がんのガイドライン、その他の患者安全の対策というのを、私は種として見ています。それから、その種をまく環境、この場合は環境整備として、ハーバード・ビジネス・スクールを利用して、MGHはこのようなガイドライン、いわば種を受け入れる状況に達しました。これは病院内の文化、リーダーシップ、人材を変えていくカルチャーです。安全文化を作り上げていく基盤の一つです。

先ほどお話ししたように、より安全な医療をつくるための要素がいくつかありますが、やはりいい種だけが大事なのではなく、土も耕すことが大事だと思います。実際に何が必要かというと、エビデンスに基づいた患者安全の対策、これが種。そして対策を受け入れて実行できる医療環境、これが土です。

さらに、医療保険会社と医療過誤保険会社と合意したインセンティブ、これも環境づくりの一つとして重要です。最後に患者の声。これら4つをうまく組み合わせていくことが、患者安全の普及に必要な条件だと思います。

以上です。(拍手)

【高久】　佐藤先生、どうもありがとうございました。

お慣れになっていない日本語でご講演いただきまして、しかし完璧な日本語で非常に感銘を受けました。本当にありがとうございました。

まだ少し時間がありますので、もしどなたかご質問がおありでしたら、普通特別講演はあまり質問はないんですけれども、時間がありますので、どなたかもしご質問されたい方がおありでしたらどうぞ。

よろしいでしょうか、どうぞ。

【江原】　神戸大学医療安全管理室の江原ですけれども、先ほどちょっと先生お話しになったところで、ディスクロージャーというところで、そういう医療事故の調査分析を病院でやった上で、患者さんにどの程度ディスクロージャーすべきかという、弁護士さんからはそれはあまりしてはいけないというふうに言われているんですけども、その辺のところ、ハーバードのお考えを教えていただきたいんですけども。

【高久】　できれば。

【佐藤】　そのディスクロージャーが非常に難しいというのは、この場合は飛行機事故でも同じですが、事故が起きてから得られる事実が非常に限られている、ということによると思います。

事実がない状況で、これは英語で speculation と言うのですが、日本語で何と言うのでしょうか。要するに事実がない状況の guess work、「guess」ですか。

【高久】　推測。

【佐藤】　推測ですね。事実がない状況の中では推測が中心になります。その推測によってクレームが来る場合が非常に多いのです。だから、自分が持っている事実の範囲内で何をディスクローズするか、という問題なら、私としては全然問題ないと思います。

しかし、どこまでが事実で、どこまでが推測なのかを見分けるのは非常に難しい問題で

す。両方のバランスを取ることが非常に難しいので、それに対するディスクロージャーのトレーニングが必要だと思います。それも病院で毎日毎日起こっているようなものではないので、病院側としては、英語で言えばSWATチーム(特殊機動隊)のような人たちを備えていればよいのではないでしょうか。何か事故が起きたときにその人たちに電話して、こういう状況なんですよ、どうすればいいんですかというアドバイスを得て、そこから進んでいくという方針を私たちは立てようとしています。

【江原】　ありがとうございます。

【高久】　どうもありがとうございました。どうぞ、じゃあ、それでおしまいにしていただきます。

【長尾】　京都大学の安全管理室の長尾と言います。大変貴重な講演ありがとうございます。

先生のお書きになった論文の中に、アメリカでのいわゆる保険危機の発生した原因が、アメリカが当時とった対策のまずさにあるのではないかというご指摘があって、そのアメリカが当時とった対策というのは、つまり医療者の犯したミスの肩がわりを保険会社が行う、あるいは第三者機関で医療過誤かどうかの判定をするといったような対策が当時行われて、それで保険料がどんどん高騰していったと。つまりお金で医療者を救済するという立場をとったがために、保険のいわゆる訴訟の嵐というのが吹き荒れていって、その高騰を招いたと。

それで、私思うんですけれども、今のそのハーバードの取り組み等を見ておりますと、逆にそれが非常によく働いて、その一つのアウトカムが賠償金であるとか、そういったものでアウトカムしながら、対策を非常に現実的に取り組んでおられるという感じがいたします。日本は今、訴訟の嵐が今後吹くかどうかという時期に来ていると思いまして、その行っている対策も、あるいはしようとしている対策も、第三者機関の設立であるとか、あるいは保険会社、国立大学病院が保険会社に加入したといったような、ちょうど米国が当時置かれた状況に非常によく似ているなと思うんですけれども、ただ日本は訴訟の嵐を経験しないで、できればリスク・マネジメントを完成させたいというふうに思っていると思うんですが、佐藤先生のお考えとして、果たしてどういうあり方が今後の日本に求められているのかということを率直なご意見をお伺いしたいんですが。

【佐藤】　今、日本で一番問題だと思うのは、非難的な文化で、たとえば医療事故が起きた場合、警察が乗り込んでくるという、その環境ですね。今、日本は医療過誤に対して比較的まだ新しい道にようやく入ったところだと思うのですが、アメリカの場合は、コストが上がった理由というのは裁判で、juryという人達がいます。

【高久】　陪審員ですね。

【佐藤】　はい。陪審員の陪審によって賠償金が決まるのですが、アメリカの裁判には弁護士と弁護士との「ショー」のような要素があります。陪審員達に、医療過誤の原告(被害者)がいかに苦労しているか、この人が立ち直るためにこれだけのお金が必要です、という

主張がいつも出て、そのおかげで賠償額がますます上がっています。

特に9・11テロ以降、被害者・犠牲者に対する賠償金額は非常に高くなってきました。このようなアメリカの現象を victimization(犠牲にすること)と言う人もいます。それも加わって、さらに賠償額は上がる傾向にあります。日本も幾らかそういうことを経験するべきだとは言いません。理想としてはもちろんそれはないほうがいいと思います。

しかし、日本の場合には、患者の声を導入した医療システムというのはあまり発達していないようなので、逆にアメリカのような動きが出てくると思います。この二つのバランスはいつか将来とれると思いますが、私には今それだけしか言えません。

【高久】　どうもすみません、もう時間になりましたので。

先生、どうもありがとうございました。

【佐藤】　どうもありがとうございました。

Effective Adoption and Spread Strategy for Patient Safety and Quality Improvement

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In 1999 the Institute of Medicine (IOM) published their report, *"To Err Is Human: Building a Safer Health System"*. This report among other things introduced numerous important concepts that were foreign to healthcare. The first important concept was notion of a "system", where a system is a set of interdependent elements interacting to achieve a common aim. These elements may be both human and nonhuman (equipment, technologies, environment etc.). The second important concept that the IOM report introduced was Human Factors which is the study of the interrelationships between humans, the tools they use, and the environment (people/systems/organizations) in which they live and work. These definitions were excerpted from the National Patient Safety Foundation list of patient safety terms. One of the highlights that were introduced in this report was the fact that 98,000 Americans died each year as a result of preventable medical errors. And the associated costs with these medical errors were $29 billion annually. The number of deaths from medical error is more than twice the number of deaths from automobile accidents and over 10 times more from workplace related deaths. Another important issue this report raised was the fact that healthcare was mainly a "systems" problem and the challenge was to redesign these systems. Finally the report emphasize to the US government to need to make safety a national priority.

If you compare the relative dangers associated with activities in healthcare to others which include the spectrum from riding a train in Europe to mountain climbing and bungee jumping the statistics are somewhat overwhelming and depressing. The

relative hazard associated with each activity by plotting total lives lost per year against the number of encounters for each fatality indicates that healthcare has a relatively high number of lives lost per each encounter.

What can we say about the state of risk management and patient safety in the United States since the release of the IOM report seven years ago? In the U.S., there are 10 common misconceptions about Patient Safety and Risk Management which need to be clarified.

1. **Misconception:** It is safer to be admitted to a hospital rather than to fly in an airplane.
   Fact: The opposite is true and people are far more likely to die from medical errors than flying in an airplane. In the November 7, 2006 issue of the Daily Post in Liverpool, Sir Liam Donaldson who is part-time chairman of the World Health Organization's World Alliance for Patient Safety and the Chief Medical Officer for England stated that healthcare was already a "high-risk environment" due to the complex nature of providing care in making decisions based on human behavior.
2. **Misconception:** Wrong site surgeries rarely occur in the United States.
   Fact: Surgical errors are not uncommon and wrong site operations occur frequently in the US. A study in the September 2006 issue of the Archives of Surgery reports the problem may be 20 times more common than previously thought and that the prevention efforts may be inadequate. Using multiple databases including a repository of malpractice payments and actions call the National Practitioner Data Bank estimate that wrong site surgery occurs between 1,300 and 2,700 times a year. A 10 year review of the malpractice claims within the Harvard system uncovered approximately 25 cases with a payment of over $5,000,000.
3. **Misconception:** Disclosure and apology in the United States is occurring in every hospital.
   Fact: In the October 16, 2006 issue of Newsweek, Lucian Leape M.D. states that a recent survey of several thousand physicians showed that in response to four different scenarios depicting errors, even clear-cut errors, less than half (42%) would inform the patient that an error had occurred and even fewer (37%) would provide information about preventing future errors. This study reflects what is happening every day in hospitals and doctor's office in the United States.

4. **Misconception:** Physicians and nurses are working together to move forward patient safety.
   Fact: In 2004, the IOM published another report called *Keeping Patients Safe: Transforming the Work Environment of Nurses* to highlight the importance of nursing care in preventing medical errors and the need for institutions to recognize this and to implement appropriate management restructuring to address the work environment in healthcare.
5. **Misconception:** A culture of safety is pervasive in the United States.
   Fact: A culture of blame is still present in healthcare and people find it difficult to learn from mistakes. Although the situation in the United States is not as bad as in Japan where some medical errors are considered criminal acts and the police becomes involved in the investigations. However, because of the strong regulatory oversight of healthcare in the United States by various state and federal government agencies, and the often punitive nature and tone of their inspections, these regulatory agencies still foster a culture of blame in healthcare organizations and therefore nurturing a culture of safety is still difficult and hard to maintain.
6. **Misconception:** Majority of hospitals, clinics, and physicians have embraced electronic order entry systems and electronic medical records.
   Fact: Only 10% of the physicians are utilizing a high end electronic medical record system whereas 24% are using some basic medical record system. Of the 6,000 hospitals in the United States, only 5% have adopted a Computer Physician Order Entry System (CPOE).
7. **Misconception:** E-mail is the preferred way of communicating between health care providers and patients.
   Fact: This concept is just about to be piloted in Minnesota. Some of Minnesota's largest healthcare providers, including HealthPartners and Blue Cross Blue Shield are beginning to cover electronic visits between physicians and patients by piloting an unusual program in an attempt to contain exploding healthcare costs. In this program, patients pay the same co-pay as they would for an office visit and physicians would get reimbursed approximately $35 for each patient e-mail they respond to. It is said such electronic visits (or e-visits) could yield billions of dollars per year in savings as well as cut down on time and travel for patients with routine medical issues.
8. **Misconception:** Patient safety initiatives are being implemented in all hospitals across the United States.

Fact: Healthcare is extremely regulated by local, state and federal agencies and often imposes requirements, regulations, policies, and mandates on healthcare institutions. These requirements often compete with the hospital's own patient safety and quality improvement initiatives and therefore organizations have a difficult time prioritizing which ones to do at all. Medical malpractice data could provide a different perspective for the healthcare organizations to prioritize what initiatives needs to be implemented first. For example, focusing on initiatives that overlaps with the medical malpractice data, regulatory agency mandates and the institution's own patient safety initiatives then becomes the priority.

9. **Misconception:** In the United States, risk managers, patient safety officers, and quality improvement staff are working collaboratively together.
   Fact: From our perspective we often see this not to be the case. In our opinion, these three areas should all report to a position often called the Chief Medical Officer or CMO. The fact of the matter is these various areas including risk safety and quality improvement need to all react to the same data and be coordinated by a single individual across the institution. We often see the risk manager reporting to the General Counsel of the hospital while the patient safety officer reports to the chief medical officer and the quality improvement director reporting to a different individual. How the organization restructures itself to optimize the information coming in from these various departments is the key.
10. **Misconception:** In the United States the medical malpractice tort system is viewed to be a problem.
    Fact: Malpractice data, under the right conditions is extremely well analyzed and therefore can be an effective means of uncovering areas of high-risk within an organization. In addition, the fear of being sued can be a strong motivating factor for changing behavior.

If one summarizes the critical success factors required for safer care, they would fall into two categories. The first category is institutional process reengineering, redesign and implementation. In order for this to happen effectively, the institution needs to make sure the following elements are present including, leadership, data, peer review protection, process and outcome measures, a non-blame the environment, and transparency. The second category falls under multiple stakeholders working together. The stakeholders include healthcare providers which include the hospitals, physicians,

and nurses, the medical malpractice provider, the healthcare insurance provider, government and private regulatory agencies, and patient advocacy groups. Together with these two categories of factors one could start seeing a change in the effectiveness of improving safety.

Over the years, our strategy to work with the healthcare institutions that we ensure has evolved. In the 1980s are approach was a traditional legalistic risk management strategy. In the 1990s we incorporated a more clinical perspective to our risk management strategy. And in 1999 when the IOM report was published we jumped on the patient safety bandwagon and incorporated patient safety as a key element into our strategy. Presently we have evolved this patient safety strategy to more a change management type approach. You could say our strategy has evolved from risk management to change management. In order to ensure the proper of adoption and spread of patient safety within the Harvard healthcare system think about this analogy of seeds and the soil. Through the use of medical malpractice claims data we identify high-risk areas and focus on initiatives and interventions to address these high-risk malpractice claims. Our goal was to develop a Harvard wide program which incorporates an organizational framework and consensus process that's designed to identify content and prioritize best practice models, standards and interventions to implement. These may include algorithms, clinical standards, surgical safety initiatives and others. These fall under "seeds". Implementing these initiatives is another issue. Our goal is to embed these practices into the fabric of each healthcare organization to maintain sustainability; in other words this is an operationalization problem. The way to achieve this is to think about the "soil". One needs to prepare the soil and make sure the environment is able to accept the seeds you plant.

In conclusion, one has to have the following four conditions for successfully adopting and spreading patient safety initiatives. First is an appropriate set of evidence-based patient safety initiatives. Second is a healthcare environment ready and capable of accepting and implementing these initiatives. Third is the proper incentives aligned with regulators, payers and medical malpractice insurers. Finally, forth is the inclusion of the voice of the patient.

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略歴

米国ボルチモア州出身
1982年　ブラウン大学応用数学部卒業
1986年　ボストン大学医学部卒業
1990年　ボストン大学医学部脳神経内科専門医研修修了
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1993－1998 年　ブリガム・アンド・ウィメンズ病院医療情報担当
1998－2002 年　リスク・マネジメント財団副理事長(最高情報責任者)
2002 年より　　同財団副理事長(最高医療責任者)として現在に至る。

専門は、ハーバード大学付属・関連病院の医療事故データ分析による「患者の安全」および「医療の質」の向上を目指したプログラムの開発。

シンポジュウム１

Keeping Patients Safe: Transforming the Work Environment of Healthcare Workers

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Introduction

The magnitude of the patient safety problem facing hospitals and other healthcare organizations was documented in the Institute of Medicine (IOM) report, "To Err is Human (2000)." The report described how thousands of people die each year in hospitals from medical errors. Although there may be a tendency to blame individuals for medical errors (e.g., doctors and nurses), the problem lies with the failure of healthcare organizations to develop and implement high reliability systems that can prevent errors from occurring, and when errors do occur, prevent them from reaching the patient.

In 2004 the IOM released a follow-up report, "Keeping Patients Safe: Transforming the Work Environment of Nurses." The goal of the report was to identify what is known about creating and managing high reliability organizations (safety sensitive) and to assess the relevance of the evidence for hospitals, nursing homes, and other healthcare organizations. The committee found extensive scientific evidence from industries outside of healthcare, including manufacturing, airlines, and the military, as well as more recent research from healthcare organizations. Based on the evidence,

the committee concluded that healthcare organizations can and should immediately take steps to become high reliability organizations. The specific steps are embodied in the report's review of evidence and the recommendations made by the committee. The following summarizes the committee's findings and key recommendations.

Magnitude of the Challenge for Healthcare Organizations

The experiences of organizations that have transformed themselves to achieve the goal of high reliability (safety) provide models which can be adapted to healthcare organizations. In becoming high reliability, organizations have transformed themselves through leadership and management, changes in organizational culture, and have actively involved workers in making decisions and in the design of work and work environments. Generally it has taken years of leadership and management commitment to achieve the goal of high reliability. The IOM committee concluded that healthcare organizations can achieve high reliability but this will not be easy. It will require leadership that can achieve transformational change in the organization, its culture, and the involvement of healthcare workers in making decisions about work processes and the design of work environments.

The IOM committee organized its report into four major areas, providing a blue print for healthcare organizations to become high reliability organizations. Hospitals and other healthcare organizations will require leadership that can transform the organization, its management, and how patient safety is valued. Specifically, healthcare organizations have to adopt a culture of safety, where patient safety becomes as important, or more important, than production efficiency. The workforce will need to have the capacity to support safe practices, including appropriate training, adequate staffing levels, and effective teamwork. Work processes will need to be redesigned to ensure safety (reliability). Redesign of the work environments should remove impediments to patient safety and support new work processes. The challenge for healthcare organizations is great, but the cost of failure is greater. If the frequency of medical errors continues to increase, more human lives will be lost and more patients will suffer needless injuries from the medical care that is supposed to benefit them. Increasingly at risk is the essential trust of patients in their doctors, nurses and hospitals as places of healing that will do their best to return the patient to good health. The committee detailed the essential steps each healthcare organization must undertake to be able to provide a safe environment for patients.

Transformational Leadership and Evidence-based Management

Leadership that can transform an organization differs from the leadership of many organizations that effectively manages by making incremental changes over time to improve performance and respond to changing circumstances. Truly transformational leadership has to have the capacity to change the beliefs and attitudes of management and the workforce and fundamentally change work processes and redesign work environments. This type of leadership is less common yet essential. Transformational leaders are often described as "elevating" and "inspirational." They have the capacity to communicate a new vision for an organization. In doing this, they involve managers and healthcare workers at all levels of the organization. The result is a set of shared organizational goals that are pursued jointly by managers and workers through a continuing two-way communication.

While the committee's recommendations are based on scientific evidence, it may be less common to think of management practices being based on evidence. The concept of "evidence-based" management is relatively new. As with evidence-based medicine, it involves the application of scientific evidence in everyday practice. The committee identified the bodies of management evidence that should guide organizational changes to improve patient safety within healthcare organizations. These include the critical role of leadership in initiating and sustaining change and in creating a culture of trust. Skills are needed by managers at all levels to actively manage the change process and to involve workers in making decisions about work processes and work environment. The goal is to create a "learning organization" that continually creates and applies knowledge to change what it is doing and do it better.

Balancing Production Efficiency and Reliability

Healthcare organizations have to deal with financial pressures and the needs for greater efficiency. Leadership must balance these pressures against the resource requirements needed to improve reliability and patient safety. Specifically, high reliability organizations incorporate equipment and personnel redundancy to ensure safety if one component fails. Redundancy that is essential for patient safety may be seen inefficient. At the same time medical errors and the treatment of resulting adverse medical events can be very costly, as well as posing substantial risks to life and causing patient suffering. The value placed by the healthcare organizations on patient safety cannot be dependent solely on economic valuation and must recognize the core values of medicine and the mission of the healthcare organization. Leadership is pivotal in communicating the value and importance of patient safety and that it is valued as much, if not more, than efficiency.

Creating and Sustaining a Climate of Trust

Responsibility for medical errors can be difficult for healthcare professionals and workers to admit to patients and peers. If medical errors are hidden and not discussed, the healthcare organization is at risk of repeating the same error many times in the future. Communication of medical errors will not occur unless the healthcare workforce has trust in leadership and peers. Trust is strongest when each person believes the other to be competent and to have their personal interests at heart. Research has found factors related to trust vary between leaders and subordinates. Leaders trust subordinates with complete information and to make decisions when they believe subordinates to be competent. Subordinates trust leaders when they perceive the leaders to be able, benevolent, and to have integrity. Understanding these differences can help the organization as it works to create a climate of trust. Establishing a climate of trust is essential to becoming a high reliability organization.

Actively Managing the Process of Change

Managing organizational change can be challenging and requires skills beyond those needed to manage routine operations. There may be organizational resistance to change unless leadership and all levels of management clearly communicate the reasons for change, the specific changes that are needed, and how change can further the mission and goals of the organization. Communication is an ongoing process and

includes feedback on success as well as problems. In addition to effective communication, change management research has documented the importance of multiple factors toward achieving a successful organizational outcome. The workforce needs be trained with the knowledge and skills that will be needed to function successfully in the changed work environment. As change progresses, there needs to be individual and collective mechanisms for feedback on performance and the extent to which changes are meeting expectations. The change process will be more successful if management gives it their sustained attention. It will also be more successful if workers are involved in the decision-making processes, the design of changes, and their evaluation.

Involving Workers in Decision-making

Worker involvement in decision-making is associated with a range of positive outcomes, including increased commitment to the organization and greater productivity. The inherent nature of healthcare services creates a decision-making environment in which there is high variability. Variability arises from each patient having somewhat different needs; patients may respond differently to the same treatment; and unpredictable problems may arise at any time. To make decisions about work processes and work environment in a high variability environment, decision-making should be flexible and delegated to the lowest level in the organization with the necessary knowledge to make the decision. It should be noted that this model of delegated and flexible decision-making is inconsistent with a strongly hierarchical organization.

Delegating decisions to the lowest level with the necessary knowledge needed to make the decision is empowering for workers and leads to better outcomes. For workers to exercise control over the content and context of their work, they need to have access to resources, including training, information, support services, and other resources consistent with the person's level in the organization. This process of empowering workers, acquiring and using information, making decisions, and evaluating outcomes are part of what many now call a "learning organization."

Creating a Learning Organization

A learning organization is "skilled at creating, acquiring, and transferring knowledge, and at modifying its behavior to reflect new knowledge and insight" (Garvin, 1993:80). The learning organization is continually changing as it acquires new knowledge, applies the knowledge to make changes, and evaluates the changes to learn their effectiveness, thus creating new knowledge. In Japan, there is a world renowned high reliability organization that applies the management concepts described above and is a learning organization.

In the Toyota Production System (TPS), you will find four signature practices:

- **How people work:** Workers follow exacting specifications even when the tasks are complex. Although this might appear to be an inflexible system, it enables workers to more easily identify needed changes to work processes and to rigorously evaluate new work processes when tested.
- **How workers connect:** Communication is direct between workers and between workers and managers. When workers encounter a problem they are

expected to ask for help immediately instead of trying to solve it themselves. When assistance is requested, it is expected to be given immediately. This maximizes accountability, promotes trust, and minimizes the opportunity for problems to persist over time.

- **How work is constructed:** Work is designed to maximize reliability. The production processes follow a specified plan that does not change unless the process is redesigned. This facilitates redesign through experimentation.
- **How work is improved and errors reduced:** The above are designed to identify production problems and this last practice creates a learning organization in which errors are continually identified and reduced.

The key elements of a learning organization can again be seen in the operations of Toyota in which:

- Workers are taught how to change. Improvements in work processes must be made in accordance with the scientific method. This is done under the guidance of a teacher and decisions to change processes are made at the lowest level of the organization possible.
- All workers are taught the scientific method at all levels of the organization.
- Workers are expected to learn directly from their on-the-job experiences.

The learning organization is dynamic and continually changing to incorporate the best methods available to ensure reliability and to promote quality and safety. The IOM report recommends adopting this model in healthcare organizations. Specifically the committee recommended that: "Healthcare organizations emphasize safety to the same extent as financial goals and employ management structures and processes that (a) demonstrate and promote trust with workers, (b) actively manage the process of change, (c) engage workers in the design of work processes and work flow, and (d) establish a "learning organization." Furthermore it is recommended that healthcare organizations acquire nurse leaders at all levels of management who will participate in executive decisions, achieve effective communication between nursing and clinical leadership, and provide the input of direct-care nurses into the design of work processes and work flow decisions.

Creating and Sustaining a Culture of Safety

The concept of a culture of safety embodies organizational values elevating the importance of safety and the empowerment of healthcare workers to be an equal partner with management and clinical leadership in preventing medical errors. Empowerment of workers to be a partner in patient safety requires that there be mutual respect, mutual trust, and organization-wide training in the methods for evaluating the causes of errors and in the design of systems to prevent errors.

In organizations that have successfully established a culture of safety, surveys of healthcare workers report highly positive attitudes about management's commitment to safety, willingness to report medical errors, and readiness to learn from own errors and those of others, including (Sexton et.al. 2004):

- I am encouraged to report safety concerns.
- I can learn from the mistakes of others.
- Medical errors are handled appropriately.
- Physician and nurse leaders listen to my concerns.

- Management does not knowingly compromise safety for productivity.
- I would feel safe being treated as a patient here.

These statements are representative those included in a survey questionnaire which asks individuals to rate level of agreement as measures of the organizational culture. Confidential surveys of reported safety-related attitudes and behaviors provide organizational leadership with information that is critical to judge the current culture and identify areas that need attention.

The IOM specifically recommended that healthcare organizations create and sustain a culture of safety by (IOM 2004):

- Setting objectives and providing feedback at all levels
- Annual confidential survey on safety culture
- Instituting confidential reporting system
- Training in error detection, analysis, and reduction
- Analyzing errors and providing feedback
- Instituting rewards and incentives for error reduction

The culture of safety is created and sustained through leadership, having a culture of trust, actively managing the change process, and creating and sustaining a "learning organization."

Maximizing Workforce Capability

The committee focused on specific areas of workforce capability that have been shown to have a substantial impact on reliability (safety). These include adequate nurse staffing to meet patient care needs, appropriate training of the healthcare workforce in use of technologies and work processes, and effective communication among the members of the healthcare team. In addition, the creation of a learning organization requires investments in workforce training and support.

Research has demonstrated a statistically significant relationship between the adequacy of nurse staffing (numbers and level of training) and the occurrence of adverse events for patients, including mortality (Aiken 2002). The research demonstrates patient safety and outcome relationships in hospital intensive care units (ICU; Dang 2002) and in nursing home settings (Harrington 2002). The evidence was not adequate to establish minimum staffing levels for nursing requirements in general hospital beds. The committee made specific minimum staffing recommendations for hospital ICUs, stating there should be one licensed nurse for every two patients (i.e., 12 hours of a licensed nurse per patient day). For nursing homes, the minimum staffing is recommended to be one registered nurse (RN) for every 32 patients, one licensed nurse for every 18 patients, and one nursing assistant for every 8.5 patients. These are minimum staffing levels and may not be adequate to meet all patient care needs.

IOM further recommended that "nurse staffing for each patient care shift should:

- Involve direct-care nurses in design/evaluation of staffing
- Incorporate elasticity in staffing for unpredictable variations in patient volume and acuity

- Empower nurses to regulate work flow (admission and transfers of patients)
- Involve nurses in identifying causes of nurse turnover and ways to improve retention"

High reliability organizations commit significant resources to the training of the workforce including when new employees join the organization, when new technologies are introduced, and when there are changes in the work processes. The IOM committee found American healthcare organizations spend less than other employment sectors on worker training. Many examples were identified where lack of training directly contributed to medical errors. The committee recommended that "healthcare organizations should devote significant resources to support acquisition of knowledge/skills by the workforce:"

- **Assign experienced nurse to precept nurses newly practicing in a clinical area:** newly graduated nurses and those moving into a new clinical area can benefit from having an experienced mentor to answer questions and provide training.
- **Annual educational plan and money allocated for each nurse:** individuals have different training needs and there should be an annual process to assess needs and develop a training plan to meet these needs.
- **Training for new technology or changes in work:** Healthcare organizations are continually integrating new technologies into practice and frequently may purchase different products that are similar technologies. Lack of adequate training can contribute to medical errors.
- **Provide decision support, involve direct care nurses:** The need for decision support tools for all healthcare workers is a means to acquire new information, to avoid errors of memory, and to facilitate implementation of uniform practices. Decision support tools may simple technologies (e.g., check lists) or be more complicated computerized decision tools

Training should extend beyond the individual and should involve training of interdisciplinary teams of health professionals. The prevention of medical errors requires effective team work. Traditionally in healthcare there has been less reliance on teams and teamwork and greater emphasis on individual initiative and individual decision-making. This is changing as the advantages of teamwork are being documented in achieving patient safety and better patient outcomes. There are many factors that influence the effectiveness of a group to function as a team. Research has shown that necessary conditions for effective teamwork include all team members being perceived as having clinical competence and there being mutual trust and respect among team members.

Team collaboration is enhanced by having: (1) shared understanding of goals and roles among team members, (2) effective communication, (3) shared decision-making, and (4) skills in conflict management. Training can help individuals learn to function in teams and to gain skills in communication, shared decision-making and conflict management. The IOM committee specifically recommended: "healthcare organizations should support interdisciplinary collaboration by mechanisms such as: (a) interdisciplinary rounds and (b) formal education and training in interdisciplinary collaboration for all healthcare providers on a regularly scheduled, continual basis."

Work and Workspace Design to Prevent and Mitigate Errors

The design of work processes and the work environment can substantially influence the risk of errors and can help prevent errors from reaching the patient. The IOM committee drew attention to the problem of healthcare worker fatigue associated with working long hours and with working shifts, day, evening, or night. Human factors engineering has found that human error rates increase after nine hours of work, double after 12 hours of work, and triple after 16 hours. Working long hours may be a result of organizational policies or may be an individual's choice. The research clearly shows fatigue should be prevented and long working hours should be strongly discouraged. The committee made a specific recommendation: "Reduce error producing fatigue by: (a) regulators and organizational policies prohibiting any combination of nurse patient care shifts and overtime in excess of 12 hours in any 24 hour period and/or 60 hours in any 7 day period, and (b) schools should educate nurses about fatigue and errors." Although this recommendation is directed at nursing, the recommendation is equally relevant for all healthcare professionals and workers.

The design of work environments can have an impact on many aspects of patient care, including the risk of medical errors. One study of hospital nurses in medical and surgical units showed that only 10% to 25% of their time was actually spent with patients and a majority of their time was spent walking between patient rooms and the nursing station (Hendrich and Lee 2003). This and other findings suggest that nurses spend a majority of their time on less essential activities. Changes in work space design to reduce the time spent on these activities including going to and from the patient's room and increase time available for direct patient care.

The committee identified five questions that should be considered in designing work and work space:

- What are the characteristics of the individual performing the work?
- What tasks are being performed?
- What tools and technologies are being used to perform tasks?
- What aspects of the physical environment can be sources of errors?
- How does the organization prevent or allow errors to occur?

Answering these questions provides the information needed to begin the redesign of work processes and the environment in which work is being done. The design process can benefit from adopting the following guiding principles which have been demonstrated to improve design outcomes:

- **Involve workers in the design process:** Workers bring experience and knowledge not readily available to those who are removed from the work setting. Adoption of new work processes and changes in the work environment are improved by including workers in the decision-making.
- **Simplifying and standardizing common work procedures and equipment:** Complexity and variability can contribute to errors.
- **Avoid reliance on the individual worker memory:** Memory is imperfect and tasks or procedures may not be remembered at the time when they should be done.
- **Decrease interruptions, distractions, and interferences:** Errors increase when individuals cannot concentrate on the task being done and are distracted or interrupted to pay attention to other tasks or patients.

- **Install redundancy and back-up systems:** One way to improve the reliability of a system is to try to identify all the ways in which the system might fail and identify what should be done to prevent failure or prevent harm to patients due to failure. Every system involved in patient care needs one or more back-up systems.
- **Reducing and compensating for hand-offs:** Hand-offs are transfers of patient care responsibilities which occur at the end of each nursing shift, when a patient goes from surgery to the recovery unit and to a regular bed, and when patients transfer to or from the ICU. Experience shows transfers provide many opportunities for errors to occur. For example, full information on the patient's condition and treatment may not be communicated at the time of the transfer, and if communicated may not be remembered and acted upon.
- **Improving information access:** Information on the patient, on the use of an unfamiliar technology, on side-effects of medications, and other patient care relevant knowledge should be easily and reliably accessible. Lack of timely and accurate information can contribute to errors.

Application of these principles in the design of work processes and work environments will promote safety and assist in identifying work and environmental factors that are contributing to medical errors.

Conclusions

The report, *Keeping Patients Safe*, was written with a focus on nursing and the healthcare organizations in which they work. The evidence reviewed and recommendations made by the committee have broad relevance for all healthcare professionals and workers. The recommendations define specific actions healthcare organizations need to initiate in order to protect the safety of their patients. Full implementation of these recommendations can transform healthcare organizations into high reliability organizations, substantially reducing medical errors and improving quality of care. Immediate action is needed to save patient lives and prevent suffering caused by medical errors.

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