Ibid.*

The Pew Commission also recommended the establishment of uniform complaint and disciplinary processes across the professions and between states and the use of consistent regulatory terminology and uniform standards for entry to practice. Montana is one of the states that has adopted the consistency recommendations of the Pew Commission when it adopted a uniform licensing Act for all professional and technical occupations[83] as has Virginia.

In the past, licensure bodies have attempted to ensure the initial competence of professional by enforcing education and examination requirements but have largely ignored the problem of ongoing competence.[84] Historically, licensure bodies have monitored ongoing competence through policing continuing education requirements and investigating complaints. Many states have in place continuing medical education (CME) requirements for physicians seeking re-licensure as a means of ensuring ongoing competence.[85] As part of the MCARE Act, physicians in Pennsylvania seeking biennial licensure renewal (for the period from Jan 1st, 2005 to Dec 31st, 2006) will be required to complete 100 hours of CME and at least 12 of those hours must be completed in activities concerning patient safety and risk management. The Board will conduct random audits to ensure compliance with the requirements and non-compliance may result in disciplinary action. Completion of continuing education credits focused on patient safety is also a condition of licensure in Florida.[86] Many question the effectiveness of continuing education mechanisms as a tool for ensuring quality and note that at best such programs help a professional to retain a more current knowledge base it certainly cannot assure competence.[87]

The responsibility for competence has therefore largely been borne by the disciplinary process. Professional regulation acts in all states set out quality related criteria such as incompetence as a ground for discipline. Acts may also authorize disciplinary actions for repeated malpractice or negligent conduct and for individual incidents of gross negligence. Some Acts also specify that certain acts are grounds for disciplinary action such as the use of steroids to enhance athletes' performance. Lastly, sanctions are available for physical or mental impairment, substance abuse etc. In order to invoke the disciplinary process boards must: identify professionals with disciplinary problems; investigate; prove incompetence; and respond with sanctions. Boards have primarily used patient complaints to identify problem practitioners. Although increasingly Boards may also conduct investigations on the basis of reports or referrals from other bodies, such as

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[83] *Uniform Professional Licensing and Regulatory Procedures,* Mont. Code Ann. tit. 37 § 37-1:301-19 (1995).

[84] Timothy S. Jost, "Oversight of the Competence of Healthcare Professionals," in T. Jost ed. *Regulation of the Health Professions* (Chicago: Health Administration Press, 1997).

[85] Federation of State Medical Boards, *Protecting the Public: How State Medical Boards Regulate and Discipline Physicians* online: FSMB <www.fsmb.org>. Critics of traditional continuing education (CE) note, that while it may help the professional have a more current knowledge base, that it does little to ensure professionals actually are practicing competently and studies have shown little relationship between traditional CE and actual quality of care. They argue competency evaluation should look at actual care processes and outcomes, rather than just general knowledge, and should be specific to the practitioner's area of practice. Jost, *supra* note 84.

[86] Fla. Stat. § 456.013 (2005).

[87] Jost, *supra* note 84 at 32.

malpractice insurers or hospitals that revoke privileges, and certain reports or referrals are mandatory under federal law and the laws of many states. Cited as a potential model for other states, the Massachusetts Board of Registration in Medicine conducts a clinical review of doctors who have made three or more malpractice payments.[88] Under Pennsylvania's 2002 *Medical Care Availability and Reduction of Error Act* (MCARE Act), physicians are required to self-report to the State Board of Medicine any civil malpractice claim brought against them within 60 days, as well as any controlled substance convictions and other serious criminal offenses.

Thus, the Boards enforce reactively rather than proactively. The focus is usually on whether the complaint is valid not whether the professional is competent. The Board may refer the matter for disciplinary action if it feels that it is warranted. Usually, disciplinary action is undertaken with the (reluctant in some cases) assistance of the state attorney general's office. Disciplinary action is long and expensive and so many boards resolve meritorious complaints though the use of consent agreements (settlements). Some states have mechanisms for informal dispute resolution systems aimed at resolving complaints at a low level. Consent agreements often do not address underlying competency problems and so may not protect the public.[89] If no consent agreement is reached, the Board may apply sanctions, the greatest of which, revocation, is not used often. Boards can also place conditions on practice and suspension. In general, Boards have increased the public's ability to access information following the trends towards more open disclosure. Some have gone even further and have practitioner data on the internet that includes disciplinary information and information about volumes and comparative success rates, for example in Massachusetts.[90]

Legislation in many jurisdictions allows reviews for mental, physical or competency assessment where there is reason to suspect incompetence and such reviews have been considered constitutional by the courts. Maryland for example has a peer review program, Virginia an intervention program and Ohio has a quality intervention program.

At the federal level, a National Practitioner Data Bank was established through the *Health Care Quality Improvement Act of 1986* (HCQIA). The legislation was enacted because Congress believed increasing occurrences of medical malpractice litigation and quality of care concerns required a national response. The database is intended to minimize the risk of incompetent physicians moving from state to state by providing a centralized information repository that permits bodies reviewing practitioner credentials to confirm practitioner supplied information. By law, malpractice insurers must report malpractice payments made as part of a settlement or a judgment to the database. State medical licensing boards, hospitals, managed care organizations and professional societies must report certain adverse actions taken for reasons related to professional competence or conduct. For example, hospitals are required to report any professional review action that adversely affects a physician's clinical privileges for longer than 30 days. The Act requires information to be reported on a least a monthly basis and contains

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[88] Robert Pear, "Panel Seeks Better Disciplining of Doctors" *The New York Times*, (5 January 2005).
[89] Jost, *supra* note 84 at 17.
[90] Online: MHQP< http://www.mhqp.org/default.asp?nav=010000>.

various sanctions for failing to report, with malpractice insurers facing fines of up to 10,000 dollars. Hospitals must query the databank when first granting clinical privileges to physicians and once every two years thereafter.

Overseen by the federal Department of Health and Human Services, the databank is required to provide information requested by state licensing boards and other health care entities that are in or may be considering an employment relationship with the physician. Physicians can self-query the databank. The information is otherwise confidential and it is not accessible by the public. Query fees fund costs associated with the databank.

A survey conducted by the Institute for Health Services Research and Policy Studies at the University of Illinois at Chicago indicated that the databank's information changed nearly 40,000 credentialing or licensing decisions each year.[91] The Office of the Inspector General estimates that information from the databank influences hospital and managed care organization credentialing decisions about two to three percent of the time.[92] Some point to these numbers as proof that the databank has a minimal effect and argue that it should be abolished; others suggest that two percent could involve the identification of hundreds or even thousands of practitioners who in the course of practice could endanger thousands of patients.[93] However, the system suffers from underreporting and a lack of timely reporting, and federal officials acknowledge that no fine or penalties have ever been imposed for non-compliance.[94] Other loopholes that allow a physician to avoid being reported include the requirement that only physicians named in final settlements are reportable. In these cases, physicians may not agree to a settlement until their names are removed. Some patient safety advocates say that the databank should be abolished and replaced with a different system that investigates both organizations and individuals, as the databank's focus on malpractice claims settled by individual physicians "perpetuates blame and holds systems-thinking back."[95]

Another federal initiative is a drug utilization review (DUR) scheme. The Department of Health, Education and Welfare issued regulations in 1974 requiring monthly review of prescription drug regimens for Medicaid patients in skilled nursing facilities. In 1990 Congress strengthened the requirements for DUR in Medicaid programs requiring that by 1993 states were to establish DUR programs for covered outpatient drugs "in order to assure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse events".[96] So states were to implement programs containing

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[91] Christopher Conover & Emily P. Zeitler, *National Practitioner Databank: Health Facilities Regulation,* (Working Paper No. P 5) (Durham, N.C.: Duke University Center for Health Policy, Law and Management, 2004); online at: <www.hpolicy.duke.edu>.

[92] Mark Yessian & Joyce Greenleaf, "The Ebb and Flow of Federal Initiatives to Regulate Healthcare Professionals" in T. Jost ed. *Regulation of the Healthcare Professions* (Chicago: Health Administration Press, 1997) at 182.

[93] *Ibid.*.

[94] Cheryl W. Thompson, "Poor Performance Records are Easily Outdistanced" *Washington Post* (12 April 2005) A01.

[95] Martin J. Hatlie & Susan Sheridan, "The Medical Liability Crisis of 2003: Must We Squander the Chance to Put Patients First?" (2003) 22:4 Health Aff. 37.

[96] 42 U.S.C. § 1396r-8 (2005).

prospective drug review, retrospective drug use review, and educational outreach. However, the chief impetus for the changes was cost containment. The federal government requires the states to submit annual reports but does not more than that to oversee the program. Most states have established prospective systems such as statewide online DUR systems that require submission of Medicaid claims online at point of sale. Claims are then screened against set criteria and payment may be disallowed or an explanation demanded if it does not meet those standards. They have also established retrospective systems of prescription review; physicians who do not comply with the standards are sent an educational letter. A review team assembled by the American Pharmaceutical Association found that "assessments of the impact on quality of care were limited to anecdotal evidence".[97]

Products Regulation

The Food and Drug Administration (FDA) is the federal agency responsible for ensuring the safety, effectiveness and quality of drugs, biological products, and medical devices available for use in the United States. The agency regulates medical products using a risk management framework aimed at maximizing the benefits and minimizing the risks of medical product use for the American public. [98] As part of the Department of Health and Human Services, FDA carries out a wide range of regulatory activities in order to protect consumers, such as:

1) assessing the safety and effectiveness of products before they are permitted to enter the market (pre-market review);
2) monitoring the safety and efficacy of products once they enter the market (post-market surveillance);
3) setting standards for the labeling, packaging and manufacturing of medical products.

The *Federal Food, Drug, and Cosmetic Act of 1938,* as amended, gives FDA the authority to establish and enforce regulations governing medical products. The Act, its amendments and regulations contain provisions that outline new product approval requirements, post-marketing reporting rules and manufacturing standards for medical products.

Pre-marketing Surveillance

Most agency resources are devoted to pre-marketing surveillance. All drugs and devices must gain approval before they can be marketed and that approval also relates to the

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[97] E.E. Lipowski & T. Collins, *Medicaid DUR Programs 1993* (Washington D.C.: American Pharmaceutical Association Foundation, 1995).

[98] U.S. Food and Drug Adminstration, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*: (Rockville, MD: Food and Drug Adminstration, 1999) at 21, online: <http://www.fda.gov/oc/tfrm/riskmanagement.html>.

proposed use for the drug. The FDA conducts assessments of the safety and effectiveness of drugs. However, it uses and analyses data provided to it by the drug's manufacturer, gained through laboratory and clinical trials. It also ensures that it is safe to conduct clinical trials on human volunteers with newly developed drugs.

The FDA has recently been the subject of sustained criticism over the way it undertakes surveillance of the pre-marketing safety of drugs and devices. Since the adoption in 1992 of the *Prescription Drug User Fee Act*, which allowed the FDA to charge "user fees" median approval times for standard drugs decreased from 27 months in 1993 to 14 months in 2001, but as a consequence, drug recalls increased from 1.56% for 1993-1996 to 5.35% for 1997-2001.

There was also a cultural change within the FDA which placed a premium on getting drugs approved quickly and placed pressure on staff to complete evaluations. Rates of approval for new drugs became part of employees' performance evaluation. Employees who raised concerns about the safety of drugs were said to be systematically suppressed. When concerned were noted about possible serious side-effects approvals were still given for a number of drugs, many of which subsequently were withdrawn from the market.[99]

In addition, an investigation of 18 FDA expert advisory panels revealed that more than half of the members of these panels had direct financial interests in the drug or topic they were evaluating and for which they were making recommendations.[100]

Post-Marketing Surveillance

Medwatch is the FDA Safety Information and Adverse Event Reporting Program. It administers voluntary and mandatory adverse event reporting programs in relation to drugs, biologics and devices.

The Medical Device Reporting (MDR) Regulation allows FDA to identify and monitor significant adverse events involving medical devices.[101] It establishes mandatory reporting requirements for manufacturers, importers, and user facilities (i.e. nursing homes and hospitals) in relation deaths and serious injuries attributable to device use. The MAUDE (Manufacturer User Facility and Distributor Experience) is a searchable on-line database contains data from both mandatory reports and voluntary reports submitted by consumers and health professionals.

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[99] Diedtra Henderson and Christopher Rowland, Once 'Too Slow,' FDA Approvals Called 'Too Fast'" *Boston Globe* (10 April 2005), online: Boston Globe <http://www.boston.com/business/articles/2005/04/10/fda_criticized_as_too_quick_to_ok_drugs/>.

[100] Phil B. Fontanarosa, Drummond Rennie & Catherine D. DeAngelis, "Postmarketing Surveillance—Lack of Vigilance, Lack of Trust" (2004) 292:21 JAMA 2647 and D. Cauchon "FDA Advisers Tied to Industry" *USA Today* (25 September 2000) A1.

[101] 21 C.F.R. § 803 (2002).

A separate database for drug related adverse events, entitled AERS (Adverse Event Reporting System), receives reports from drug manufacturers as required by regulation. Mandatory reporting is required for drugs and biologics for:

- adverse drug experiences on marketed prescription drugs for human use without approved new drug applications[102]
- investigational new drug applications[103]
- post-marketing surveillance[104]

In respect of serious adverse events, manufacturers have 15 days to report to the FDA.

Together with the CDC, the FDA sponsors the VAERS reporting system, a national vaccine safety program that receives reports of adverse events relating to vaccine use. The *National Childhood Vaccine Injury Act* requires health care providers to report adverse events that may be associated with vaccines.[105] However, patients and families can report voluntarily. It is difficult often to establish causation in regard to vaccine related injuries because technical data required to conduct analyses is often omitted from reports.[106]

Medwatch also provides a forum for both healthcare professionals and the public to report voluntarily serious adverse events, product quality problems, or product use errors associated with the use of drugs, devices, biologics, or dietary supplements regulated by the FDA. It is an online system. As part of its role, it provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements, and infant formulas).[107]

Information from these programs is analysed, the FDA issues public safety alerts, and, in some cases, the FDA may recall products.

The FDA's post-market surveillance system has been the subject of profound criticism. Critics note its reliance on voluntary reporting, the poor quality of reports with little detail and poor documentation, underreporting of adverse events, difficulty in calculating adverse event rates, limited ability to establish causal relationships and difficulty in determining whether the adverse event related to the drug or the disease the drug was to treat.[108]

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[102] 21 C.F.R. § 310.305 (2002).
[103] 21 C.F.R. § 312.32 (2002).
[104] 21 C.F.R. § 314.80 (2004).
[105] *National Childhood Vaccine Injury Act of 1986*, codified as *Public Health Service Act* §2111, et seq., 42 USC § 300aa-11 et seq (1986).
[106] Centers for Disease Control, "Overview of Vaccine Safety" National Immunization Program <http://www.cdc.gov/nip/vacsafe/>
[107] Medwatch, online: FDA <http://www.fda.gov/medwatch/What.htm>.
[108] Fontanarosa, et al. *supra* note 100.

Critics suggest that the major problem with the current system is that drug manufacturers are largely responsible for collecting, evaluating, and reporting data from post-marketing studies of their own products. This is problematic in a number of ways. It appears that fewer than half of the post-marketing studies that manufacturers have made commitments to undertake as a condition of approval have been completed and many have not even been initiated. Despite the mandatory adverse event reporting system for companies subject to the FDA's post-marketing safety reporting regulations, drug manufacturers may be tempted to conceal available data that may signal the possibility of major risks. In some cases, the FDA and drug manufacturers may fail to act on that information and fail to conduct appropriate studies to examine a potential risk rigorously and promptly.[109] In some cases, serious adverse drug events are quite uncommon, and detecting them accurately and using them to determine incidence rates can be difficult with the reactive voluntary reporting systems for adverse drug events. Some companies may neglect to acknowledge reports that indicate harm and fail to initiate proper studies to determine risk. Companies may be well aware of analyses of serious adverse drug event data but may fail to report them or report them in a less than timely manner. Pharmaceutical companies may a number of tactics to protect their interests and prevent the release of information damaging to the interests of their products.[110]

In response to the sustained criticism, the FDA announced in 2005 that it is taking measures to strengthen the safety program for marketed drugs. It is sponsoring an IOM study of the drug safety system, implementing a program to adjudicate differences of opinion between FDA staff and outside experts, appoint a director of drug safety (position had been vacant for 13 months), conduct drug safety and risk assessment consultations and public risks assessment guidelines. It has also created a Drug Safety Oversight Board (DSB) to oversee the management of drug safety issues. The DSB will oversee the management of important drug safety issues within the Center for Drug Evaluation and Research (CDER). The DSB will comprise members from the FDA and medical experts from other HHS agencies and government departments (e.g., Department of Veterans Affairs) who will be appointed by the FDA Commissioner.[111]

Monitoring

The FDA monitors compliance with the regulations through an inspections process. The FDA can issue warning letters if inspection demonstrates that there are significant deviations or violations from the regulatory requirements. If there are a pattern of violations that are not remedied then injunction, citation or prosecution can be considered.[112]

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[109] *Ibid.*
[110] *Ibid.*
[111] Food and Drug Administration, Press Release "Improvements in Drug Safety Monitoring" (15 February, 2005).
[112] U.S., FDA, *Enforcement of the Postmarketing Adverse Drug Reactions Reporting Regulations* online: FDA <http://www.fda.gov/cder/aers/chapter53.htm>.

Medication Errors

Since 1992, the FDA receives and monitors reports on medical errors associated with medication use from the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). It also reviews Medwatch reports for possible medication errors. The Center for Drug Evaluation and Research's Medication Error Prevention Program analyses data to provide feedback to others at the FDA and to provide warnings and education to providers and the public about medication errors.[113]

Inquiry Processes

Death investigations in the U.S. are undertaken by Coroners and/or Medical Examiners depending on the jurisdiction. Approximately, 10 states have coronial systems, 25 have medical examiners and 18 have mixed systems. Around 25 percent of the U.S. population is serviced by state controlled systems, while the remaining 75 percent are serviced by a patchwork of regional, county, or city based systems for death investigation.[114]

In 1986, responding to concerns that there was a lack of uniformity in death investigation policies, poor communication between jurisdictions, and that there needed to be a mechanism to disseminate death investigation data, the Centers for Disease Control and Prevention (CDC) established the Medical Examiner and Coroner Information Sharing Program (MECISP). Funding for this program was terminated in 2004. The goals of the MECISP were to:

- To improve the quality of death investigations in the United States and to promote the use of more standardized policies for when and how to conduct these investigations.
- To facilitate communication among death investigators, the public health community, federal agencies, and other interested groups.
- To improve the quality, completeness, management, and dissemination of information on investigated deaths.
- To promote the sharing and use of Medical Examiner and Coroner death investigation data.[115]

The MECISP, amongst other things:

- Developed model death investigation forms and file structures.

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[113] See Center for Drug Evaluation and Research website at <http://www.fda.gov/CDER/drug/MedErrors/default.htm

[114] Centers for Disease Control, "Death Investigation Summaries," online: <http://www.cdc.gov/epo/dphsi/mecisp/summaries.htm>.

[115] Centers for Disease Control, "About MECISP," online:<www.cdc.gov/epo/dphsi/mecisp/about.htm>.

- Developed model formats for annual and statistical death investigation reports. The reports were then distributed to and used by ME/C offices.
- Collaborated with medical examiners, coroners, public health researchers, and others in epidemiologic studies of deaths routinely investigated by ME/C offices.
- Conducted studies to identify problems associated with methods of collecting death investigation and mortality data.
- Consulted with ME/C offices to help establish computerized data systems. [116]

In 2003 the NIH convened a Workshop on the Medicolegal Death Investigation System that focused on "the role of the medical examiner/coroner death investigation system and its promise for improving: the criminal justice system; health and medical care; public health surveillance; epidemiologic research; prevention programs; and response to bioterrorism."[117] Some of the conclusions were that the ability for coroners/medical examiners to contribute to these areas, especially health and medical care, was limited due to variability in the statutory criteria for coronial review (with only some requiring review of deaths relating to medical quality of care issues), variability in the scope, extent, and quality of individual investigations, variability in the extent of examination and the quality of the evidence produced, and variations in the types of deaths investigated,[118] thus indicating that the CDC initiative had not resulted in significant change.

In New York State, for example, the mixed coronial/medical examiner system investigates deaths:[119]

- By violence, whether criminal violence, suicide or casualty.
- Caused by unlawful act or criminal neglect.
- Occurring in a suspicious, unusual, or unexplained manner.
- Caused by suspected criminal abortion.
- While unattended by a physician, so far as can be discovered, or where no physician is able to certify the cause of death as provided in public health law and in form as prescribed by the Commissioner of Health can be found.
- Of a person confined in a public institution other than a hospital, infirmary or nursing home.
- Death occurring to an inmate of a correctional facility.

In Massachusetts the following deaths must be reported to the Coroner:[120]

- death where criminal violence appears to have taken place, regardless of the time interval between the incident and death, and regardless of whether such violence appears to have been the immediate cause of death, or a contributory factor;

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[116] *Ibid.*

[117] National Institutes of Health, *Workshop on the Medicolegal Death Investigation System* (2003) online: NIH <http://www.iom.edu/event.asp?id=6360>.

[118] R. Hanzlick, "The Medicolegal Death Investigations Systems in the U.S." presented to National Institutes of Health, *Workshop on the Medicolegal Death Investigation System* (2003) online: NIH <http://www.iom.edu/event.asp?id=6360>.

[119] NYCL § 673.

[120] Mass. Gen. Laws Ann. ch. 38 § 1 et seq.

- death by accident or unintentional injury, regardless of time interval between the incident and death, and regardless of whether such injury appears to have been the immediate cause of death, or a contributory factor;
- suicide, regardless of the time interval between the incident and death;
- death under suspicious or unusual circumstances;
- death following an unlawful abortion;
- death related to occupational illness or injury;
- death in custody, in any jail or correctional facility, or in any mental health or mental retardation institution;
- death where suspicion of abuse of a child, family or household member, elder person or disabled person exists;
- death due to poison or acute or chronic use of drugs or alcohol;
- skeletal remains;
- death associated with diagnostic or therapeutic procedures;
- sudden death when the decedent was in apparent good health;
- death within twenty-four hours of admission to a hospital or nursing home;
- death in any public or private conveyance;
- fetal death, as defined by section two hundred and two of chapter one hundred and eleven, where the period of gestation has been twenty weeks or more, or where fetal weight is three hundred and fifty grams or more;
- death of children under the age of 18 years from any cause;
- any person found dead;
- death in any emergency treatment facility, medical walk-in center, day care center, or under foster care; or
- deaths occurring under such other circumstances.

The medical examiner may choose whether to undertake an examination in Massachusetts.

There appears to be no national repository of coroner or medical examiner reports and no central database to track deaths related to medical error.[121]

Public inquiries seem to be a tool of limited use in the United States. Senate and congressional committees at the federal and state level can convene public inquiries through the Committee review process. At the federal level, a national commission of inquiry can also be convened if Congress introduces legislation for its creation. For instance, Congress introduced a bill to establish a commission looking into the disaster response on Sept. 8th after Hurricane Katrina.

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[121] Further information (last updated in 2004) about the structures surrounding Coroner and Medical Examiners jurisdiction for all U.S. states and Canadian provinces is available at: Centers for Disease Control, "Death Investigation System Description," online: <www.cdc.gov/epo/dphsi/mecisp/death_investigation.htm>.

Compensation Systems

Medical malpractice claims in the United States are addressed through the common law tort system. Limited exceptions include a federal no fault compensation program for injuries caused from children's vaccines and no fault compensation programs for certain severe injuries to newborns in Florida and Virginia.[122] Traditionally, tort law has primarily been a subject of state, rather than federal, authority.[123] During the past 30 years, states have increasingly enacted legislation modifying common law tort rules and establishing other tort reform measures in response to medical indemnity crises.[124] These tort reforms have primarily focused on controlling the frequency and costs of litigation using measures such as damage caps rather than reducing medical error.[125] The United States appears to be emerging from a medical indemnity crisis in the early 2000s that saw major physician insurers exit the market and dramatic increases in liability premiums in many states.[126]

Since the release of the IOM report *To Err is Human* in 2000, increased attention focused on how the current US medical liability system affects patient safety.[127] In terms of the deterrence function of tort law, the few existing analyses provide "very limited evidence that providers who experience malpractice claims have fewer adverse events and instances of negligence in the future."[128] Other shortcomings of the system are that only a small percentage of patients who are injured because of negligence pursue a claim and even fewer receive compensation, while studies have shown a large portion of malpractice claims do not involve a negligent injury.[129] Injury prevention in the tort system has been described as "piecemeal rather than systematic" and annual costs of medical liability litigation and defensive medicine have been estimated at 28 billion.[130]

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[122] Randall R. Bovberg & Laurence R. Tancredi, "Liability Reform Should Make Patients Safer: 'Avoidable classes of Events' are a Key Improvement" (2005) 33:3 J.L. Med. & Ethics 478.

[123] Peter Budetti & Teresa M. Waters, *Medical Malpractice Law in the United States* (Menlo Park, CA: The Kaiser Family Foundation 2005) at 1.

[124] *Ibid.* at 4. Common tort reforms include caps on non-economic damages, abolishing joint and several liability and allowing periodic payment of damages. Mimi Marchev, *The Medical Malpractice Insurance Crisis: Opportunity for State Action* (Portland, ME: National Academy for State Health Policy, 2002) at 9-12.

[125] *Ibid.* at 2, 9 & 18.

[126] M. Mello, C. Kelly & T. Brennan, "Fostering Rational Regulation of Patient Safety" (2005) 30:3 J. Health Pol. 375 at 389. Bovberg & Tancredi *supra* note 122 at 478.

[127] Joint Commission on Accreditation of Healthcare Organizations, *Healthcare at the Crossroads: Strategies for improving the medical liability system and preventing patient injury* (Wash., D.C.: JCAHO, 2005); Mimi Marchev, Medical Malpractice and Medical Error Disclosure: Balancing facts and fears (Portland, ME.: National Academy for State Health Policy, December 2003); T. Brennan & M. Mello, "Patient Safety and Medical Malpractice: A Case Study" 2003 139:4 Ann. Int. Med. 267.

[128] Mello *et al supra* note 126 at 389. Scholars concluded that it was impossible to determine whether the medical malpractice system "actually stimulates cost justified injury prevention" from the existing data. However, the evidence suggests a positive cost-benefit impact on practices around physician-patient discussion of treatment risks and institutional injury prevention programs. Don Dewes *et al.* "Medical Accidents" in D. Dewes, D. Duff, M. Tribelcock, eds., *Exploring the Domain of Accident Law: Taking the Facts Seriously*, (New York: Oxford University Press, 1996) at 112.

[129] JCAHO, *supra* at note 127 at 13. Mello *et al.*, *supra* note 126 at 388.

[130] Bovberg & Tancredi *supra* note 122; JCAHO, *supra* note 127 at 4.

The current tort system has been seen as working against patient safety on another front, as fear of litigation keeps providers from sharing information needed for patient safety improvements and has been cited as a factor in the underreporting of adverse events.[131]

To address its medical malpractice crisis, the state of Pennsylvania passed in 2002 the *MCARE Act*, which contained patient safety, tort law and insurance reforms. Under the Act, hospitals and other facilities are required to report all adverse events and near miss incidents to an independent non-regulatory state agency. The Act also requires facilities to provide written notification of an adverse event to the affected patient within seven days. This notification does not constitute an admission of liability. A number of states have also passed laws that protect provider apologies from being used in court.[132]

At the federal level, the *Fair and Reliable Medical Justice Act* Bill was introduced in June 2005 in the Senate. The act aims to "restore fairness and reliability to the medical justice system and promote patient safety by fostering alternatives to current medical tort litigation, and for other purposes."[133] The bill would allow the federal government to fund state based demonstration projects of alternatives to the current tort systems. States seeking a federal grant would have to demonstrate how their project will foster prompt and fair resolution of disputes, the early disclosure of health care errors, enhanced patient safety and access to liability insurance. A State will be deemed to meet the criteria if they choose from one of the models already described in the Act, which include an early disclosure and compensation model, an administrative determination of compensation model and a special health court model.

The *National Childhood Vaccine Injury Act* of 1986 created a no fault compensation program for injuries arising from children's vaccinations in response to concerns that tort liability was causing drug manufacturers to stop producing vaccines. Claimants receive automatic compensation if their injury is listed in the Vaccine Injury Table. If their injury is not listed, they may also qualify for compensation if they can prove that a vaccine caused their condition or significantly aggravated a pre-existing condition. There are time limits for making a claim under the program. Eligible claimants are compensated up to $250,000 for death and in the case of injuries, they receive payment for all past and future otherwise uncovered medical expenses, nursing home or custodial care, loss of earnings, reasonable legal costs and up to $250,000 for pain and suffering. A federal court special master resolves disputes and decisions can be appealed. Rejected claimants or claimants who refuse the offered compensation may only sue in federal court. The program is believed to have encouraged safer vaccines, stabilized the vaccine market and provided a less adversarial and more efficient system of compensation. However, one study found pertussis vaccine claim results to be inconsistent with epidemiological knowledge. [134]

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[131] Bovberg & Tancredi. *supra* note 122 at 478; JCAHO, *supra* note 127 at 4; Marchev, *supra* note 127 at 2.
[132] JCAHO, *supra* note 127 at 11.
[133] U.S., Bill S. 1337, *Fair and Reliable Medical Justice Act,* 109th Cong., 2005.
[134] Bovberg & Tancredi, *supra* note 122 at 478.

In the late 1980's, both Virginia and Florida enacted legislation that created a no fault compensation program covering children who experienced severe neurological injuries at birth.[135] To be eligible, the child's injury must meet the legislative definition of "birth-related neurological injury."[136] In both states, eligible infants are those who suffered brain or spinal cord injury due to oxygen deprivation or mechanical injury. In Florida, these injuries must have resulted in permanent and substantial mental and physical impairment, while in Virginia, injuries that permanently disable motor function, result in developmental or cognitive disabilities, and necessitate permanent assistance for all activities of daily living are covered. Eligibility decisions in Florida are made by an administrative law judge and in Virginia, they are made by the Worker's Compensation commission. Coverage includes all reasonable and necessary medical, hospital, custodial care, residential, rehabilitative, special equipment and related travel expenses not already covered by other programs or private insurance. In Virginia, families also receive compensation for the child's lost earnings, while in Florida, they can receive an award of up to $100,000 dollars. Rights and remedies under the programs are exclusive and eligible families are not entitled to compensation through the tort system, unless there is clear and convincing evidence of intentional or willful harm and the civil suit is filed before the payment of an award under the program. The compensation funds are maintained through annual assessment payments from physicians and hospitals.

An evaluation of the programs after eight years of operation found administrative costs were very low compared to the tort system, and compensation and parental satisfaction was similar under the two systems. The number of claims was less than expected, which helped in preventing cost overruns but made the programs too small to conduct patient safety analysis.[137] An academic study of Florida's system published in 2000 found that in its first ten years, it provided relatively efficient, equitable and generous compensation to nearly 100 infants. However, it concluded that NICA's compensation role was at best a modest one, as almost the same number of severe birth-related injuries received malpractice awards of $250,000 or more during the program's operation as in the period prior to its establishment.[138]

Other Patient Complaint Mechanisms

Health care complaint mechanisms exist at the federal, state and institutional level. Section 1154(a) (14) of the *Social Security Act* requires quality improvement

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[135] *Virginia Birth-Related Neurological Injury Compensation Act*, Va. Code Ann. §§ 38.2-5000 to 38.2-5021; Va STAT 2-5000 to 5021); the statutory basis for Florida's Birth-Related Neurological Injury Compensation Plan, Fla. Stat. §§ 766.303-766.316 (2004). Florida's program is modeled after Virginia's. George Coppolo and Saul Spiegel, "Medical Malpractice No fault systems," OLR Research Report (December 8, 2003).

[136] Additional conditions apply. In Florida, obstetrical services must have been given in a hospital by a physician who participates in the program, while in Virginia, the infant must have been delivered in hospital by a participating physician or in a participating hospital. Participation by physicians and hospitals is voluntary.

[137] Bovberg & Tancredi, *supra* note 122 at 478.

[138] Coppolo and Speigel, *supra* note 135.

organizations to review all written complaints from Medicare beneficiaries that allege the quality of the covered services received did not meet professionally recognized standards of health care.

Adverse Event Reporting Systems

Adverse event reporting systems exist at the national and state level. Legislative debate and action in this area has been influenced by the recommendations of the 2000 IOM report *To Err is Human*. The report recommended the establishment of a nation wide mandatory reporting system supported by federal legislation, which would legally obligate health care institutions to report a defined list of adverse events resulting in serious harm or death in a standardized format. [139] This data would be collected by state governments, who would analyze reports and take follow up action. This system's primary purpose would be to hold providers accountable for improvements. Separate voluntary reporting systems would be encouraged in the health care industry to complement the mandatory reporting system and would be afforded legal protections.[140] Voluntary systems would focus on less serious adverse events and near miss incidents and data would be used to identify emerging concerns and patient safety improvement strategies.

National Level Adverse Event Reporting Systems

Since the release of the report, numerous pieces of proposed legislation meant to encourage medical error reporting have been introduced at the federal level in Congress.[141] The federal *Patient Safety and Quality Improvement Act of 2005* became law on July 29, 2005 and "reflects difficult negotiations and many compromises over almost five years of consideration."[142] The Act aims "to reduce the incidence of events that adversely effect patient safety" by creating a confidential voluntary reporting

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[139] IOM, *To Err supra* note 19 at 87, 88 & 104.
[140] *Ibid.*
[141] They include: U.S., Bill H.R. 3672, *Medical Error Prevention Act of 2000,* 107th Cong., 2000; U.S. Bill H.R. 5404, *Medicare Comprehensive Quality of Care and Safety Act of 2000,* 106th Cong. 2000; U.S. Bill S. 2038, *Medical Error Reduction Act of 2000,* 106th Cong., 2nd Sess. 2000; U.S. Bill S. 2378 *Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act,* 106th Cong. 2nd Sess. 2000; U.S. Bill S. 2738, *Patient Safety and Errors Reduction Act*, 106th Cong. 2nd Sess., 2000; U.S. Bill S. 2743, *Voluntary Error Reduction and Improvement in Patient Safety Act,* 106th Cong. 2nd Sess., 2000; U.S. Bill S. 720, 108th Cong. 2003; U.S. Bill H.R. *663, Patient Safety and Quality Improvement Act*, 108th Cong. 2003.
[142] *Patient Safety and Quality Improvement Act of 2005*, Pub. L. No. 109-41, 119 Stat. 424 (codified at amended at 42 U.S.C. 299 et seq. (2005)). It is identical to the Bill H. 3205, *Patient Safety and Quality Improvement Act of* 2005, 109th Cong. 2005. Senator Jeffords, (I-VT), "P The Patient Safety and Quality Improvement Act of 2005" *Congressional Record-Senate p.* S8744, (July 22, 2005), Senator Jeffords sponsored the legislation.

system.[143] The legislation provides a framework in which health care providers and hospitals can report information on medical errors and near miss incidents to patient safety organizations (PSOs). Certified by the Secretary of the federal Department of Health and Human Services, a PSO is a public or private entity that performs the following activities:

(a) efforts to improve patient safety and the quality of health care delivery,
(b) the collection and analysis of patient safety work product[144]
(c) The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols or information regarding best practices
(d) the utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk,
(e) the maintenance of procedures to preserve confidentiality with respect to patient safety work product
(f) the provision of appropriate security measures with respect to patient safety work product
(g) the utilization of qualified staff (including licensed medical professionals)
(h) activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.[145]

Known as "patient safety work product," information created specifically for patient safety reporting purposes by providers or by PSOs while conducting the above activities is protected by confidentiality and evidentiary privilege provisions that seek to encourage voluntary reporting and information sharing while protecting access to other separate health information.[146] These legislative protections are meant to address barriers to open communication, such as the fear of malpractice litigation, and reflect "the belief that a culture of patient safety can flourish best in an environment where information, data, processes and recommendations enjoy legal protection and privilege."[147] By setting limits

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[143] Preamble, *Patient Safety and Quality Improvement Act of 2005*. J. Jeffords, Press Release "Sen. Jeffords' Patient Safety Bill passes House, Heads to President," (27 July 2005) online: <http://jeffords.senate.gov/~jeffords/press/05/07/072705patientsafety.html>

[144] Patient safety work product is defined in Section 921 (7) as any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which are developed or assembled by a provider for reporting to a PSO and are reported to a PSO; or are developed by a PSO for the conduct of its patient safety activities, which could result in improved patient safety or identify/constitute parts of a patient safety evaluation system. It does not include a patient's medical record, billing and discharge information, other original patient or provider records or information that is collected, maintained or developed separately from a patient safety evaluation system.

[145] *Public Health Service Act* § 921(4)(5), 42 U.S.C. as amended by the *Patient Safety and Quality Improvement Act of 2005, supra* note 142. Additional criteria for certification as a patient safety organization is listed in Section 924 (b) (1), such as the primary function of the entity is to conduct activities to improve patient safety, the entity must have bona fide contracts with more than 1 provider and fully disclose any lack of independence from providers it contracts with, the entity is not a component of a health insurance issuer and the entity collects patient safety work product from providers in a standardized manner to allow for comparisons with other providers to the extent practical.

[146] *Ibid.*. §§ 921 (7) and 922.

[147] Jeffords, *supra* note 142.

on what is to be considered confidential and privileged, the legislation seeks to strike a balance with the need to access certain information in order to seek legal redress.

Privileged patient safety work product is not admissible into evidence or subject to subpoena or discovery in any civil, criminal or administrative matter at the federal, state or local level.[148] The privilege also applies to the federal *Freedom of Information Act* and similar federal, state or local legislation, as well as professional disciplinary proceedings.[149] There are three exceptions from both the privilege and confidentiality protections:

- disclosure for use in a criminal proceeding only if a court in camera determines that the data contains evidence of a criminal act, is material and cannot be found elsewhere;
- disclosure for use to extent required when an employee is bringing a civil action against a provider who took adverse employment action against them for reporting;
- disclosure of identifiable patient safety work product authorized by the identified providers.[150]

Additional exceptions from confidentiality include disclosures for patient safety activities, for accreditation purposes when given voluntarily by the provider and of non identifiable patient safety work product.[151] Privilege protections do not apply to voluntary disclosures of non identifiable patient safety work product.[152] These legislative protections are not to be interpreted as altering or preempting a provider's reporting requirements (of non patient safety work product) under State law or to the FDA. [153]

The Act also contains other protections. An accrediting body is unable to require a provider to reveal its communications with PSOs and is not permitted to take accrediting action against a provider based on the provider's good faith participation in the collection, development, reporting or maintenance of patient safety work product.[154] A provider may not take 'adverse employment action' against an employee if he or she in good faith reports information to the provider or a patient safety organization and the employee has the right to bring a civil action against the employer for violations of this section.[155]

The Act also requires the Secretary for Health and Human Services to maintain a network of patient safety databases to act as "interactive evidence-based management resource for providers, patient safety organizations and other entities."[156] The network of databases must have the capacity to accept, aggregate, and analyze non-identifiable patient safety

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[148] *Supra* note 145 at § 922(a).
[149] *Ibid.*
[150] *Ibid.* at § 922 (c)(1).
[151] *Ibid.* at § 922 (c)(2).
[152] *Ibid.* at § 922 (c)(3).
[153] *Ibid.* at § 922 (g) (5) and (6).
[154] *Ibid.* at § 922 (d) (4) (B).
[155] *Ibid.* at § 922 (e).
[156] *Ibid.* at § 923(a).

work product voluntarily reported by these groups. This information will be used to analyze national and regional statistics, including trends in medical error, and the results are to be made available to the public and to appear in annual quality of care reports.[157] The Secretary may determine common data standards, reporting formats, and a standardized computer interface for information maintained in the network of patient safety databases.[158] Within 18 months after the network is operational, the Secretary must prepare a draft report concerning effective strategies for reducing medical errors and measures to encourage their use, which shall be submitted to the Institute of Medicine and made available to the public.[159] A final report must be submitted to Congress within 30 months of network's operation. The law is expected to cost 58 million over a four year period (2006-2010) and a report by the US Comptroller General on its effectiveness is to be submitted no later than February 1, 2010.[160]

The JCAHO and VA systems described below are not legislatively created, however, they are often referred to in the literature as systems of significance. The Department of Veteran's Affairs has both an internal and external reporting system for medical errors. Established in 1999 by the VA, the National Centre for Patient Safety promotes a systems approach to patient safety in all VA hospitals in the U.S. The Center developed an internal, confidential, non-punitive reporting and analysis system for adverse events, sentinel events and close calls. Multi-disciplinary teams conduct root cause analysis (RCA) of reported events, depending on the event's level of risk, and suggest strategies for systems improvement. Feedback is given to reporters and reports and RCAs are confidential. Information is collected in the Patient Safety Information System (PSIS). The system itself is not blame free. Those who undertake activities that are intentionally unsafe i.e. a criminal act, related to alcohol or substance abuse, are held to account, as these reported events are sent to the facility's director. Since its implementation, the NCPS has seen a 900 increase in close call reporting and a 30-fold increase in adverse event reporting.[161] In 2000, the VA developed a Patient Safety Reporting System (PSRS) in conjunction with NASA. This system is modeled on NASA's Aviation Safety Reporting System (ASRS), which since its creation in 1975 has been noted for its contributions to improving aviation safety.[162] PSRS is a voluntary, external, non-punitive reporting system available to all VA employees. Employees can confidentially report adverse events or close calls. NASA receives the data, de-identifies it and it is then entered into the PSRS database. Analysis is undertaken by a multidisciplinary team who

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[157] *Ibid.* at § 923(c).
[158] *Ibid.* at § 923(b).
[159] *Ibid.* at § 925(j).
[160] Congressional Budget Office, "Cost Estimate: S.544, Patient Safety and Quality Improvement Act of 2005" (31 March 2005), Congressional Budget Office, online at: <http://www.cbo.gov>. *Ibid.* at § 925(c).
[161] C. Stephen Redhead. "Health Care Quality: Improving Patient Safety by Promoting Medical Errors Reporting" (Congressional Research Service Report) (24 March 2005) at 11.
[162] *Ibid.* at 9. Factors for ASRS's success, according to its administrators, include: it is administered by an independent agency (NASA), rather than the industry's regulator (FAA); timely feedback is given to reporters; and reports are confidential and reporters are granted immunity from disciplinary action for potential violations of federal air regulations provided that they report within 10 days and the violation was inadvertent and was not a criminal offence or an action that indicates a lack of qualification or competency. In addition, the individual must not have been found guilty of a violation in the five year period before the incident occurred.

look for procedural and system deficiencies and their responses are published internally in patient safety bulletins. In its first two years of operation, the external system received a relatively small number of reports (400) as compared to the internal system (140,000 in 5 years), which has been viewed as suggesting that there is a high level of trust in the VA's internal system.[163]

In 1996 the Joint Commission introduced a sentinel events reporting system as part of its accreditation process. Under the accreditation standards relating to sentinel events reporting, accredited organizations are to identify and respond to all sentinel events by undertaking a root cause analysis (RCA) of the event, developing and implementing an action plan for improvement, and monitoring the effectiveness of the changes. While organizations have some flexibility in defining what constitutes a sentinel event, their definition must be consistent with JCAHO's general definition[164] and must, at a minimum, include a list of sentinel events subject to review by JCAHO.[165] Accredited organizations are encouraged to voluntarily report reviewable sentinel events, as it facilitates early consultation with JCAHO during the RCA process, allows events to be analyzed and entered into JCAHO's sentinel event database and permits lessons to be shared with other accredited organizations through its newsletter, *Sentinel Events Alert.* Should JCAHO become aware of a reviewable sentinel event (either from the organization itself or another third party), the organization must prepare and submit to JCAHO an RCA and an action plan within 45 days, or else its risks being placed on accreditation watch. Failure to develop an acceptable RCA and to implement the appropriate changes could result in a loss of accreditation. Organizations concerned about confidentiality can share information with JCAHO using a variety of mechanisms, and JCAHO has advocated for enhanced state and federal legislative protections. Although it accredits nearly 18,000 health care organizations and programs in the US, JCAHO has received relatively few reports on sentinel events. Hospitals have been reported as viewing the program to be "cumbersome, time-consuming, unresponsive and potentially risky."[166] Concerned about the confidentiality of submitted information, hospitals fear the potential for public disclosure and its possible consequences, such as litigation, a loss of its license or accreditation or damage to its reputation.

State Level Adverse Event Reporting Systems

Adverse event reporting systems at the state level can be traced back to the 1970s. Mandatory adverse event reporting programs that preceded the IOM report were

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[163] Commonwealth Fund "Case Study: NASA/VA Patient Safety Reporting System," The Commonwealth Fund, October 2004, online at: <http:www.cmwf.org>.

[164] JCAHO's defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof." "Sentinel Event Policy and Procedures Updated: June 2005", JCAHO webpage, online at:<www.jcaho.org>

[165] Reviewable sentinel events include events resulting in unexpected death or permanent loss of function (not due to the natural course of the patient's underlying condition), rape, suicide, patient abduction, and surgery on the wrong individual or body part. For a full list, see "Part IV: Sentinel Event Policy and Procedures Updated: June 2005", JCAHO webpage, online at:<www.jcaho.org>

[166] *Supra* note 161 at 12.

established in response to medical liability insurance crisis in the 1970s and 1980s (in exchange for legal reforms to medical malpractice laws, states sought greater oversight through reporting systems), highly publicized events involving medical error, and initiatives to improve quality. Historically, these programs were focused on the investigation of individual incidents, rather than the reduction of medical errors. Since the release of the report, several states have either legislatively created new systems or modified existing ones. As of June 2005, twenty-three states had in place statutes or regulations with provisions mandating the reporting of adverse events, including New York, California, Massachusetts, Pennsylvania, Florida, Texas and Minnesota. In its mandatory adverse events reporting system established pursuant to the *Minnesota Adverse Health Care Events Reporting Act of 2003*, Minnesota used a list of 27 serious reportable events in healthcare developed through consensus by the National Quality Forum.[167] The Minnesota Department of Health analyzes the reports by and provides hospitals with feedback. The Department also creates an annual report that is facility specific but uses aggregated data on corrective actions. A one year review of the scheme reported pressure for more disclosure but it was decided that detailed information would remain private.

An example of a state with a voluntary adverse event system is Oregon, and a few states with mandatory reporting systems, such as Florida, have legislation that authorizes the establishment of voluntary reporting systems for close calls or near miss events. Other states lack or are in the process of developing statewide adverse event reporting systems.

The State of New York implemented its first mandatory adverse event reporting system in 1985. Operated by the Department of Health, the current system, the New York Patient Occurrence Reporting and Tracking System (NYPORTS) was established in 1998 with input from stakeholders. Its statutory basis is New York Public Health Law Section 2805-1, Incident Reporting. Under this provision, hospitals are required to report patient deaths and impairments other than those related to "the natural course of the illness, disease or proper treatment in accordance with generally accepted medical standards." Regulations require that the Department of Health be notified of reportable incidents within 24 hours of their occurrence and a certain subset of events must be investigated by

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[167] A private, not-for-profit, open membership organization, the National Quality Forum (NQF) is a voluntary consensus standards-setting organization, as defined by the *National Technology Transfer and Advancement Act of 1995, Pub. L. No.* , 104-113, 110 Stat. 775 (NTTAA) and the Office of Management and Budget Circular A-119. The NTTAA was designed to encourage governments to use private sector standards and states that if there are voluntary consensus standards in the private sector, they should be used unless there are good reasons for not doing so. The NQF's consensus process is designed to meet NTTAA requirements. It endorses standards (including quality indicators, reporting guidelines and performance measures) that have achieved consensus from its members. Established as a forum to bring public and private health care stakeholders together to promote standardized quality measures, the NQF is designed to give stakeholders an equal voice and its members include federal and state agencies such as CMS, consumer groups such as Consumers Advancing Patient Safety, hospitals and professional associations such as the American Medical Association and private purchasers, such as General Motors. There are four councils in the NQF: a consumer council, a purchaser council, a research and quality improvement council and a health professional, provider and health plan council. Each member receives one vote within their council and their votes are tallied to determine whether the overall vote of their council is affirmative or negative.

the hospital.[168] Upon completion of the investigation, an investigative report specifying hospital actions taken to analyze and correct identified problems must be provided to the area administrator within 24 hours. All serious occurrences require a root cause analysis. Public Health Law Section 2805-m protects the confidentiality of submitted reports and disclosure is not permitted under New York's Freedom of Information Law.[169] NYPORTS is a secure, internet-based, user friendly system based on a clearly defined list of included and excluded events.[170] The focus is on systems improvement and hospitals can create their own reports to identify trends within their systems or to compare their performance to regional, statewide or peer group aggregate data. Data analysis results and improvement strategies are shared through the *NYPORTS News and Alert* newsletter, publicly available annual reports, letters to CEOs of health facilities and regional forums. Incident reporting is a condition of licensing and the Department of Health has the authority to investigate incidents, impose fines or suspend/ revoke licenses. During 2000, 3 facilities were fined for failure to report or other quality violations.

An article written by the members of the New York Department of Health shares lessons learned over the course of the mandatory adverse events system's development and found a number of elements to be critical to its success.[171] These elements include:

- information is useful and meaningful to those reporting events. Hospitals can retrieve their own data and create their own reports, which provides timelier access than in earlier systems;
- the system is statute based and has legal protections from discovery;
- the system was developed collaboratively with all stakeholders;
- a stakeholder advisory group provides ongoing assessment and recommendations;
- clear and objective reporting criteria exist;
- the system is secure and web-based, and there are adequate resources for its maintenance;
- users receive feedback regarding their own performance;
- data can be analyzed at the facility and state wide level and lessons learned are disseminated.

They note the tension between the public's desire for improved accountability through mandatory systems, while physicians and hospitals fear liability and damage to their reputations and support voluntary systems, whose primary goal is to learn from past

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[168] N.Y.C.R.R. tit. 10, § 405.8.

[169] P Ellen Flink et al., "Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems," *Advances in Patient Safety: From Research to Implementation, v.3* (Washington, D.C.: Agency for Healthcare Research and Quality, April 2005) at 137.

[170] *Ibid.* at 138. NYPORTS contains data on 54 specific reportable events.

[171] The article notes how NYPORTS data has been used by facilities and the Department of Health to develop protocols for areas of concern. In the case of wrong-patient/ wrong site events, decreases in these adverse events were noted to be a result of protocol adoption and NYPORTS data analysis. It also highlighted the "potential utility" of mandatory reporting by comparing their reporting numbers with those of JCAHO and its voluntary system. From 1995 to 2003, JCAHO received 106 sentinel event reports from 1326 NY accreditated hospitals, compared to the 11,028 reports of similar occurrences from 250 NY hospitals from 1998 to 2003. *Ibid.*. at 142, 144.

mistakes. They conclude that the NYPORTS system provides accountability within a learning environment.[172]

In 2002, Pennsylvania became the first state to pass legislation that establishes mandatory reporting requirements in relation to both adverse events and near miss incidents. Under the *Medical Care Availability and Reduction of Error (MCare) Act,* health care workers are required to report "serious events"[173] or "incidents"[174] within 24 hours to their medical facility.[175] Facilities are in turn required to report these occurrences to the Patient Safety Authority, an independent state agency. Non-regulatory and non-punitive in nature, the Authority evaluates reports and recommends solutions to facilities for improving health care practices and procedures.[176] Serious events must also be reported to the Department of Health, which is responsible for investigating these events and approving the Authority's recommendations.[177] Under the Act, serious event and incident reports cannot contain the name of the patient or "any other identifiable individual information" and information concerning individual health care workers and patients is not collected.[178] Reports are not discoverable or admissible as evidence in civil or administrative proceedings and cannot be requested under the state's Right-to-Know law.[179] Health care workers are protected from retaliatory action for reporting and the Act permits workers to submit anonymous reports concerning serious events directly to the Authority if they feel the facility has not complied with the Act's requirements.[180] Should the facility learn that a licensed health care worker failed to report a serious event,

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[172] *Ibid.* at 148.

[173] *Medical Care Availability and Reduction of Error Act (MCARE)*, 2002 Penn. Law Act 13,§. 302, 40 Pa. Cons. Stat. § 1303.301 et seq. (2003). A serious event is defined in § 302 as "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident." The Patient Safety Authority's 2004 annual report notes that many facilities have reported difficulties determining whether complications are "unanticipated" injuries and the Authority was working towards clarifying this issue (Pennsylvania) Patient Safety Authority, Annual Report for 2004, vol. 1 at 13-14; online: <www.psa.state.pa.us/psa/lib/psa/annual_reports/psa_annual_report_for_2004_-_final_elec_version.pdf>.

[174] An incident is defined at § 302 as "An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event."

[175] The Act defines medical facilities as hospitals, birth centers and ambulatory surgical facilities. Under § 307 of the Act, facilities must have in place a Department of Health approved patient safety plan. The plan must establish a reporting system for health care workers that is accessible 24/7, a patient safety officer to investigate reports and a patient safety committee to evaluate reports and make recommendations.

[176] Patient Safety Authority, *supra* note 173 at 5. Under the Act, the Authority can issue recommendations to a facility or on a statewide level only after consultation and approval by the Department of Health. The Authority is governed by an eleven member board, which by law must include a physician, a nurse, a pharmacist and a non-health care worker. *MCARE* §§ 303(b), 304(a)(7).

[177] *MCARE* § 306. Under this section, approved recommendations may be considered by the Department during licensure decisions, but cannot be mandatory unless adopted as regulations. Statewide recommendations must be made publicly available on the Department's and the Authority's website as per § 304(a)(7).

[178] *MCARE* § 313 (a)-(b); Page 9, Patient Safety Authority, *supra* note 173 at 9.

[179] *MCARE* § 311(a), (d) and (h).

[180] *MCARE* § 308 (c) and 304(b); Patient Safety Authority, *supra* note 173 at 9 & 59.

the facility must notify the appropriate licensing board. The Department of Health may impose penalties against a facility that fails to report a serious event, including an administrative fine of $1,000 a day.

In effect since June 2004, the statewide mandatory requirements apply to over 400 healthcare facilities. [181] Facilities submit reports using the Pennsylvania Patient Safety Reporting System (PA-PSRS), a web-based reporting program that contains a series of 21 questions[182] and a free text narrative section. A clinical team analyzes the reports and the Patient Safety Authority issues *Patient Safety Advisories* via email to health professionals and facilities. The *Advisories* provide information about "actual or potential patient harm" and preventative steps facilities can implement to avoid future incidents.[183] The Authority's 2004 annual report noted that more than 30% of responding hospitals indicated when surveyed that they had made protocol changes based on patient safety information in the *Advisories*.[184] The Authority can look at statewide trends based on aggregate data and under the MCare Act, they must submit an annual report to the general assembly and the public that contains the number of reported serious events and incidents on a geographical or regional level and any recognized patient safety trends identified from the data. The PA-PSRS system also contains analytical tools that managers can use to identify trends within their own facilities. The Authority and its activities are funded through assessments on reporting facilities, the total which cannot exceed 5 million dollars plus CPI adjustments. At the end of 2004, the system had received 70,851 reports, with 95% of reports involving incidents and 5% involving serious events.[185] This compliance level staff attributed to the system's usefulness, the confidentiality protections afforded to the system, and the training provided to facilities.[186]

Other Legislative Instruments

Rules of Evidence and Peer Review Legislation

Nearly every state in the U.S. has some type of statute protecting records from internal hospital review proceedings from discovery or admission into evidence. For example, California, Pennsylvania and Texas have incorporated such protections into law.

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[181] Patient Safety Authority, *supra* note 173 at 1.
[182] The questions gather information about demographics, contributing factors, root causes of serious events and procedures the facility suggest will prevent such an event in the future. *Ibid.*. at 9.
[183] *Ibid.* at 6.
[184] *Ibid.* at 3.
[185] *Ibid.* at 2.
[186] *Ibid.* at 7.

In California, the *California Evidence Code*[187] creates such evidentiary protections. It states:

> 1156. (a) In-hospital medical or medical-dental staff committees of a licensed hospital may engage in research and medical or dental study for the purpose of reducing morbidity or mortality, and may make findings and recommendations relating to such purpose. Except as provided in subdivision (b), the written records of interviews, reports, statements, or memoranda of such in-hospital medical or medical-dental staff committees relating to such medical or dental studies are subject to Title 4 (commencing with Section 2016.010) of Part 4 of the Code of Civil Procedure (relating to discovery proceedings) but, subject to subdivisions (c) and (d), shall not be admitted as evidence in any action or before any administrative body, agency, or person.
>
> (b) The disclosure, with or without the consent of the patient, of information concerning him to such in-hospital medical or medical-dental staff committee does not make unprivileged any information that would otherwise be privileged under Section 994 or 1014; but, notwithstanding Sections 994 and 1014, such information is subject to discovery under subdivision (a) except that the identity of any patient may not be discovered under subdivision (a) unless the patient consents to such disclosure.
>
> (c) This section does not affect the admissibility in evidence of the original medical or dental records of any patient.
>
> (d) This section does not exclude evidence which is relevant evidence in a criminal action.

In Pennsylvania, the Pennsylvania Legislature determined that because the practice of medicine requires a level of expertise which can only be reviewed by other medical professionals, the medical profession should police its own activities through peer review organizations. The Legislature wanted to ensure that patients and the general public are protected and offered quality care by physicians and hospitals by requiring them to maintain appropriate professional standards of care. It also recognized that health care providers hesitate to provide information or to discuss other providers' activities due to concerns that they may face legal proceedings or found liable for their involvement.[188]

Pennsylvania law therefore provides protections to peer review organizations, individuals who serve on peer review committees and information used by these committees.[189] Peer review protection grants immunity to members of peer review organizations and also ensures the confidentiality of certain documents and information used by such organizations in order to foster free and frank communications when discussing matters such as quality assurance, medical cost containment and medical staff credentials and qualifications. Peer review protection is granted listed licensed health care providers: physicians, dentists, podiatrists, chiropractors, optometrists,

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[187] Cal. Evid. Code § 1157.

[188] Office of Legal Affairs, University of Pennsylvania Health System, "Peer Review Protection" online at University of Pennsylvania Health System <http://www.uphs.upenn.edu/legal/prp.html>.

[189] *Peer Review Protection Act,* (63 P. S. § 425.1 et seq.

psychologists, pharmacists, registered or practical nurses and physical therapists. In addition, health care facility administrators, corporations or organizations acting as health care facilities, committees evaluating the quality of health care and credentialing committees are also covered. Individuals who supply information to a peer review committee/organization are generally protected from criminal and civil liability. However, this immunity is not absolute. The individual is not granted immunity if the information he or she reported is unrelated or irrelevant to the peer review committee's functions and scope. The individual is also not protected if the information reported was false and the individual knew or had reason to believe it was false. In addition, the immunity does not apply if the individual's appearance before the peer review organization was motivated by malice.

Documents used and information recorded by peer review committees are not subject to discovery or admissible as evidence in a civil action against a health care provider, if the civil action stems from a matter which is the subject of committee review. However, this protection is not absolute. If the document used by the peer review committee can be obtained from its original source, then the peer review protection does not apply and the document may be disclosed in accordance with applicable law. For example, incident reports concerning a patient fall are not usually protected under peer review. In addition, persons reporting to a peer review committee cannot be compelled to testify at civil hearings as to:

(1) evidence which was produced or relied upon at the proceedings;

(2) conversations, opinions, or evaluations discussed during the proceeding; or

(3) his or her testimony before a peer review protection committee or opinions formed as a result of the committee hearings. However, a person in attendance is not immune from testifying at other civil proceedings as to information within his or her own personal knowledge and learned outside the peer review proceeding.

Texas has similarly enacted such protections, although with broader effect:[190]

§ 161.032. RECORDS AND PROCEEDINGS CONFIDENTIAL.

(a) The records and proceedings of a medical committee are confidential and are not subject to court subpoena.

(b) Notwithstanding Section 551.002, Government Code, the following proceedings may be held in a closed meeting following the procedures prescribed by Subchapter E, Chapter 551, Government Code:

(1) a proceeding of a medical peer review committee, as defined by Section 151.002, Occupations Code, or medical committee; or

(2) a meeting of the governing body of a public hospital, hospital district, hospital authority, or health maintenance organization of a public hospital, hospital authority, hospital district, or state-owned teaching hospital at which the governing

[190] *Texas Health and Safety Code§ 161.032.*

body receives records, information, or reports provided by a medical committee, medical peer review committee, or compliance officer.

(c) Records, information, or reports of a medical committee, medical peer review committee, or compliance officer and records, information, or reports provided by a medical committee, medical peer review committee, or compliance officer to the governing body of a public hospital, hospital district, or hospital authority are not subject to disclosure under Chapter 552, Government Code.

(d) The records and proceedings may be used by the committee and the committee members only in the exercise of proper committee functions.

(e) The records, information, and reports received or maintained by a compliance officer retain the protection provided by this section only if the records, information, or reports are received, created, or maintained in the exercise of a proper function of the compliance officer as provided by the Office of Inspector General of the United States Department of Health and Human Services.

(f) This section and Subchapter A, Chapter 160, Occupations Code, do not apply to records made or maintained in the regular course of business by a hospital, health maintenance organization, medical organization, university medical center or health science center, hospital district, hospital authority, or extended care facility.

One of the difficulties with these types of protections are that some are written in such a way that they do not protection information disclosed by a person who is in attendance to the quality assurance protections and therefore does not encourage participation by health providers.

Disclosure

A number of states have systems in place which require patient notification after an adverse event. Florida, Nevada, and New Jersey for example, require a system of notifying patient that they are the subject of an adverse incident.[191]

[191] Florida S0002D/H0001D – Title 29, chap. 2003-416, Nev. Rev. Stat. 439.855. N.J. Stat. § 26:2H-12.25.