

COMMITTED TO SAFETY: TEN CASE STUDIES ON REDUCING HARM TO PATIENTS

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ABSTRACT: This report presents 10 case studies of health care organizations, clinical teams, and learning collaborations that have designed innovations in five areas that hold great promise for improving patient safety nationally: promoting an organizational culture of safety, improving teamwork and communication, enhancing rapid response to prevent heart attacks and other crises in the hospital, preventing health care–associated infections in the intensive care unit, and preventing adverse drug events throughout the hospital. Participating organizations ranged from large integrated delivery systems to small community hospitals. The cases describe the actions taken, results achieved, and lessons learned by these patient safety leaders, with suggestions for those seeking to replicate their successes.

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PREFACE

This paper presents longer versions of case studies briefly described in a related article, "<u>Stories from the Sharp End: Case Studies in Safety Improvement</u>," by Douglas McCarthy and David Blumenthal, published in the *Milbank Quarterly*, vol. 84, no. 1, 2006 (pp. 165–200). Additionally, the article provides background on the patient safety movement in health care, a framework for analyzing the cases, overall lessons learned across the case studies, and policy implications.

Some of these cases appeared in shorter form in The Commonwealth Fund's online newsletter, <u>Quality Matters</u>, during 2004 and 2005. Findings from this paper were presented at The Commonwealth Fund Quality Improvement Colloquium, "Patient Safety Five Years After *To Err Is Human*," held in Washington, D.C., on November 4, 2004. A Webcast of this event is available at <u>http://www.cmwf.org/General/General_show.htm?doc_id=249059</u>.

DEFINITIONS

Throughout the report, several terms are used in ways that have been defined by the Institute of Medicine, the federal Quality Interagency Coordination Task Force, the federal Agency for Healthcare Research and Quality, and other experts.

An **adverse event** is an injury caused by medical management rather than the underlying condition of the patient. A **preventable adverse event** is an adverse event attributable to an error or system failure (IOM 1999).

A close call or near miss is an event or situation that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention (QuIC 2000).

Error is failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim (IOM 1999; Reason 1990).

Failure modes and effects analysis is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures in order to identify the parts of the process that most need change (IHI 2004a).

High reliability organizations are highly complex, technology-intensive organizations that must operate, as far as humanly possible, to a failure-free standard (Reason 1997).

Human factors is the study of the interrelationships between humans, the tools they use, and the environment in which they live and work (IOM 1999).

Patient safety is freedom from accidental injury, or, more broadly, avoiding injuries to patients from the care that is intended to help them (IOM 1999, 2001).

Root cause analysis is a structured process for identifying the causal or contributing factors underlying adverse events or close calls (AHRQ 2005).

A **system** is a set of interdependent elements interacting to achieve a common aim. These elements may be both human and nonhuman (equipment, technologies, etc.) (IOM 1999).

EXECUTIVE SUMMARY

In 1999, the <u>Institute of Medicine</u> (IOM) shocked the nation with its estimate that 48,000 to 98,000 Americans die each year in the hospital—not from the illnesses or injuries for which they sought treatment, but because of mistakes and oversights in medical care. Although the numbers cited by the IOM were eye catching, the statistics were compelling because they captured a troubling idea: people can be harmed by care meant to help them.

The title of the IOM's report, <u>To Err Is Human: Building a Safer Health Care System</u>, emphasizes the fact that humans are prone to error. Therefore, the report contends, keeping patients safe from harm cannot depend on human perfection. Industries such as aviation and nuclear power achieve highly safe operations by taking human fallibility into account when people are trained, systems are designed, and organizations are managed (Roberts 1993; Reason 1997; Weick et al. 1999). This safety vigilance is applied within organizations in the following ways:

- People are taught to practice safe behaviors and techniques so that errors are prevented or caught and corrected before they cause harm. Examples include promoting assertive communication that helps team members bring safety concerns to one another's attention, and requiring or empowering team members to perform independent checks to ensure adherence to critical steps in a process.
- Systems incorporate properties that help avert errors or prevent them from causing harm. Examples include standardizing and simplifying processes to reduce unnecessary variation and complexity, and designing "forcing functions" into devices or processes to constrain individuals from taking unsafe actions or to guide them to appropriate actions or decisions.
- Organizations adapt so that mistakes and close calls are freely shared and analyzed to discover and address the latent system failures that permit errors and harm to occur. Examples include instilling a nonpunitive culture that encourages the reporting of safety concerns, and training staff to use analytic tools that facilitate the discovery of root causes and corrective measures.

The IOM report raised public and professional awareness of the need for change and galvanized positive action from many parts of the health care system. Before its publication, experts and leaders were working to educate others about the problem and to discover and demonstrate practical means for improvement. In more recent years, these efforts have intensified and more organizations and individuals have joined the cause. Nevertheless, experts agree that far more needs to be done to realize the vision of the IOM report.

This report, commissioned on the fifth anniversary of *To Err Is Human*, illustrates innovations in five areas that hold great promise for improving patient safety if applied nationally:

- promoting an organizational culture of safety,
- improving teamwork and communication to promote patient safety,
- enhancing rapid response to prevent heart attacks and other crises in the hospital,
- preventing health care-associated infections in the intensive care unit, and
- preventing adverse drug events throughout the hospital.

Several of these approaches are being disseminated and replicated in the field as part of the Institute for Healthcare Improvement's <u>100,000 Lives Campaign</u>. Thousands of U.S. hospitals are participating in this project to implement changes to improve patient care and prevent avoidable deaths, with the goal of saving 100,000 lives during the course of its 18-month campaign (Berwick et al. 2006).

Using 10 case studies, this report describes the actions taken and lessons learned from organizations, teams, and collaborations, with suggestions for those seeking to replicate these successes. The organizations studied range from large integrated delivery systems to small community hospitals. Some have been recognized as leaders, while others are lesser-known innovators. Likewise, some of these efforts are now mature, while others are showing great promise. Overall, the cases demonstrate that improvement can occur in any organization where there is leadership, purposeful application of methods, and the will to change for the sake of patient safety.

One overriding lesson emerges: the programs identified organizational cultural change—the creation of a "patient safety culture"—as the critical element in making patients safer. Organizations seemed to differ chiefly in the methods used to instill a safety culture. The first two case studies examine organizations that have undertaken wide-ranging organizational change strategies, while the others describe more specific approaches. Regardless of method, the goal is a safety culture that promotes continuing innovation and improvement.

The organizations and teams studied for this paper have reported impressive improvements in patient safety and related organizational performance, including:

- substantial reductions in observed adverse events and certain hospital-acquired infections;
- apparent elimination of serious errors such as reported wrong-site surgeries;
- reduction in death rates;
- improvement in safety attitudes, teamwork, and communications behaviors associated with improved safety performance;
- increased reporting of safety incidents and more effective investigations into their causes, leading to more useful recommendations for changes to prevent recurrence;
- enhanced nursing morale and decreased nursing turnover and vacancies;
- more efficient use of staff time by eliminating repeated work and delays; and
- cost-savings resulting from shorter hospital stays.

Many of the cases demonstrate a correlation between patient safety and other domains of quality improvement. For example, collaborative rounds improved awareness of safety issues as well as patient- and family-centeredness of care and clinical outcomes. Interventions to improve safety through teamwork and communication improved staff morale and reduced nursing turnover. Empowering staff with improvement tools and knowledge is likely to have spillover effects on other domains of quality. The individuals, teams, and organizations studied were frequently engaged in other types of quality improvement activities or were considering ways to apply their learning to additional areas. These signs of collateral benefits and connections suggest that patient safety should not be approached as an isolated domain of quality.

The organizations profiled here would readily admit to being on only the first leg of the journey. Much more work is needed to achieve a truly safe environment for patients. These experiences, therefore, should be seen as a source of inspiration and encouragement to achieving even higher levels of performance. Although the cases focused on hospital settings, the lessons learned here are potentially applicable to ambulatory care environments, where patients receive most of their health care.

Organization	Setting	Intervention	Selected Results
Sentara Norfolk General Hospital, Norfolk, Va.	A 569-bed, level 1 trauma center; one of six hospitals operated by Sentara Healthcare, a regional integrated health care delivery network	Accelerate patient safety improvement through a multifaceted culture change program involving setting and monitoring behavioral expectations, enhancing analytic capabilities, and streamlining and focusing on critical policies	 42% increase in expected communications behaviors 50% reduction in events of harm per 10,000 adjusted patient days when culture change strategies were applied system-wide
U.S. Dept. of Veterans Affairs, National Center for Patient Safety, Ann Arbor, Mich.	An integrated health care system that serves 5.1 million veterans and 7.6 million enrollees at more than 1,300 sites nationwide	Lead organizational cultural change by empowering local facilities and frontline staff with proven tools, methods, and initiatives for patient safety improvement	 30-fold increase in internal safety incident reporting 100% increase in perceived preventability of safety events studied by root cause analysis teams
Kaiser Permanente, Orange County, Calif., and Northern California region	Local medical centers of an integrated group-model health maintenance organization with 8.2 million people enrolled nationally	Initiate a preoperative safety briefing and a perinatal patient safety project as part of a program of organizational learning to promote effective teamwork and communication in high- risk areas	 A near doubling in the proportion of operating room staff reporting positive teamwork climate Two-thirds reduction in the turnover rate among operating room nursing staff
Concord Hospital, Concord, N.H.	A 295-bed community hospital that annually treats 250 patients in its cardiac surgery program	Use collaborative rounds involving all members of the care team with the patient and patient's family to proactively identify and prevent potential errors and safety threats	 56% lower than expected risk-adjusted mortality among cardiac surgery patients 15% to 32% higher staff ratings of teamwork and work satisfaction compared to traditional rounds
Missouri Baptist Medical Center, St. Louis, Mo.	A 489-bed acute care hospital within BJC HealthCare, a health system comprising 13 hospitals and other facilities	Establish a rapid response team to intervene early with patients showing signs of medical deterioration before they suffer acute crises	 60% decrease in emergency calls for respiratory arrest 15% decline in cardiac arrests 3.95% reduction in hospital mortality rate (continued on next page)

Table ES-1. Summary of Case Study Sites, Interventions, and Results

(continued on next page)

Organization	Setting	Intervention	Selected Results
Johns Hopkins Hospital, Baltimore, Md.	A 14-bed oncology surgical ICU and a 15-bed surgical ICU within a 900-bed academic medical center; one of three acute care hospitals in the Johns Hopkins Health System	Implement a comprehensive unit-based safety program that empowers staff to identify and eliminate patient safety hazards following eight action steps	 49% to 91% increase in the proportion of ICU staff reporting positive safety climate Elimination of 43 observed catheter-related bloodstream infections, saving eight lives One-day reduction in average ICU length of stay, saving an estimated \$2 million annually
VHA, Inc., Transformation of the Intensive Care Unit National Collaborative	More than 40 ICUs in diverse community hospitals nationwide that are members of VHA, a health care cooperative serving not-for-profit health care organizations	Focus all members of the care team on adhering to a "bundle" of evidence-based care practices associated with improved patient outcomes	 29% to 41% reduction in combined rates of ventilator-associated pneumonias 11% to 15% decrease in average lengths of stay across participating ICUs 18% lower mortality
Allegheny General Hospital, Pittsburgh, Pa.	A medical ICU and a cardiac care ICU in an 829-bed academic health center, part of six-hospital West Penn Allegheny Health System	Apply the Perfecting Patient Care approach, modeled on principles of the Toyota Production System, to specify best practices, eliminate variations from standards, and work toward ideal performance	 76% reduction in rate of central-line associated bloodstream infections, saving 18 lives per year \$2 million savings by reducing unreimbursed costs of care
Institute for Healthcare Improvement, Cambridge, Mass. and Premier, Inc., San Diego, Calif.	A nonprofit organization that works with health care institutions worldwide to spread quality improvement, and an alliance of more than 200 not- for-profit hospitals and health systems	Develop a simple trigger tool that organizations can use to measure the incidence and kinds of adverse events, so as to prioritize areas for improvement, design appropriate interventions, and track the effect of changes over time.	• 50-fold increase in detection of adverse drug events as compared to other common methodologies such as incident reports, pharmacy interventions, or billing codes
OSF St. Joseph Medical Center, Bloomington, Ill.	A 165-bed acute care hospital, part of OSF HealthCare, a six- hospital integrated health care network based in Peoria, Ill.	Reduce adverse drug events by improving the process of medication reconciliation, the safe use of high-risk medications, and the reliability of medication dispensing	 10-fold reduction in detected adverse drug events 8% improvement in perceived safety culture among hospital staff

Table ES-1. Summary of Case Study Sites, Interventions, and Results(continued)

Note: ICU = intensive care unit.

THE ORGANIZATIONAL CULTURE OF SAFETY

In *To Err Is Human*, the Institute of Medicine (IOM) noted that "[t]he importance of a strong culture of safety . . . is viewed by many in the safety field as being the most critical underlying feature of their accomplishments" (IOM 1999). Likewise, a more recent review of several high-profile patient safety failures occurring in health care organizations internationally found that "preventing future failures depends on cultural as much as structural change in health care systems and organizations" (Walsche and Shortell 2004).

The IOM recommended that health care organizations "develop a culture of safety such that an organization's design processes and workforce are focused on a clear goal—dramatic improvement in the reliability and safety of the care process." To achieve this goal, "safety must be an explicit organizational goal that is demonstrated by clear organizational leadership and professional support . . ." (IOM 1999).

Although there is no agreed-upon definition of organizational safety culture, one developed in the nuclear power industry provides a useful guidepost:

Safety culture is the product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety programmes. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures (ACSNI 1993).

Survey tools have been developed to measure organizational safety culture based on the attitudes and perceptions of workers and leaders (Nieva and Sorra 2003; Scott et al. 2003; Sexton and Thomas 2003; Singer et al. 2004; Sorra and Nieva 2004). In addition, behavioral observation can measure the extent to which workers practice desirable safetyenhancing behaviors (Morey et al. 2002; Healey et al. 2004). The willingness of staff to report safety incidents has been used as an indicator of safety culture; an increase in reporting can be a sign that workers trust their feedback will be used for constructive purposes (Edmondson 2004a; 2004b). Safety culture depends on much more than reporting errors or avoiding unsafe behaviors. It also requires a shared sense of responsibility and vigilance for ensuring safety throughout the organization (Weick et al. 1999; IHI 2004b). Some research suggests that organizational culture and leadership, among other factors, can affect the adoption of quality improvement strategies, the incidence of adverse events, and performance on clinical outcomes (Shortell et al. 1994, 1995; Nelson et al. 2002; Pronovost et al. 2005). The safety and reliability of anesthesia and aviation has improved through the cumulative effects of making many small improvements in practices (Leape et al. 2002). Organizational safety culture could change gradually through the adoption of discrete tools and techniques for improving safety, although results may occur more rapidly when part of a broader organizational change management process.

Several health care organizations have been recognized for their efforts to improve overall safety culture and performance. We highlight two that have undertaken innovative work in this regard: Sentara Norfolk General Hospital, winner of the 2004 American Hospital Association Quest for Quality prize and the 2005 John M. Eisenberg Patient Safety and Quality Award sponsored by the Joint Commission for Accreditation of Health Care Organizations (Case Study 1); and the National Center for Patient Safety at the Veterans Health Administration, winner of the 2004 Eisenberg Award (Case Study 2).

Case Study 1. Accelerating Patient Safety Improvement by Strengthening the Culture of Safety—Sentara Norfolk General Hospital*

Organization. <u>Sentara Norfolk General Hospital</u> (SNGH) is a 569-bed, level-one trauma center located in Norfolk, Va. It is one of six hospitals in a regional integrated health care delivery network operated by not-for-profit <u>Sentara Healthcare</u>.

Objective and intervention. SNGH sought to accelerate patient safety improvement by strengthening its organizational culture of safety. To transform its culture, SNGH pursued a multifaceted program involving setting and monitoring behavioral expectations, enhancing analytic capabilities, and streamlining and focusing on critical policies and procedures.

Date of implementation. SNGH initiated the Sentara Safety Initiative in 2002.

Process of change. Historically, SNGH relied on three approaches to create a safe environment for patients: 1) the use of technology to incorporate information and decision support into patient care; 2) creating highly reliable processes built on the findings of human factors research; and 3) hiring, training, and retaining competent people.

Despite making steady progress in meeting goals for specific technology and process improvements, the hospital's leaders, including Gary Yates, M.D., vice president and medical director of clinical effectiveness, were frustrated that the overall pace and scope of organizational change was not greater. "It was hypothesized that the missing piece was a stronger organizational culture focused on patient safety," Yates wrote (Yates et al. 2004).

To assist its efforts at accelerating culture change, SNGH retained an industrial consulting firm, Performance Improvement International, with a reputation for safety improvement in the nuclear power and airline industries. Although culture change was seen as the most important strategy for improving safety, the lesson gleaned from other industries was not to focus on the organizational culture itself, but on making safe behaviors a regular part of everyday practice, Yates said.

^{*} This case study is a synthesis of information obtained from personal interviews with Gary Yates, M.D., vice president, clinical effectiveness, Sentara Norfolk General Hospital, and executive medical director for clinical effectiveness, Sentara Healthcare; Kerry Johnson, senior partner, Performance Improvement International; and Thomas Krause, Ph.D., CEO of Behavioral Science Technology, Inc.; and from a review of supporting articles (Yates et al. 2004, 2005; Runy 2004).

A baseline assessment was conducted of previous adverse events, safety culture, and error management systems. The assessment identified a few common behaviors as sources of most errors, such as inadequate communication or attention to detail, noncompliance with policy, and failure to recognize high-risk situations or use error-reduction techniques.

In response to this assessment, four strategies were identified to promote the practice of safe behaviors:

- Expectation setting: developing three sets of behavior-based expectations (BBEs) linked to techniques for error prevention for all hospital staff, hospital leaders, and physicians;
- Operational focus: establishing "red rules" to focus employees' attention on highrisk procedures that can result in patient harm if not followed exactly (e.g., positive identification prior to any action with a patient, site verification before surgery);
- Effective tools: developing an enhanced root-cause and common-cause analysis process that was more timely and geared toward producing long-term, systems-oriented changes; and
- Streamlined rules: adopting an approach for simplifying policies and procedures (e.g., identifying and standardizing key steps in a checklist).

Staff and leadership BBEs were developed by a grassroots group of 20 employees. A separate group of 14 physicians and two nurses developed the physician BBEs. The groups reviewed and adapted proven error-management behaviors—tools and techniques from other high-risk industries modified to fit the health care environment. These were internalized in five BBEs applicable to all staff:

- Pay attention to detail; for example, by using the mnemonic SAFE (Stop, Analyze, Focus, and Evaluate) to focus attention on the task and decrease skill-based errors;
- Communicate clearly; use repeat-backs and clarifying questions;
- Have a questioning attitude; stop actions when unsure about their safety, use the verify and validate technique;
- Handoff effectively using a "5P" checklist to ensure that all elements of a successful transfer are followed: Patient/Project, Plan, Purpose, Problems, Precautions;

• Never leave your wingman, which means using peer checking and peer coaching when appropriate (e.g., staff are empowered to stop anyone violating a "red rule").

In addition, BBEs have been translated into specific techniques for each work unit. Physician BBEs include the use of a coordinating physician in the care of patients and use of clear, physician-to-physician communication for consultations. Leadership BBEs include responsibility for building accountability and making changes stick.

All hospital staff were educated on error-prevention methods and techniques. Admitting physicians and SNGH leadership were given additional specific training. To help make expected behaviors "stick" as habits, supervisors provide everyday feedback on BBEs, which serve as core competencies on staff performance reviews. Managers make informal observations on progress when on walk rounds in hospital units. Trained observers from the hospital's clinical effectiveness department use validated tools adapted from other high-risk industries to ensure that critical safety junctures, such as shift change reports, handoff communications, and pre-procedure briefings, are handled appropriately. These observations form the basis for measuring overall BBE progress through a system called Real-Time Behavior-Based Monitoring.

Annual system-level quality and safety goals are selected based on internal data on problem-prone areas and external performance standards, such as those established by the Joint Commission on Accreditation of Healthcare Organizations, the National Quality Forum, the Centers for Medicare and Medicaid Service, and the Leapfrog Group. The process includes specific safety metrics that are part of an integrated performance indicator system "to ensure that the right behaviors are encouraged, taught, and reinforced" (Runy 2004). Indicators include:

- leading measures that form a culture index based on annual culture surveys;
- real-time measures that include observational data on specific behaviors (including BBEs) for error prevention, a predictive error rate, and status of improvement recommendations;
- lagging measures that include adverse events and errors (e.g., patient falls, pressure ulcers, wrong-site procedures, retained foreign objects, patient identification errors, and serious medication errors), nosocomial infections and other clinical outcomes, employee injury and illness rates, losses incurred through malpractice claims, pharmacy interventions, and progress on selected high-impact safety improvement projects.

Progress toward reaching goals on safety initiatives is evaluated monthly and reported to the board quarterly. One-quarter of variable executive compensation is linked to these goals. Fifty percent of annual employee gain-sharing bonus is based on achieving safety goals, which can amount to the equivalent of a full paycheck for nurses. Medical staff reappointment also includes patient safety goals as a criterion.

SNGH's Philosophy of Fairness "encourages systematic improvements based on learning from errors, yet demands accountability for job performance" (SNGH 2004). Staff are encouraged and recognized for reporting events and near misses. On the other hand, honest mistakes are distinguished from a knowing violation of performance expectations using the "just culture" framework developed by James Reason (1997).

Preliminary results. Staff increased their use of expected communications behaviors (such as using repeat-backs and clarifying questions) by 42 percent from 2003 to 2004. Ventilator-associated pneumonias were reduced by 84 percent from 2001 through June 2004, and the device-associated bloodstream infection rate fell 63 percent from 2002 through June 2004 (Yates et al. 2004).

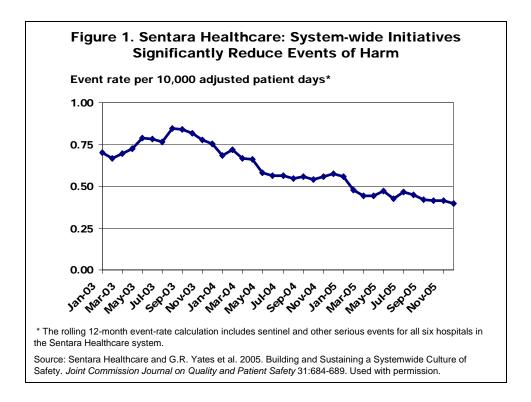
Lessons learned. A key factor in SNGH's success was that senior leadership made the safety initiative the organization's number-one priority and ensured the availability of time and resources. Organizational buy-in was promoted by empowering a team of five midlevel operational leaders to lead implementation and communication. Developing a physician-specific BBE list helped to gain the support of medical staff. Now, the hospital's challenge is to "continue to accelerate improvement while simultaneously holding gains previously made" (Yates et al. 2004).

SNGH's effort to accelerate organization-wide change built on its previous efforts that provided a foundation of safety culture from which the organization could grow. When adapting approaches or tools from outside the institution, SNGH started with a baseline diagnosis to determine whether the environment was comparable. In some cases, the approach needed tailoring, but, according to Dr. Yates, 80 percent of new tools and approaches were readily accepted without modification.

Based on SNGH's experience, Dr. Yates believes that health care leaders need to exhibit "measured impatience" if they want to see breakthroughs and move to the next level of performance. SNGH has made great progress, but managers realize they have only reached "the first mile marker on a marathon," he said. In the past, hospital leaders have advised staff to "be diligent," but this does not provide sufficient direction on how to improve. SNGH has learned that behavioral expectations must be translated into specific techniques applicable to each unit's work and that staff need coaching to understand how to effectively "set up their best shot" for improved performance. Yates also emphasizes the power of telling and retelling success stories that illustrate how employees' actions prevented errors.

The overall goal is to make error prevention reliable through an engineered structure that prevents errors, while at the same time detecting and correcting latent vulnerabilities that lead to error, said Kerry Johnson, senior partner with Performance Improvement International, the consultant to SNGH. This requires understanding the "anatomy of error"—the human, process, and system failures that lead to error—and adopting a systematic approach for addressing them by: setting behavior expectations to achieve prevention goals, educating on techniques to meet those expectations, and holding everyone accountable to perform expected behaviors and techniques.

Replication and related results. A behavior-based approach to improving the culture of patient safety has been expanded system-wide in Sentara Healthcare's six hospitals and other sites of care. Although this approach is being adapted locally in each institution, there is less need for adaptation than was expected, according to Dr. Yates. This effort has been associated with a 50 percent reduction in events of harm per 10,000 adjusted patient days from January 2003 through December 2005 (Yates et al. 2005) (Figure 1).



Many companies and some medical centers have instituted behavior-based workplace safety programs comparable to the program at SNGH. Thomas Krause, Ph.D., CEO of Behavioral Science Technology, Inc., in Ojai, Calif., describes behavior-based safety as a comprehensive program for continuously improving the safety environment by identifying workplace behaviors that are critical to safety, removing barriers to their practice, and reinforcing desired behaviors through observational feedback (Krause 2002). His study of behavior-based workplace safety programs in 73 companies found that they resulted in significant reductions in reported occupational injuries (Krause et al. 1999).

Implications. SNGH's experience models the idea that culture change is enhanced by embedding specific tactical safety improvement projects and activities in a larger organizational strategy. "Organizational culture drives behaviors and behaviors drive outcomes," said Johnson. The process also works in reverse, in a self-reinforcing circular fashion. Hence, an organization can use behavioral observation, coaching, and feedback as a form of social engineering to promote the practical learning of new safety-enhancing skills and behaviors that, over time, can become the internalized norms of a safety culture.

Some labor unions have criticized behavior-based workplace safety programs, which they perceive can lead managers to blame workers for unsafe acts, avoid responsibility for correcting hazardous conditions, and reward the suppression of injury reporting (Lessin 2002). Thomas Krause, Ph.D., one of the fathers of behavior-based workplace safety, acknowledges that some poorly implemented approaches focus on rewards rather than genuine employee involvement or fail to adequately consider behavior in the context of systems. In a well-designed program, hazards should be addressed as close to their source as possible, he says. For example, hearing protection should not be promoted as a safe behavior if the source of noise can be eliminated in the first place.

Given these considerations, three elements of SNGH's approach should be noted:

- Strategies originating in other industries were evaluated and internalized to the health care setting through the participation of frontline staff in implementation.
- Behavior-based expectations were implemented in concert with enhanced organizational capability to conduct rigorous systems analysis.
- Behavioral observation occurred within a framework that eschews blame for honest mistakes while encouraging the reporting of errors for organizational learning.

Through a multifaceted approach, SNGH appears to have achieved a reasonable balance for meeting safety goals incorporating individual behaviors, systems design, and organizational factors.

Case Study 2. Creating a Culture of Safety in the U.S. Department of Veterans Affairs Health Care System*

Organization. The Veterans Health Administration, a component of the Department of Veterans Affairs (VA), operates the nation's largest integrated health care system, providing care to more than 5.1 million veterans and 7.6 million enrollees at more than 1,300 sites of care nationwide. In response to public and congressional concerns about the quality of care in VA facilities, the VA undertook a broad organizational transformation during the 1990s, which included "rationalization of resource allocation, explicit measurement and accountability for quality and value, and development of an information infrastructure supporting the needs of patients, clinicians, and administrators" (Perlin et al. 2004).

Objective and intervention. Former VA Undersecretary for Health, Kenneth Kizer, M.D., stated the VA's objective in this way: "To make health care safe, we need to redesign our systems to make errors difficult to commit and create a culture in which the existence of risk is acknowledged and injury prevention is recognized as everyone's responsibility" (Weeks et al. 2000). The VA established a <u>National Center for Patient</u> <u>Safety</u> to lead organizational culture change and empower local facilities and frontline staff with proven tools, methods, and initiatives for patient safety improvement.

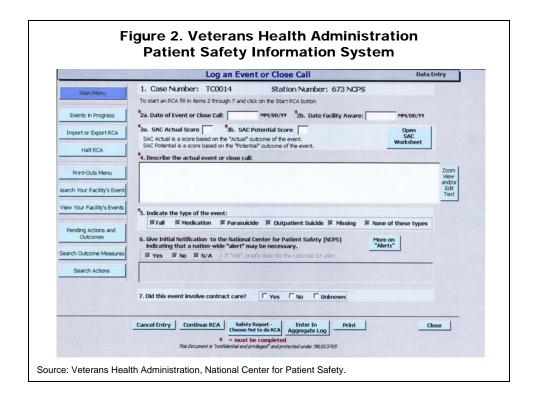
Date of implementation. The VA was a pioneer in instituting a comprehensive patient safety program within a large health care system, beginning its journey toward a culture of safety in 1997—two years before the publication of the IOM's *To Err Is Human* report. These efforts led to the creation of the VA's National Center for Patient Safety in 1999.

Process of change. The VA's culture change program drew upon human factors principles and the experience and lessons from industries such as aviation and nuclear power. To create a culture of safety, the VA adopted a nonpunitive approach to patient safety. "No one commits an error to hurt someone on purpose, but they are punished as if they did," said James Bagian, M.D., director of the VA's National Center for Patient Safety. That kind of "name and blame" approach doesn't correct the underlying system issues. "Now we ask, 'What happened? Why did it happen? What can we do to prevent it from happening in the future?" he added.

^{*} This case study is a synthesis of information obtained from personal interviews with James Bagian, M.D., director of the VA's National Center for Patient Safety, and Linda Connell, M.A., R.N., director of the NASA/VA Patient Safety Reporting System; and from a review of supporting publications and presentation materials (Weeks and Bagian 2000; Bagian et al. 2001; 2002; Hegit et al. 2002; DeRosier et al. 2002; Johnson et al. 2002; VA 2002; Neily 2003; Gosbee 2003; Perlin et al. 2004; NCPS 2004; Meterko et al. 2004).

On the other hand, an organization cannot promise a "blame-free" environment because some willful actions are blameworthy. To make this distinction clear, the VA sought the cooperation of Congress, the Joint Council on Accreditation of Healthcare Organizations (JCAHO), and the unions with which it works to define what acts would be subject to blame or punitive action. These were defined as criminal acts; any act involving alcohol, substance abuse, or patient abuse, or a purposefully unsafe act (i.e., the individual knew it was unsafe but did it anyway). The VA clarified that these blameworthy acts should be dealt with administratively, not within the patient safety system. This policy did not lead to any loss of data, Dr. Bagian noted, since such events are unlikely to be reported by those who commit them. Furthermore, the policy gives confidence to those who have not committed blameworthy acts that they will be treated in a nonpunitive manner when they report honest errors.

The National Center clarified that employees should report all adverse events and close calls (i.e., events that could have resulted in patient harm but did not) to their facility's patient safety manager, who would then use a computer system to centrally report these incidents (Figure 2). Because close calls are much more common than adverse events, they can provide valuable information to diagnose latent system weaknesses that may lead to errors. Reports are protected under federal statute. The individual filing the report remains identified until a root cause analysis is completed so that he or she can be notified of and comment on the findings. External reports, described below, are similarly protected.



To discover and learn from a fuller range of patient safety issues, in April 2002, the VA instituted an external patient safety reporting system modeled on NASA's aviation safety reporting system. Operated by the NASA Ames Research Center, the patient safety reporting system is intended to provide a "safety valve" for those who are not comfortable reporting adverse events or close calls to the internal VA patient safety reporting system. Reporters are encouraged to include identifying information so that they can be contacted in case additional details are needed to fully characterize the incident, but the record is stripped of all identifiers once it is deemed complete. Reports are analyzed by a team of NASA patient safety experts.

The National Center designed easy-to-use, computer-aided, root-cause analysis tools and cognitive aids for multidisciplinary teams of frontline staff to analyze reported safety incidents. Triage questions and rules of causation help teams identify actionable root causes in six major categories. For example, one of the rules of causation specifies that a violation of procedures cannot be a root cause, since the factors that led to the violation must themselves be investigated. Facility managers were given a standardized methodology (known as the "safety assessment code matrix") to prioritize incidents based on their severity and probability of occurrence. The National Center conducted three-day training programs over a period of nine months to teach frontline staff how to use these tools, and provides ongoing support to facility staff through calls and site visits. The findings of root cause analyses are presented to the facility's CEO, who either approves recommendations for corrective action or proposes alternatives until there is mutual agreement on the remedies to be taken. The National Center maintains a database of root cause analyses, which it uses to investigate selected issues. Aggregate analyses of similar events are used to identify common systems issues and develop action plans based on findings from multiple cases. Topics have included patient falls, medication errors, missing patients, and suicidal behavior.

The National Center adapted a systems engineering tool for prospective risk assessment, known as Healthcare Failure Modes and Effects Analysis. This tool is used to proactively identify critical system vulnerabilities that might cause patient harm and to design and assess the effectiveness of system improvements. The VA also has been a leader in adopting information technologies, such as a computerized medical record system that provides timely access to clinical information for VA providers whenever and wherever they need it to inform diagnosis and treatment. A medication bar coding system helps improve patient safety by reducing errors in medication ordering and administration.

Results. Within 10 months of enhancing its internal patient safety reporting system, the VA experienced a 30-fold increase in the reporting of incidents, indicating that the promise of confidential, nonpunitive reporting was important to the workforce (Bagian et al. 2001). The relatively small number of reports received by the external patient safety reporting system—fewer than 400 in two years of operation as compared with hundreds of thousands submitted internally in five years—suggests that the VA has achieved a high level of trust in its internal reporting system.

Since the creation of enhanced tools and training, nearly all root cause analyses identify a recommended action, whereas previously about half the reviews of patient safety incidents failed to identify an action. The average number of root causes identified has increased from one to three per incident, while the types of root causes identified have shifted from a focus solely on patient behavior and professional training to human factors and systems issues (Bagian et al. 2002). These trends suggest that teams no longer consider circumstances giving rise to error as nonremediable.

Reported medication administration errors substantially decreased after the introduction of medication bar coding (Johnson et al. 2002). An employee culture survey conducted in 2000 found that inpatient facilities that rated higher on teamwork culture tended to have higher levels of patient satisfaction than those with lower teamwork ratings (Meterko et al. 2004). According to Dr. Bagian, one measure of culture change at the VA

is that personnel want to lead the way by exceeding—as opposed to simply meeting—JCAHO requirements.

Lessons learned. The critical success factors identified by Dr. Bagian include:

- creating a culture of safety that emphasizes system learning;
- defining what actions are blameworthy, assuring the confidentiality of safety investigations, and promising nonpunitive responses to reporting;
- providing easy-to-use tools to understand causes of errors and ways to prevent them, and
- understanding and surmounting obstacles to success.

"Creating a culture of safety is the only way to create a sustainable organizational focus on patient safety," said Dr. Bagian. The goal of a patient safety program must be focused on outcomes—preventing patient harm—not just on the process of reducing errors. The aviation industry provides an apt analogy; airline passengers do not want to know how many cockpit errors were averted, they simply want the plane to reach its destination safely and on time.

Because people will never be perfect, systems must be designed to be "fault tolerant." That is, the systems should prevent errors from occurring or from resulting in patient harm when they do occur. If a system relies on people to be perfect and for everything to go right, then harm will certainly continue to occur. Commercial airlines, for example, have at least two engines in case one should fail. "In health care, we are still flying a single-engine aircraft," said Dr. Bagian.

Creating an easy-to-use, effective capability for frontline staff to analyze and take action from incident reports was "the single most noteworthy means of changing the culture," Dr. Bagian said. "Someone shouldn't need a degree in human factors engineering to do root cause analysis," he added. Involving frontline staff created a sense of ownership and promoted new ways of thinking that have transferred to other quality improvements. One physician who was trained to perform root cause analysis said, "I look at my whole job differently now; I'm seeing things that I can fix that I didn't even know I could solve." This kind of positive "buzz" from frontline staff creates demand for training and tools, creating the perception that the patient safety program is useful to care providers and not just a mandate from headquarters. Internal reporting systems cannot be used for punishment if they are to obtain the trust of staff. "Reporting errors is not about finding fault. Managers should ask 'who' and 'why' only to fix the problem," Dr. Bagian said. Safety culture surveys conducted at the VA suggest that the biggest obstacle to creating a transparent culture is not the fear of malpractice litigation but the sense of humiliation that professionals say they would feel when admitting to an error.

A voluntary external safety reporting system complements internal reporting systems by providing additional insights into broad system vulnerabilities. The usefulness of such reports does not depend on the volume of data collected, but from the veracity of information obtained. This complements the information obtained through investigations of internal reports, which is more precisely actionable. A combination of internal and external reporting systems helps the VA demonstrate its commitment to a culture of safety and organizational learning, says Dr. Bagian. The volume of reports received by the external system allows managers to gauge how well the internal reporting system is working; a large increase in external reports, for example, might suggest a need to increase the staff's confidence in the trustworthiness of the internal reporting system.

To identify and overcome obstacles, the National Center proactively approaches skeptics within the organization for criticism. This feedback provides a candid assessment of how programs are viewed by frontline staff.

Replication and related results. The VA's experience has been of wide interest both domestically and internationally, with methods and tools adopted in Australia, Canada, Denmark, Hong Kong, Japan, the Netherlands, Singapore, Sweden, and the United Kingdom. As the nation's largest provider of medical education, the VA has developed a patient-safety curriculum for medical residents, medical students, nurses, pharmacists, and other allied health care professionals. "Our goal is to start new health care professionals thinking about patient safety early in their careers, something that generally hasn't been done in the past," Dr. Bagian said in a press release announcing the initiative.

The VA's ability to collect and analyze incident reports across multiple institutions can be compared with the external reporting efforts undertaken by other institutions. Organizations participating in collaborative efforts, such as the Pittsburgh Regional Healthcare Initiative, find that reporting medication errors and health care–associated infections to external databases permits useful analyses across multiple organizations (Sirio et al. 2003). A few states have established nonregulatory patient safety centers to promote statewide patient safety reporting and analysis (Rosenthal and Booth 2004). **Implications.** Patient safety incident reporting is not an end in itself, but can benefit the organization when coupled with an effective analytic and management process that drives organizational learning and action. Barriers to reporting include concerns about confidentiality, fear that information will be used punitively, lack of time to make reports, and failure to receive feedback after an error is reported (Jeffe et al. 2004). Management must provide feedback to frontline staff on lessons learned and actions taken in order to promote organizational buy-in.

A crucial element in the VA's success—not only in gaining employee participation in reporting but also in taking effective action from reports—was its ability to guarantee the confidentiality of reports under statute. Violation of this trust can destroy a reporting program; for example, one national aviation safety reporting system failed after an identifiable incident was disclosed (Connell 2000).

The aviation industry's experience suggests that a centralized safety reporting system can improve safety awareness if it is nonpunitive, confidential, independent, and easy to use; and if it produces timely, expert, and systems-oriented feedback (Leape 2002). The newly enacted federal Patient Safety and Quality Improvement Act may contribute to these goals by protecting the voluntary, confidential reporting of safety data to independent, federally certified patient safety organizations.

TEAMWORK AND COMMUNICATION

Teamwork and communication have been important factors in improving safety in high-risk industries by overcoming hierarchical barriers, human limitations, and system vulnerabilities (Helmreich 2000; Leonard 2004b). Studies of flight crews indicate that focusing on individual human performance does not produce optimum safety in a team environment (Gaba 2004). Likewise, inadequate teamwork and suboptimal communication among health care professionals are major causes of preventable adverse events and other undesirable outcomes, such as delays in surgery (Risser et al. 1999; Gawande et al. 2003; Lingard et al. 2004; JCAHO 2004; Sexton 2005).

Physicians and nurses may have different interaction styles and clinical vocabularies, which can lead to communication gaps. Surveys of surgical and intensive care teams find that nurses are less satisfied with the quality of teamwork, collaboration, and communication compared with physicians (Sexton et al. 2000; Thomas et al. 2003). For example, critical care nurses frequently reported that "it is difficult to speak up, disagreements are not appropriately resolved, more input into decision making is needed, and nurse input is not well received" (Thomas et al. 2003). For similar reasons, many nurses say they do not see the value of participating in patient rounds with physicians (Corley 1998). On the other hand, better perceived teamwork and organizational support for nursing is associated with lower nursing staff burnout and turnover and higher patient satisfaction (Rosenstein 2002; Gifford et al. 2002; Thomas 2004; Vahey et al. 2004).

Effective teamwork and communication are especially important when responding to critical events in perinatal care. A review of malpractice insurance claims found that potentially preventable adverse events, though rare, comprise a disproportionate share of significant patient injuries. Recurring safety problems include delays in critical decisionmaking, poor communication between disciplines involved in care, failure to escalate communication to obtain help, failure to recognize and respond to fetal distress and initiate timely cesarean delivery, and inconsistent mobilization for emergency interventions (Nunes et al. 2004).

Most training in health care is discipline-specific; professionals rarely train together in teams, though they must work together to deliver high-quality care. In response, the IOM recommended that health care organizations establish team-training programs to improve patient safety in critical areas such as the operating theater (IOM 1999). The IOM pointed to the aviation industry's crew resource management (CRM) training as a model to emulate, while also noting that it must be adapted to the health care setting. CRM training "considers human performance limiters (such as fatigue and stress) and the nature of human error, and it defines behaviors that are countermeasures to error, such as leadership, briefings, monitoring and cross checking, decision making, and review and modification of plans" (Helmreich 2000).

CRM training has enhanced safety attitudes and behaviors and improved flying safety and mission effectiveness among flight crews when used as part of a comprehensive error management strategy (Helmreich et al. 1999; Grubb et al. 2001). Anesthesia crisis resource management training, developed at Stanford University, was the earliest successful application of CRM principles to medicine (Howard et al. 1992). It has been adopted at institutions worldwide and adapted to other areas such as emergency medicine and critical care (Gaba et al. 2001).

At Kaiser Permanente, anesthesiologist Michael Leonard, M.D., physician leader of patient safety, and his colleagues have collaborated since 2000 with the Human Factors Research Project at the University of Texas, Austin, led by professor Robert Helmreich, Ph.D., to explore how the lessons of the aviation industry can be applied to medicine (Case Study 3). Kaiser Permanente has also adapted research on high-reliability perinatal care developed by Eric Knox, M.D., professor of obstetrics and gynecology at the University of Minnesota, and colleagues (1999). A multidisciplinary team led by Kaiser Permanente anesthesiologist Paul Preston, M.D., developed simulation-based perinatal critical event team training, drawing ideas from the work of David Gaba, M.D., and the Stanford Center for Advanced Pediatric Education (Halamek et al. 2000).

Multidisciplinary rounds are a key component of many patient safety initiatives that seek to improve communication and break down barriers between disciplines. Paul Uhlig, M.D., and his team at Concord Hospital in New Hampshire, created a program of multidisciplinary collaborative rounds that involved the entire cardiac care team, adapting learning from human factors science, aviation safety, and high-reliability organizational theory (Case Study 4).

Case Study 3. Promoting High Reliability Surgery and Perinatal Care Through Improved Teamwork and Communication at Kaiser Permanente*

Organization. <u>Kaiser Permanente</u> (KP) is a group-model HMO serving 8.2 million people in nine states and the District of Columbia through an integrated health care delivery system. The KP Anaheim Medical Center served as the pilot site for a preoperative briefing project. Four Northern California KP medical centers, located in Hayward, San Francisco, Santa Teresa, and Walnut Creek, served as pilot sites for a Perinatal Patient Safety Project.

Objective and intervention. To instill a culture of safety, Kaiser Permanente instituted a program of organizational learning to promote effective teamwork and communication among care teams working in high-risk areas such as surgery and obstetrics. Through collaboration with human factors experts and experience translating human factors principles to medicine, KP has learned several techniques that are helpful in accomplishing this objective:

Briefing. A briefing is a "structured type of interaction used to attain clear and effective communication in a timely manner" (Leonard 2004b). Briefings may be conducted on a periodic or situational basis depending on needs. For example, they may be held at the beginning of each shift, before surgery (as required by JCAHO Patient Safety Goals), at patient handoffs, and in situations requiring a clinician's immediate attention (IHI 2004c). Briefings at the start of surgery provide an opportunity for the surgeon to set the stage for effective team formation, ensuring, for example, that team members know one another's names.

Appropriate assertion. Investigations of several serious accidents showed that team members knew something was wrong but failed to speak up or only communicated concerns indirectly. Health care workers must be taught how to "politely assert themselves in the name of safety" (Leonard et al. 2004a). Critical language must be used to communicate safety concerns in a way that ensures the team does not shrug off the

^{*} This case study is a synthesis of information obtained from personal interviews with Michael Leonard, M.D., physician leader of patient safety at Kaiser Permanente (KP); James DeFontes, M.D., physician director of surgical services for KP Orange County; Julie Nunes, R.N., M.S., director of risk management for the KP Northern California region and principal investigator for the perinatal patient safety project; and Paul Preston, M.D., anesthesiologist and assistant chief of quality at the KP San Francisco Medical Center and assistant clinical professor in the Department of Anesthesia and Perioperative Care at the University of California–San Francisco; and from a review of supporting publications and presentation materials (DeFontes and Subida 2004; Leonard et al. 2004a; 2004b; Leonard 2004; McFerran et al. 2005; Nunes et al. 2004; Nunes and McFerran 2004a; 2004b; 2005; Preston et al. 2004).

concerns, but instead stops and listens with the understanding that there is a potentially serious problem to be addressed.

Structured communication. Situation-Background-Assessment-Recommendation (SBAR) is an easy-to-remember framework for communicating essential information in critical situations requiring a physician's immediate attention. This technique was adapted from the U.S. Navy by KP's vice president of safety management, Doug Bonacum, who witnessed its effectiveness while serving on a navy submarine. SBAR facilitates critical thinking and responsiveness by structuring communication in a logical sequence that clearly defines the patient's current situation and clinical status, a short assessment of the problem, and a recommended action.

Situational awareness. Performance is enhanced when individuals in a team maintain "a shared understanding of the situation at hand, what is likely to happen next, and what to do if the expected does not happen" (Leonard 2004a). When team members know how a procedure should normally occur, plan for contingencies, and cross-monitor each other's performances, they are better able to catch and mitigate errors and deficiencies and recover from unexpected events (deLeval et al. 2000; Salas et al. 2003).

Debriefing. After an event or activity, the team asks itself the following questions: What did we do well? What did we learn? What could we do better? What systems need correcting? Who is responsible for following-up? The quality of the debriefing is directly related to the quality of the briefing. Debriefing after an adverse event has occurred can be especially important to help team members cope and recover.

Date of implementation. The KP Anaheim Medical Center launched a preoperative safety briefing pilot project in February 2002. A Perinatal Patient Safety Project began in 2002 at four labor and delivery sites in the KP Northern California region.

Process of change. Multidisciplinary educational sessions combine conceptual and procedural (i.e., an opportunity to practice skills) learning and emphasize embedding skills in everyday practice. The message, according to Michael Leonard, M.D., physician leader for patient safety, is "here are specific things you can do tomorrow." These sessions are reinforced with site visits and ongoing collaborative calls.

Surgical briefings. At the KP Anaheim Medical Center, a multidisciplinary team designed a preoperative safety briefing to enhance basic patient safety practices required by JCAHO, such as the "time out" for surgical site verification. The process involves the

surgeon telling the team what he or she thinks they need to know and then other team members telling the surgeon what they actually need to know. A one-page checklist was developed to guide team member preparation based on their respective roles, including practices to assess and mitigate safety risks. Similar to the preflight checklist used in the airline industry, the surgical checklist is adapted for each case and is posted throughout the operating theater as a mental prompt.

The operating room administrator and the assistant chief of surgery, who is also the patient safety director, conduct periodic in-service training sessions for operating room personnel on human factors principles that highlight the value of team briefings. This training is followed by a short self-assessment for reinforcement. Operating room personnel were surveyed throughout implementation to refine the briefing process. Based on one suggestion, for example, wipe boards were installed in each operating room, on which each team member's role and name are written for each surgery to facilitate name recognition and role definition.

The first surgical team to adopt briefings conducted them after anesthetizing the patient, but subsequent surgical teams have conducted them when the patient is awake. These teams report that "early indications are that patients really like the process," which is presented "as a last opportunity to make sure that the surgical team is all on the same page" (Leonard et al. 2004a).

In the aviation industry, crew resource management training involves integrating lessons from specific safety incidents with performance and behavior data of flight crew during normal line operations (Musson and Helmreich 2004). Borrowing from this idea, KP is starting a program of direct observation to measure the degree to which teams engage in expected behaviors for high-reliability surgery (e.g., briefings and debriefings, assertive communication, situational awareness). Feedback will be provided to the team about their own performance, and will also be aggregated across teams to identify common patterns for learning and improvement.

Perinatal Patient Safety Program (PPSP). The PPSP provides comprehensive training for labor and delivery personnel on safety science, accident causation, high-reliability theory, and communications skills. Four pilot sites adapted interventions for improvement to fit their local settings based upon analysis of prior birth injuries, results of safety culture surveys, and self-assessment of gaps in meeting the characteristics of a high-reliability perinatal unit, as defined by research from Knox et al. (1999). Interventions included:

- multidisciplinary rounds to assure shared understanding of the care plan among all perinatal care professionals;
- assertion and structured communication skills and techniques to assure proactive, accurate, and action-oriented briefings;
- commitment of physicians to come whenever they are called and a communication escalation policy to get help when needed to avoid delays in responding to potential critical events;
- pre-procedure briefings to promote situational awareness, and debriefings to help team members recover from poor outcomes.

Perinatologists at KP agreed upon a standard definition of fetal well-being that provides a common language and bridges differences in clinical vocabulary used by physicians and nurses. The definition also serves as an algorithm for interpreting and responding to fetal distress based on fetal heart rate tracings. These interventions are on track with those recommended by JCAHO (*Sentinel Event Alert*, Issue 30).

Practicing for emergencies is a key component of high-reliability perinatal care, so KP developed a multidisciplinary critical event team training program to practice teamwork and communication skills in simulated crisis situations. Expert simulations are conducted in the operating rooms using life-size, computerized mannequins. A multidisciplinary team developed several complex training scenarios based on actual cases, such as emergency cesarean section, shoulder dystocia, difficult maternal airway, and neonatal resuscitation. These represent highly stressful, difficult situations that force the team to recover from errors. Procedures are mapped to each team member's role, indicating which team member is responsible for each step and which team members provide support or backup based on their respective clinical disciplines . Drills are videotaped for debriefing, during which the team identifies needs for human and system improvement. To promote trust and learning, the videotape is erased and simulations are never used for performance evaluation.

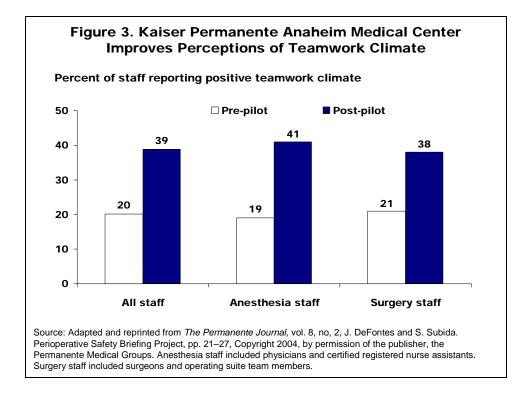
Preliminary Results.

Preoperative Briefing. After a six-month trial of preoperative briefings at the KP Anaheim Medical Center:

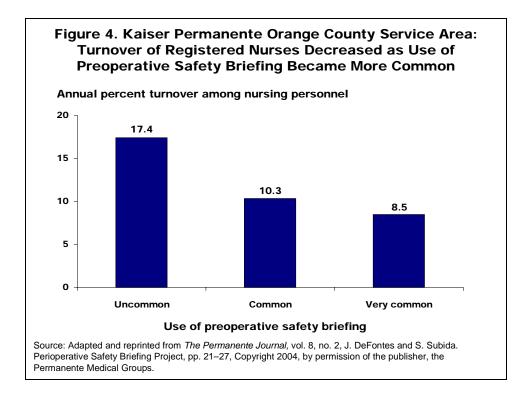
• No wrong-site surgeries were reported following the intervention, as compared with three wrong-site surgeries reported in the year prior to the intervention. (The small number of cases does not permit firm conclusions to be drawn about this

effect, although a retrospective analysis suggested that the three prior wrong-site surgeries could have been prevented by the intervention.)

• The perceived safety culture in the operating room, as measured by the University of Texas Safety Attitudes Questionnaire (Sexton and Thomas 2003), improved by about one-fourth, from 51 percent to 63 percent of respondents reporting positive ratings. Positive perceptions of teamwork doubled from 20 percent to 39 percent of respondents (Figure 3).



- The number of reports of near misses increased as did self-reported error management behaviors, such as a willingness to speak up about safety concerns and discuss mistakes. This suggests the team had greater situational awareness.
- The nursing turnover rate decreased from 23 percent prior to the intervention to 7 percent and has been sustained at a lower level than at comparison contract hospitals. Moreover, teams that often used preoperative briefings had a lower nursing staff turnover rate compared with teams that seldom conducted briefings (Figure 4).



Taking time out for team formation before surgery increased the efficient use of time overall. Use of a role-based checklist led to a better organized team with increased throughput and reduced waiting times. An enhanced understanding of the surgeon's plan helps nurses anticipate the necessary equipment and supplies and improves the ability of team members to make adjustments when the situation changes. With a reduction in unexpected events, nurses perceived that their workload decreased. The cost of the intervention at the pilot site was estimated to be \$49,500 in one-time labor and training costs plus \$15,500 to sustain the gains.

Perinatal Patient Safety Project. The University of Texas Safety Attitudes Questionnaire was administered at baseline in 2002 and follow-up in 2003 to those involved in perinatal care delivery at 11 regional labor and delivery sites. Results showed general improvements in survey scores across all sites, with even greater improvement among the four pilot sites compared with the seven nonpilot sites. Scores for KP pilot sites improved compared with results from 106 other hospitals that were surveyed using the instrument. Health plan member satisfaction ratings have improved among patients surveyed at all labor and delivery sites. A survey question asking whether doctors and nurses work well together garnered a higher positive response among patients of pilot sites compared to those at control sites. Several years of data will be needed to measure the effects of the intervention on adverse events. **Lessons learned.** Briefings are a powerful way to change the way that people think about and practice teamwork, said James DeFontes, M.D., physician director of surgical services for KP Orange County. Explicit communication helps team members focus on the common task at hand, bridges the cognitive gaps in training and experience levels among team members, and avoids unjustified assumptions about other team members' knowledge, he said.

The two most important elements that predict successful teamwork and communication in the surgical environment are sharing a common understanding of the situation so that there are no surprises, and "setting the stage" through effective team leadership, according to Dr. Leonard. Physicians must understand that they set the tone for teamwork and have a profound influence on whether and how team members feel comfortable discussing concerns about safety, he added.

The perinatal patient safety project team noted two characteristics that were especially critical to successful implementation: tailoring to the local environment by involving teams at each site with representatives from the entire perinatal continuum of care and organized labor and maintaining focus and momentum by designating a dedicated project manager to facilitate information sharing and collaboration and identify common issues and solutions. Other features important to success include:

- obtaining broad organizational buy-in through sponsorship of regional quality oversight and clinical committees and a contractual commitment to the project by all major constituents;
- convening a project steering committee that meets monthly with representatives from all sites to share challenges, best practices, and successes in a spirit of healthy competition;
- conducting teamwork under a just culture environment that permits honest and confidential discussion of errors with quality oversight protection;
- engaging perinatal professionals by designating a liaison to maintain communication with stakeholders and provide expert consultation of perinatal concerns and content,
- establishing credibility with physicians by designating a physician champion who modeled and communicated project values using real-life examples;
- training pilot sites to establish baseline knowledge before starting team activities; and
- focusing on outcomes by defining robust measures of project effectiveness.

The project leaders found that local teams responded enthusiastically when given the opportunity to undertake patient safety improvements. "If you give caring professionals the luxury of time and focus, respect and empowerment of all disciplines, and the concepts and techniques of patient safety, the teams will design and implement process improvement far beyond what we, the leaders, could have possibly envisioned," said Julie Nunes, R.N., M.S., principal investigator for the perinatal patient safety project and regional director of risk management for Kaiser Permanente Northern California.

"The most effective way to get experts to evaluate and change their behavior is to put them through [simulation-based] training and then let them debrief their own performance," said anesthesiologist Paul Preston, M.D., assistant chief of quality for the KP San Francisco Medical Center. As the trainer and simulation designer, Dr. Preston said, "I'm not here to solve [participants'] problems, but to help them solve their own. We tell them upfront, the goal is to create a self-correcting organism." For example, team training leads participants to a new awareness of how their behavior affects others, which, in turn, changes how they do their job. "People see how prone they are to error, but also how to 'trap' errors and recover when they do make a mistake," he said.

Repeating scenario-based training at multiple sites helps to discover solutions to challenging situations that have bedeviled other teams. "Everyone has their own best practices," Dr. Preston said, which leads to valuable learning when shared among the sites during regional meetings. While involving multiple disciplines in simulation-based team training is rewarding, it also has its challenges, such as developing training scenarios that "move the whole team forward and use everyone's time effectively," he noted.

Senior managers and clinical leaders can promote effective culture change by fostering a "bottom-up approach" that empowers frontline staff to take responsibility for safety, says Dr. Leonard. Processes to embed expected safety behaviors in everyday clinical practice are equally important to make such changes long-lasting. Reaching agreement for change requires defining common goals—like delivering high-quality, safe care—and then asking: What are the things that get in the way of the goal, and what do we need to do to make sure the right things happen?

Replication and related results. Similar patient safety improvement efforts have been implemented as part of a national best practice transfer program at 30 Kaiser Permanente sites. There have been applications to radiology, procedural sedation, and patient transfers. Plans are under way to embed high-reliability surgery techniques into the outpatient surgery setting. The SBAR communication technique is being promoted by the Institute for Healthcare Improvement, which has implementation materials available on its <u>Web site</u>.

Other organizations have developed medical teamwork training programs, in addition to the Anesthesia Crisis Resource Management training described previously. For example, the MedTeams training program, developed by Dynamics Research Corp, with funding from the U.S. Army, promotes the development of teamwork skills in the emergency department (ED). In a quasi-experimental field trial among 10 EDs, teamwork behaviors increased while the observed error rate decreased (Morey et al. 2002). These methods are being adapted to obstetrics in a multi-center trial led by Benjamin Sachs, M.D., at Beth Israel Deaconess Hospital in Boston, Mass. (Sachs 2004). Other teamwork training programs and learning are described in a recent review sponsored by the Agency for Healthcare Research and Quality (Baker et al. 2005).

Implications. Safety principles and techniques from other industries must be distilled to achieve the right cultural fit for medicine, said Dr. Leonard. Those implementing and studying team training should assess whether such programs can be tailored to the health care context. In order to reap the full benefit, patient safety practices like surgery site verification and team briefings must be embedded in broader culture change efforts that involve teamwork and process improvements. Beneficial side effects of this culture change may also include improved nursing staff morale and reduced staff turnover, giving these organizations a competitive advantage in the market.

Simulation-based training offers a means of improving patient safety without posing any risk to patients by allowing teams to drill for critical situations that may be rarely encountered during apprenticeship or everyday practice (Gaba 2000). Rehearsing may lead to better acquisition and retention of knowledge and skills, although viewing others engaged in simulation may also be an effective learning technique (Gaba 2004). Simulation can also provide a means for detecting latent system vulnerabilities. While there is no definitive evidence that simulation-based training improves patient outcomes (Cooper and Taqueti 2004), David Gaba, M.D., associate dean, Stanford Center for Immersive and Simulation-based Learning, noted that "no industry in which human lives depend on the skilled performance of responsible operators has waited for unequivocal proof of the benefits of simulation before embracing it" (Gaba 1992).

Case Study 4. Addressing Patient Safety During Multidisciplinary Collaborative Rounds at Concord Hospital*

Organization. <u>Concord Hospital</u> is a 295-bed, not-for-profit community hospital, located in Concord, N.H. It treats 250 patients per year in its cardiac surgery program.

Objective and intervention. In its report, *To Err Is Human*, the Institute of Medicine recommended that hospitals include pharmacists on physician rounds on patient care units as a strategy for improving medication safety. Building on this recommendation, a cardiac care team at Concord Hospital instituted a program of multidisciplinary collaborative rounds at the patient's bedside that included all members of the care team along with the patient and his or her family. The goal is to create a more informed care team and patient, providing additional opportunities to identify and prevent potential errors and to rapidly mitigate the effects of any errors that do occur.

Date of implementation. A cardiac care team led by Paul Uhlig, M.D., began meeting in 1999 to collaboratively plan improvements in patient care.

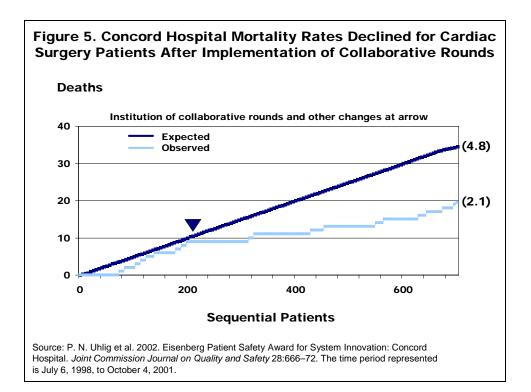
Process of change. The entire cardiac surgery care team (including the surgeon, bedside nurse, nurse practitioner or physician assistant, social worker, counselor, clinical and home care coordinators, pharmacist, dietician, therapists, and rehabilitation specialists) conducts a 10-minute daily briefing at every patient's bedside. The briefing is led by the nurse practitioner following a structured communication protocol developed by an expert in human factors science. The process is focused on developing and recapping the patient's care plan, reviewing patient progress and needs, and clarifying team responsibilities. Patients and family members are educated about the process in advance and are encouraged to actively participate by stating their concerns. Participation of patients and family members tends to increase each day.

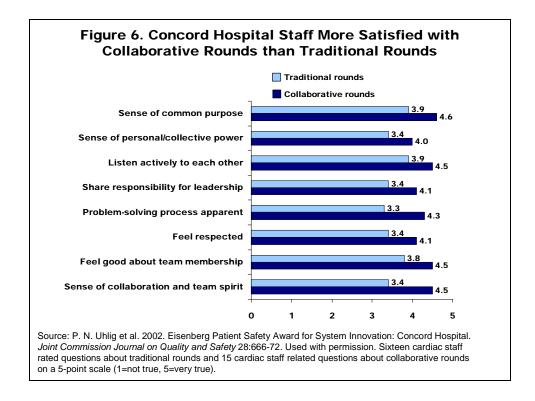
To promote medication safety, the pharmacist reads the scheduled medications for the day and addresses any questions raised by the patient, family, or care team. The pharmacist maintains a monitoring sheet with notes from rounds along with pertinent lab work and home medication reconciliation. This provides continuity among different pharmacists who may participate on rounds from day to day.

^{*} This case study is a synthesis of information obtained from a personal interview with Paul Uhlig, M.D., formerly cardiothoracic surgeon at Concord Hospital and currently vice president for quality and innovation at University Hospital, Cincinnati, Ohio; e-mail communications with other adopters of this innovation (Michael Caty, M.D., Walter Merrill, M.D., and Thomas Vander Salm, M.D.); and a review of supporting publications (Uhlig et al. 2002; Kendall 2003).

The team addresses anything that has gone wrong in the care process—called "system glitches" rather than mistakes to encourage their identification and avoid the stigma of individual blame. System glitches are documented, patterns are identified, and corrective actions taken. The team participates in biweekly system rounds, which provide a forum for discussing team goals and progress and for addressing system–level concerns.

Results. Following implementation, mortality rates declined by more than half, to 2.1 percent, compared with an expected rate of 4.8 percent based on risk-adjusted data from the Northern New England Cardiovascular Study Group (Uhlig et al. 2002) (Figure 5). Practice patterns and culture became more collaborative and providers, based on a quality of work life survey, expressed greater satisfaction with the process than with traditional rounds (Figure 6). Patients reported high levels of satisfaction on surveys. Family members informally expressed their appreciation at not having to worry about what was happening with their loved ones. They also reported that exposure to the process made them much more proactive in all their medical encounters.





Lessons learned. The Concord Hospital team discovered that bedside briefings allowed them to meet patients' needs more effectively and that relatively simple changes can have a dramatic impact on outcomes, said surgeon Dr. Paul Uhlig, M.D. Although it is not possible to tease out the specific causes of the mortality improvement, the patient-centered nature of the collaborative round suggests that patient safety can be improved as part of a broader intervention that improves quality and patient experience generally.

The rounds became a means of reorienting the care team toward a "collaborative culture of interaction" in which everyone feels they can safely make observations and suggestions that increase error detection and reporting, said Dr. Uhlig. Physician leadership in "flattening the hierarchy" set the tone for collaboration that promotes respectful interactions among the entire team.

Concord Hospital's experience with collaborative rounds demonstrates that "health care's greatest resource for improvement is the desire of practitioners to do the best for their patients," said Dr. Uhlig. Collaborative rounds may have originally seemed a waste of staff time, but they actually increased efficiency since they reduced each member's need to communicate with one another and the patient separately.

Replication and related results. Collaborative rounds have been adopted in cardiac surgery units at several other institutions including North Shore Medical Center in Salem, Mass.; University of Cincinnati Hospital; the Mayo Clinic; and in pediatric surgery at

Women and Children's Hospital of Buffalo, N.Y. Multidisciplinary rounds also have been adopted in ICUs and other units of hospitals participating in Institute for Healthcare Improvement collaboratives. Surgeons and clinicians instituting multidisciplinary rounds report improved patient care, increased patient and family satisfaction, and shortened lengths of stay (personal communications with Michael Caty, Walter Merrill, and Thomas Vander Salm 2004). Results include the following:

- A controlled trial reported slightly shorter average length of stay (0.6 day) compared with usual care and savings of \$1,409 per patient associated with of the use of collaborative team rounds at MetroHealth Medical Center, an academic hospital in Cleveland, Ohio (Curley et al. 1998).
- A noncontrolled study of ICUs in two teaching hospitals and one nonteaching hospital found a correlation between nurse reports of collaborative decision-making and better patient outcomes, including fewer deaths or ICU readmissions (Baggs et al. 1999).
- Two controlled studies have found that involving pharmacists on team rounds in an ICU at Massachusetts General Hospital, Boston, and on a general medical ward at Henry Ford Hospital, Detroit, reduced the rate of preventable adverse drug events by 66 percent and 78 percent, respectively (Leape et al. 1999; Kucukarslan et al. 2003). This resulted in an estimated \$270,000 annual savings associated with elimination of 58 adverse drug events in the ICU.

The collaborative rounds approach has been the subject of a simulation study at the Harvard Center for Integration of Medicine and Information Technology, to understand the particular cognitive, physical, and social elements that create success and to determine how these elements of the collaborative rounds process can be enhanced and replicated in everyday practice. Dr. Uhlig said this work is demonstrating "the untapped potential to use social science to transform human practice."

Implications. Efforts to improve patient safety can dovetail with other improvements in the quality of patient care. Through the process of multidisciplinary collaborative rounds, improving patient safety fit hand-in-hand with making care more patient- and family-centered. Future research should measure the impact of multidisciplinary rounds on reducing adverse events and how the participation of pharmacists contributes to this outcome. Barriers are chiefly cultural, often due to reluctance of physicians to re-orient to a less hierarchical power structure, according to Dr. Uhlig. This may be overcome by emphasizing the benefits to the physician of achieving improved outcomes. An organizational change of this nature must be supported by hospital management, emphasizing the need to embed specific process changes in broader organizational culture.

RAPID RESPONSE TEAMS

Although most hospitals have established emergency teams to quickly respond when a patient suffers a cardiac arrest, only about 17 percent of these patients survive to discharge (Peberdy et al. 2003). Patients who suffer cardiac arrest or other similar acute crises in the hospital often have measurable signs of clinical deterioration up to eight hours preceding the event—suggesting that many events are potentially preventable with proactive treatment (Schein et al. 1990; Franklin and Mathew 1994; Smith and Wood 1998; Buist et al. 1999; Hillman et al. 2001).

Patients may not receive prompt attention if floor nurses have not been trained to interpret the signs of deterioration, or if they hesitate to call for help for fear of sounding a false alarm (Crispin and Daffurn 1998; Cioffi 2000). When they do seek help, nurses may face delays in contacting the physician or in getting a response through the normal chain of command. After being evaluated, patients may have to wait to be admitted to the intensive care unit (ICU), leading to a loss of valuable time for intervention and poorer outcomes (Young et al. 2003).

To overcome these barriers, several hospitals in Australia, including Liverpool Hospital in South Western Sydney (Lee et al. 1995), Dandenong Hospital (Buist et al. 2002), and Austin Hospital in Melbourne (Bellomo et al. 2003), pioneered medical emergency teams (METs) to bring the expertise of critical care specialists to the hospital floor. Floor nurses and other medical staff call the MET when a patient meets criteria for clinical instability or if they are worried about a patient's condition. METs are empowered to quickly assess and provide appropriate treatment to stabilize the patient and to transfer the patient to the ICU or intermediate care when needed.

A controlled before-and-after trial conducted at Austin Hospital found that introduction of the MET was associated with relative risk reductions of 65 percent in cardiac arrests, 56 percent in deaths attributable to cardiac arrests, 26 percent in deaths hospital-wide, and 88 percent in hospital bed days among cardiac arrest survivors (Bellomo et al. 2003). In a separate analysis of outcomes among postoperative patients at the same hospital, use of METs was associated with relative risk reductions of 58 percent in the rate of serious adverse outcomes after surgery (including respiratory failure, stroke, sepsis, and acute renal failure), 44 percent in emergency admissions to the ICU, 37 percent in postoperative deaths; and a decrease of four days in the average length of hospital stay following major surgery (Bellomo et al. 2004).

Case Study 5. Enhancing Rapid Response at Missouri Baptist Medical Center*

Organization. <u>Missouri Baptist Medical Center</u> is a 489-bed acute care hospital located in St. Louis. It is a member of BJC HealthCare, a not-for-profit health system that includes 13 hospitals and other facilities serving the greater St. Louis area and nearby regions.

Objective and intervention. Missouri Baptist aimed to improve patient outcomes by enhancing its existing emergency response capability to intervene early with patients showing signs of medical deterioration, before they suffer crises such as cardiac or respiratory arrest. The intervention was carried out in the context of an organization-wide culture change initiative aimed at aligning the hospital's mission, structure, reward system, and leadership with patient safety goals and building a partnership with affiliated physicians to institute safety improvements (Cohen et al. 2003).

Date of implementation. Missouri Baptist instituted its rapid response team hospitalwide in April 2004, after a six-week pilot in one ward.

Process of change. Missouri Baptist had an existing, two-tier emergency response system: a traditional "code blue" team for cardiac arrests and ICU-based physician assistants who responded to other critical events, such as respiratory arrests. The hospital's management found the benefits demonstrated by rapid response teams in other institutions compelling (see Replication and related results) and determined to undertake a similar effort. Ideas for implementation were obtained from the Institute for Healthcare Improvement, using adaptations from other prior adopters, particularly Baptist Memorial Hospital in Memphis, Tenn.

The rapid response team includes a physician assistant, who acts as the team leader, a critical care nurse, and a respiratory therapist. The team is empowered to take whatever action is needed to stabilize the patient, within the scope of their practices, reporting to and consulting with the hospital's ICU physician intensivist, as needed. The patient's attending physician is notified and apprised of the team's assessment, and may order additional tests at his or her discretion. Patients are transferred to the ICU when appropriate, or to an intermediate care unit if their needs do not warrant critical care.

^{*} This case study is based on a personal interview with Nancy Sanders, R.N., performance improvement coordinator for Missouri Baptist Medical Center, supporting information contributed by John Krettek, M.D., vice president of medical affairs, and published commentary by Cohen et al. 2003.

The team was implemented using tests of change, starting on one unit during the day shift for three weeks, expanding to 24 hours on that unit for an additional three weeks, then expanding hospital-wide. They also tested the team composition by, for example, having the physician assistant respond alone and summon other team members, if needed. This approach, however, did not prove as effective as having the entire team respond to assess the patient. Typically, the ICU nurse and respiratory therapist can determine whether their presence is needed within five minutes.

Hospital staff received education on the purpose and use of the rapid response team prior to implementation. Specific clinical criteria were compiled to guide nursing staff in identifying when a patient's condition warrants calling for help (Table). In addition, hospital staff were informed that they could call for help when they were simply worried or concerned about a patient. Missouri Baptist adapted clinical criteria from other institutions and added several criteria based on its own experiences.

Table 1. Criteria for Calling the Rapid Response Team

- 1. Staff member concerned or worried about the patient
- 2. Acute change in heart rate (less than 40 or greater than 130)
- 3. Acute change in systolic blood pressure (less than 90 mm/Hg)
- 4. Acute change in respiratory rate (less than 8 or greater than 24) or threatened airway
- 5. Acute change in blood oxygen saturation (SpO₂ less than 90 percent despite oxygen)
- 6. Fractional inspired oxygen (FiO₂) of 50 percent or greater
- 7. Acute change in mental status (delirium, confusion, etc.)
- 8. Acute significant bleed
- 9. New, repeated, or prolonged seizures
- 10. Failure to respond to treatment for an acute problem/symptom

Source: Missouri Baptist Medical Center.

The team developed a form, refined and amended through multiple iterations of feedback, to record information about each rapid response team call. It uses the Situation-Background-Assessment-Recommendation (SBAR) technique to structure information about the patient, which provides a useful framework for analysis. Information is entered into a database for trend analysis. Copies of the record forms are sent to the unit manager from which the call originated to share with floor staff for feedback and learning. Every individual who called the rapid response team was surveyed during the first six months of implementation. Feedback from frontline staff was valuable for refining the process.

Results. Calls for the rapid response team steadily increased to about 70–80 per month after two months of full implementation, indicating that the floor nurses recognized the value of this resource. Respiratory problems are the most frequent reason the team is called. There has been a 60 percent decrease in emergency calls for respiratory arrest and similar crises, and a 15 percent decrease in cardiac arrests, suggesting that these acute crises were averted through early intervention. Response time for emergency calls is an average of 1.5 minutes.

The survival rate among patients assessed by the rapid response team was 81 percent as of June 2004, significantly greater than the national average of 15 percent survival for patients suffering cardiac arrest, although these rates may not be comparable due to differences in case-mix and severity. Anecdotal feedback from family members indicates they are impressed and gratified by efforts made on behalf of patients.

The hospital experienced a 3.95 percent decrease in its overall patient mortality rate during 2005 as compared with 2004. This improvement in outcome might be attributable to a combination of interventions including the rapid response team as well as protocols for effective care of heart attack patients and glycemic control among ICU patients, and evidence-based precautions to help prevent nosocomial infections such as ventilator-associated pneumonias and catheter-related bloodstream infections (see the Intensive Care Unit).

Lessons learned. John Krettek, M.D., vice president of medical affairs, and Nancy Sanders, R.N., performance improvement coordinator, offer the following critical success factors from their experience implementing the rapid response team at Missouri Baptist Medical Center:

- The purpose of a rapid response team is to rescue patients from sliding into a critical state, not to resuscitate them after the fact. It's like "putting out a brush fire before it becomes a forest fire," said Sanders.
- It is important to collect data on rapid response team efforts in order to assess impact. This effort should include a plan for information flow. For example, Missouri Baptist's performance improvement coordinator is beeped along with the team so that she can track calls.
- Educating hospital staff about the purpose and operation of the rapid response team is key to successful uptake. Reinforcement is needed to change habits, as some nurses continue to seek help through traditional channels. Sharing feedback on

incidents and success stories with nursing staff builds support for the efficacy of using the rapid response team.

• The rapid response team should be considered a support resource for frontline staff to share information. For example, an ICU nurse can share insights to help a floor nurse sharpen his or her assessment skills and learn how to proactively respond to a similar event in the future.

Missouri Baptist was able to create a rapid response team using existing staff. The hospital had already assigned physician assistants to respond to emergency calls. Staffing the rapid response team with ICU staff and respiratory care therapists that do not have assigned patient duties ensured their availability for calls. Physician assistants experienced some difficulty initially, as they adjusted from working independently to being part of a team.

Replication and related results. Many hospitals are working with the Institute for Healthcare Improvement to create rapid response teams, which is promoting the intervention as part of its 100,000 Lives Campaign (Berwick et al. 2006). Although hospitals adapt and configure rapid response teams differently, their purpose remains the same.

Some other examples of rapid response teams include:

- At the University of Pittsburgh Medical Center Presbyterian Hospital, the first U.S. hospital to institute a MET, the team consists of eight members, including an ICU physician, critical care nurses, floor nurse, respiratory therapist, and physicians to assist with assessment and procedures (DeVita et al. 2004). Increasing use of the MET was associated with a 17 percent decrease in incidence of cardiopulmonary arrests. A chart review found that 31 percent of the cases of clinical deterioration that prompted MET calls were associated with medical errors, many of them serious (Braithwaite et al. 2004). Based on root cause analyses, many improvements were made in routine care processes, notably greater standardization of procedures and equipment.
- Following the creation of a rapid response team in August 2003, 736-bed Baptist Memorial Hospital in Memphis, Tenn., experienced a 26 percent drop in cardiac arrests, an improvement in survival from 13 percent to 24 percent of those who had cardiac arrest, and a 31 percent relative reduction in the hospital's overall mortality rate (IHI 2004d). The rapid response team includes a critical care nurse and a respiratory therapist who assess the patient, make recommendations to the

attending physician, and initiate transfers to the ICU when appropriate. Earlier intervention means that most cardiac arrests now occur in a critical care unit where chances for survival are greater (Sandroni et al. 2004).

Implications. Rapid response teams bridge the divide between hospital units by bringing the expertise of emergency and critical care specialists to the hospital ward. Rapid response team interventions also provide an opportunity for on-the-job learning for floor nurses as they participate in the team's responses to clinical events. In this way, rapid response teams can promote a culture of safety by building teamwork and spreading knowledge and skills throughout the hospital. Using root cause analysis to examine the circumstances giving rise to clinical deterioration in patients can help hospitals make improvements in routine care.

THE INTENSIVE CARE UNIT

The intensive care unit (ICU) is an ideal place to start safety improvement efforts, for several reasons. Care in the ICU is expensive, accounting for nearly one-third of total hospital costs. ICU patients have a higher exposure to medical error and adverse drug events because of more intensive treatment, while having more limited ability to communicate and defend themselves from error (Vande Voorde and France 2002; Andrews et al. 1997; Cullen et al. 1997). One study found that many medical errors in an ICU were potentially preventable with better communication between physicians and nurses (Donchin et al. 1995).

About one-quarter of the estimated two million infections acquired in U.S. hospitals each year occur in ICUs (DHHS 2000). For example:

- Up to one-quarter of critically ill patients who receive mechanical ventilation for assisted breathing develop ventilator-associated pneumonia, which accounts for up to 60 percent of deaths from hospital-acquired infections, prolongs hospital stays by an average of four to six days, and increases treatment costs by up to \$40,000 per case (Weber et al. 2002; CDC 2004).
- Central-line catheters are inserted in about half of all ICU patients to provide medication, nutrition, and fluids. An estimated 80,000 central-line associated bloodstream infections develop in these ICU patients each year in the United States, resulting in up to 20,000 deaths and increased costs of up to \$56,000 per case (Mermel 2000; O'Grady et al. 2002).

There is good evidence on how to prevent many adverse events and poor outcomes among ICU patients, but this evidence is not consistently and universally applied in everyday practice, resulting in thousands of preventable deaths each year. For example, providing intensive insulin therapy to achieve tight blood glucose control in ICU patients would prevent an estimated 12,347 deaths annually (Pronovost et al. 2004).

The Idealized Design of the ICU collaborative, jointly sponsored by the Institute for Healthcare Improvement and Voluntary Hospitals of America, an Irving, Texas-based health care cooperative, brought together 15 ICUs to develop evidence-based measures and approaches for improving the care of ventilated ICU patients. These methods have become the standard for other work in the field (Pronovost 2002). Building on human factors principles, an ICU team at the Johns Hopkins Hospital led by Peter Pronovost, M.D., Ph.D., developed a comprehensive patient safety improvement program (Case Study 6). ICU physician Sean Berenholtz, M.D., and the Johns Hopkins team also demonstrated an approach for preventing catheter-related bloodstream infections in the ICU that has been adopted in other institutions.

The VHA's Transformation of the Intensive Care Unit collaborative grew out of the Idealized Design project, illustrating successful dissemination of patient safety improvement techniques through collaborative learning in diverse community settings (Case Study 7).

Separately, Richard Shannon, M.D., chairman of the department of Medicine at Allegheny General Hospital, Pittsburgh, Pa., developed another patient safety improvement approach that has achieved similarly impressive results based on the Perfecting Patient Care model promoted by the Pittsburgh Regional Healthcare Initiative (Case Study 8).

Case Study 6. Adopting a Comprehensive, Unit-Based Approach to Patient Safety at Johns Hopkins Hospital*

Organization. <u>The Johns Hopkins Hospital</u> is a 900-bed academic medical center affiliated with the Johns Hopkins University School of Medicine and is one of three acute care hospitals in the Johns Hopkins Health System. Two of the hospital's intensive care units (ICUs) are discussed in this case study: a 14-bed, oncology surgical ICU (known as the Weinberg ICU or WICU), and a 15-bed surgical ICU (SICU) for general vascular surgery, trauma, and transplant patients. In both, patients are co-managed by intensivistled multidisciplinary teams.

Objective and intervention. Intensive care physicians at Johns Hopkins developed the Comprehensive Unit-Based Safety Program (CUSP), a model for improving quality, safety, and communication. CUSP engages and empowers staff to identify and eliminate patient safety hazards by using the following eight steps:

- assess the unit's culture of safety;
- educate staff on the sciences of safety (e.g., anatomy of errors, systems thinking, interpersonal skills, blame vs. responsibility);
- identify safety concerns;
- meet regularly with a senior hospital executive who "adopts" the unit to provide support for removing system barriers and accountability for making safety improvements;
- prioritize improvements;
- implement improvements (teams adopt two or three simple, low-cost changes that can be made immediately and propose an additional two or three higher-cost changes that require hospital approval);
- share success stories and disseminate results; and
- reassess the unit's safety culture.

^{*} This case study is a synthesis of information obtained from a personal interview with Peter Pronovost, M.D., associate professor of anesthesiology and critical care medicine and of health policy and management at Johns Hopkins University and medical director of the Johns Hopkins Center for Innovations in Quality Patient Care, and from a review of supporting publications (Berenholtz et al. 2004a, 2004b; Niedowski 2003; Paine et al. 2004; Pronovost et al. 2003a, 2003b, 2005; Berman 2004).

CUSP is part of a broader institutional commitment to improve patient safety at Johns Hopkins Hospital that has been informed, in part, by a partnership with the family of a pediatric patient, Josie King, who was a victim of medical error at the hospital. The King family donated funds and worked with Hopkins physicians to create a patient safety program in the hospital's Children's Center that has served as a model for improvement at the hospital and elsewhere. The CUSP model can be tested, adapted, and rolled-out sequentially among hospital units.

Date of implementation. CUSP was pilot tested in the Johns Hopkins Hospital WICU starting in July of 2001 and six months later (January 2002) in the SICU. Its design was influenced by participation in the Institute for Healthcare Improvement's Quantum Leaps in Patient Safety collaborative. Several other related safety improvement interventions were undertaken in these ICUs before and during CUSP, as described below.

Process of change. Unit improvement teams (physician, nurse, and administrator, plus other staff who wished to join) were given dedicated time each week to identify and champion safety improvement efforts. Interventions suggested by the safety assessment included creating a short-term patient goals form (Pronovost et al. 2003a), implementing a standardized process (known as medication reconciliation, see Case Study 10) for ensuring the accuracy of medication orders at ICU discharge (Pronovost et al. 2003b), and relabeling epidural catheters to prevent misidentification. The daily goals form was instituted after a survey found that nursing staff and residents frequently did not know the goals of therapy. The form is used as a checklist during physician intensivist–led rounds to identify tasks to be completed by the care team and to discover and mitigate safety risks.

A multidisciplinary team developed a related project to reduce catheter-related bloodstream infections in the ICU (Berenholtz et al. 2004a). The project included the following elements:

- Instituting a vascular access device (VAD) policy, which requires all providers to receive education on evidence-based infection control practices and successfully complete a post-test as a precondition to inserting catheters.
- Creating a catheter insertion cart—known as a "line cart"—with standardized supplies needed to meet infection control guidelines for sterile insertion of central lines. (Physicians previously had to find supplies located in eight different places, an unnecessary barrier to compliance.)
- Using a checklist to ensure adherence to evidence-based guidelines for safe catheter insertion: inserting a line only when needed, washing hands, using full

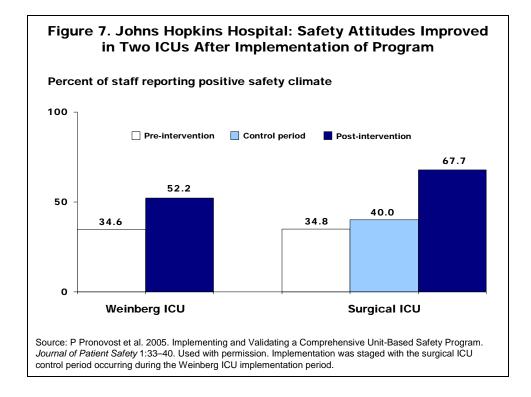
barrier precautions, cleaning the insertion area with chlorohexadine, and avoiding the femoral site if possible.

- Empowering nurses to intervene if guidelines are violated, involving a negotiated change in teamwork behaviors on behalf of patient safety.
- Adding an item to the daily goals sheet that prompts the ICU team to ask the physician during daily patient rounds whether catheters can be removed (since central lines are sometimes left in the patient longer than clinically needed).

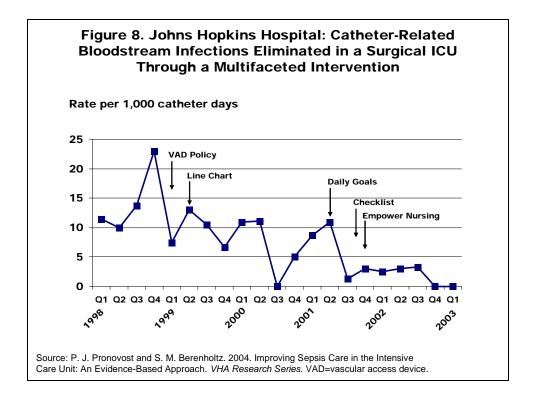
In a project designed to prevent hospital-acquired pneumonia by promoting evidence-based care of patients on mechanical ventilation, staff were surveyed to identify and overcome barriers to compliance. For example, after it was determined that four of five ICU nurses were not familiar with evidence for therapies to prevent complications, the staff members were educated about the therapies and the four care processes were added to the daily goals sheet as a checklist (Berenholtz et al. 2004b). (See Case Study 7, the VHA Transformation of the Intensive Care Unit National Collaborative, for additional discussion on preventing ventilator-associated pneumonia.)

Results. The following results were reported across several studies of complementary interventions that took place both before and during the time of CUSP implementation (Berenholtz et al. 2004a, 2004b; Pronovost et al. 2003a, 2003b, 2005). Staff perceptions of safety culture were measured using the Safety Climate Scale, a validated instrument adapted from the aviation industry (Sexton and Thomas 2003).

• ICU staff ratings of a positive safety culture increased from 35 percent to 52 percent of nursing and physician staff following a six-month implementation of CUSP in the WICU. Safety climate scores did not change significantly among staff in the SICU, which served as a control group during this period. CUSP was then implemented in the SICU. Six months later, ratings of positive safety climate had increased to 68 percent of SICU nursing staff as compared to the baseline rate of 35 percent one year earlier (Figure 7).



- By "adopting" the ICU, senior executives' involvement led to approval of structural changes, including creating specialized patient transport teams and the presence of pharmacists in ICUs.
- Self-reported understanding of goals of care increased from 10 percent of residents and nurses at baseline to 95 percent after implementing the daily goals form.
- One year after implementing CUSP, average ICU length-of-stay decreased from two days to one day in the WICU and from three days to two days in the SICU. Medication errors in transfer orders were eliminated (from 94 percent before the intervention).
- The proportion of days on which patients received all four evidence-based therapies to prevent complications of ventilator care increased from 30 percent to 96 percent during a six-week intervention period, resulting in an estimated 27 fewer deaths, 754 fewer ICU bed-days, and \$825,000 in savings annually.
- Observed catheter-related bloodstream infections were eliminated (from 11.3/1,000 catheter-days before the intervention), representing the prevention of an estimated 43 infections and eight deaths and yielding an estimated \$2 million in savings annually. The multifaceted intervention involved the implementation of several initiatives over a five year period: the VAD policy, line cart, daily goals sheet, guidelines checklist, and nursing empowerment (Figure 8).
- Nursing turnover showed a nonsignificant trend toward reduction.



Lessons learned. Although it may not be possible to stop and learn from every defect in care, staff can be given dedicated time each week to identify and develop remedies to fix defects, said Dr. Pronovost. A simple tool—the daily goal sheet—transformed daily rounds to a more patient-centered approach that improved communication, the sense of partnership between nurses and physicians, and the quality of patient care. ICU nurses reported that the daily goal checklist was especially helpful since immediate patient care needs often make it difficult to listen during daily rounds. The tool was repeatedly revised to improve its usefulness during the intervention. However, another implement adopted from the Veteran's Administration—a prioritization tool—was rarely used and dropped in favor of informal assessments.

The Johns Hopkins team discovered that promoting teamwork and basic human factors approaches, such as simplification of processes, is key to increasing the use of evidence-based practices associated with improved patient outcomes. For example, complex guidelines can be converted into simple checklists that double as data collection tools, with each item capturing a critical process measure of quality. Educating nurses on evidence for recommended therapies helps to enlist their support for providing evidence-based care. "When you create a system that reliably delivers the processes or interventions that work, spectacular performance improvement follows," Dr. Pronovost said in an interview for the *Joint Commission Journal on Quality and Safety* (Berman 2004).

In teaching different institutions how to improve, Dr. Pronovost and his team have found it helpful to adapt the well-known Plan-Do-Study-Act (PDSA) model of process improvement to make it easier to communicate and promote change. These steps include: engaging through stories of harm, educating about evidence-based interventions, executing improvements using simple tools, and evaluating and sharing results to promote culture change.

Pronovost and Berenholtz (2004) conclude: "It seems that knowledge of performance does not actually translate into better care unless all of the stakeholder are committed, work together to redesign the processes of care and implement those new processes consistently."

Replication and related results. Within Johns Hopkins Hospital, CUSP is being used as a framework for patient safety improvement within 26 hospital units, involving over 140 personnel (Paine et al. 2004). Each of the hospital's executives has adopted a care unit and works collaboratively with the unit's interdisciplinary teams to overcome barriers to improvement.

CUSP and the interventions it has generated are being transferred to hundreds of ICUs nationwide through collaborative projects with state hospital associations in Michigan, New Jersey, Maryland, and other states. In Michigan, for example, 70 participating hospitals have succeeded in reducing the rate of catheter-related bloodstream infections by 50 percent, on average, across 127 ICUs. Of these, 68 ICUs have eliminated bloodstream infections or ventilator-associated pneumonias for six months or longer. The Johns Hopkins researchers estimate that these improvements have collectively saved 1,578 lives, 81,020 hospital days, and \$165,534,736 in costs over a 15-month period, according to the Michigan Hospital Association (MHA 2005). Based on his experience, Dr. Pronovost said that state hospital associations provide a promising means of disseminating improvement methods throughout the country. An online version of CUSP, known as eCUSP, has been made available by the <u>Patient Safety Group</u>, a not-for-profit organization created by the Josie King Foundation and Johns Hopkins Medicine (Pronovost et al. 2006).

A "bundle" of evidence-based practices to prevent catheter-related bloodstream infections, such as those described above, is one of six high-impact interventions being promoted by the Institute for Healthcare Improvement as part of its 100,000 Lives Campaign (Berwick et al. 2006).

Implications. CUSP is successful because it provides a bridge between scientific validity and feasibility of adoption, said Dr. Pronovost. Many quality-improvement approaches emphasize feasibility but measurement is weak so validity cannot be assessed. Conversely, academic approaches that stress validity are often not easily replicated. CUSP is designed to provide sound principles and a flexible structure that rely on local wisdom to determine priorities for improvement, he said. Staff involvement in rapid process change and a sense of making a positive difference creates satisfaction and promotes culture transformation, creating demand for further adoption. Initiating change efforts within a single work unit and then replicating successful approaches in other units is a promising approach to building an organizational culture of safety.

Case Study 7. Improving Care of Ventilated Patients Through the VHA Transformation of the Intensive Care Unit National Collaborative*

Organizations. <u>VHA</u>, Inc. (formerly Voluntary Hospitals of America), is an Irving, Texas-based health care cooperative serving not-for-profit organizations nationwide. This initiative involves ICUs in diverse community hospital settings. One participant is the Porter Valparaiso Hospital Campus, a 300-plus bed community hospital located in Valparaiso, Ind.

Objective and intervention. The initiative—Transformation of the Intensive Care Unit (TICU)—requires all members of the care team to focus on observing evidence-based practices associated with improved patient outcomes. To reduce ventilator-associated pneumonia, the TICU collaborative set a goal: 90 percent of patients on mechanical ventilation would receive the "ventilator bundle" of care processes that have been shown to improve patient outcomes (Berenholtz et al. 2004b) (Figure 9). These include:

- ensuring appropriate sedation so patients can follow commands at least once per day, along with daily weaning assessment to determine if ventilator use can be discontinued, which decreases the duration of ventilation and ICU length of stay (Kress et al. 2000);
- elevating the head of the bed by at least 30 degrees to prevent gastric juices from being aspirated into the lungs (Drakulovic et al. 1999); and
- providing prophylaxis to prevent the development of peptic ulcers (Cook et al. 1998) and deep venous thrombosis (Attia et al. 2001).

Many ICUs in the collaborative also implemented evidence-based infection control practices to prevent catheter-related bloodstream infections (Case Study 6). In addition, some ICUs worked on achieving tight blood glucose control, which reduces complications, mortality, and length of stay (van den Berghe et al. 2001).

Date of implementation. ICUs began joining the TICU collaborative in 2001.

^{*} This case study is a synthesis of information obtained through personal interviews with Lisa Schilling, R.N., director of the TICU collaborative for VHA, Inc., and Terri Gingerich, R.N., critical care educator at the Porter Valparaiso Hospital Campus, Valparaiso, Ind., one of the participant sites, and from a review of supporting publications (VHA 2003; Pronovost and Berenholtz 2004) and presentation materials (Schilling 2003, 2004).

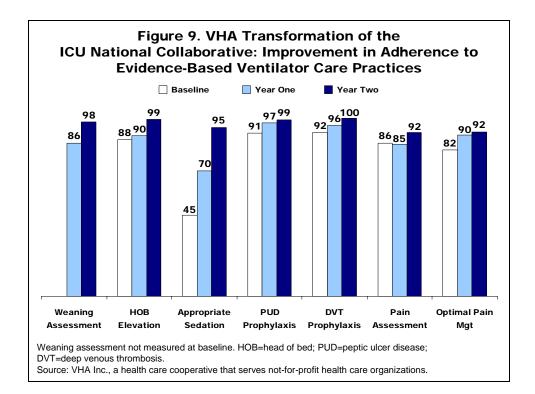
Process of change. Staff from participating institutions attended TICU-sponsored educational sessions led by quality improvement experts. Multiple improvement approaches were adopted by participating ICUs, including:

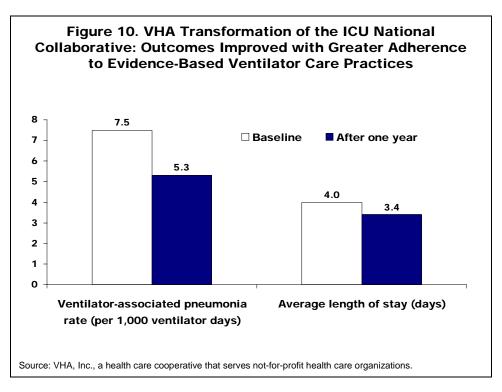
- independent system redundancies, such as standing orders, visual cues, and patient goal sheets and checklists to promote and track compliance with evidence-based processes;
- education on teamwork and weekly multidisciplinary team meetings to work on improvement goals;
- expert coaching to help remove barriers to improvement; and
- Web-based process and outcome data (i.e., clinical, financial, patient experience, and workforce) with weekly data feedback on compliance to daily goals (i.e., trend charts).

Interventions to promote compliance with evidence-based guidelines were often simple, such as posting reminders above the beds of ventilated patients about keeping the bed elevated at 30 degrees, posting signs at the entrance to patient rooms to encourage handwashing, and using wall marks or monitoring systems to indicate variance with 30degree bed elevation.

Results. For 19 ICUs participating in the first round of the initiative, compliance to the seven best-practice process goals or standards described above improved from a range of 45 percent to 92 percent at baseline, to 70 percent to 97 percent after one year, and to 92 percent to 100 percent in the second year (Figure 9). Outcome improvements included:

- a 29 percent decrease in ventilator-associated pneumonia rates among first round participants (from 7.5 to 5.3 cases per 1,000 ventilator days) (Figure 10), with several ICUs completely eliminating ventilator-associated pneumonia for six months or longer; and
- a 15 percent reduction in average length of stay among ICUs in the first round (from 4.0 to 3.4 days) (Figure 10).





Many institutions documented decreased cost per admission, increased patient and family satisfaction, reduced contract nursing and nursing turnover rates, and fewer delayed ICU admissions, diverted patients, and cancelled surgery cases.

The impact of preventing ventilator-associated pneumonia among ICU patients can be substantial: Hartford Hospital estimated annual savings of \$700,000 from reduced lengths of stay in its two participating 12-bed ICUs (VHA 2003).

Lessons learned. TICU demonstrates that an evidence-based improvement methodology can be applied in diverse settings from small community hospitals to large academic centers. While conventional wisdom has held that health care–associated infections are an unavoidable side effect of critical care, the experience of TICU participants "has expanded the limits of the possible," said Lisa Schilling, R.N., director of the TICU collaborative for VHA, Inc. Traditionally, hospitals might have been happy to reach the 25th percentile performance benchmark compared with the national average. Now there is evidence that shows it is possible to eliminate health care–associated infections of this type. And when infections do occur, the team has the tools to review the case and see what can be done to prevent future occurrences.

Measuring performance in aggregate for a bundle of care measures that relate to a common disease provides "a more robust picture of quality than any single measure," noted Sean Berenholtz, M.D., and colleagues at the Johns Hopkins Medical Institutions (2004b). While many institutions may perform well on particular care processes, few do so in providing all the evidence-based therapies for a condition. The bundled approach highlights the need for consistently providing all the care that is likely to produce better patient outcomes.

Bringing ICU staff and physicians together to work on improvement creates a heightened sense of teamwork and mutual respect, with everyone taking responsibility for the safety of every patient, said Schilling. At the Porter Valparaiso Hospital Campus, for example, if respiratory therapists or nurses see that a ventilated patient's bed is not properly elevated, they stop to correct it, regardless of whether the patient is their charge, said Terri Gingerich, R.N., critical care educator for Porter. Nurses have been empowered to respectfully question physicians if a patient is not being treated according to an evidencebased protocol. After nurses gained experience with the glucose protocol, they made suggestions for improving adherence and were given progressively more autonomy to manage the protocol over time.

Participating ICUs have found that basing process changes on evidence is critical to establishing credibility with physicians. To gain physician buy-in at Porter—where any community physician may admit patients to the ICU—a physician champion presents information on the ventilator project at medical staff meetings. Articles on the initiative

regularly appear in newsletters for the hospital's admitting physicians. ICU nurses also keep copies of relevant research studies close at hand in case physicians are not familiar with the evidence, according to Gingerich.

Collecting both process and outcomes data is labor-intensive but worthwhile as it validates the clinical success factors for the team while making the business case for the institution—both critical factors to the sustainability of improvement, Schilling says. Demonstrating successful outcomes also builds momentum for further improvement. "Once [nursing staff] know that something will make a difference to help patients, they will do anything to achieve it," said Gingerich. Hospital managers who have seen the results have been motivated to spread similar improvement methods among all their ICUs.

The improved teamwork and communication also improves nursing staff morale. Typically, the work nurses do at the bedside is not always appreciated. Now, according to Schilling, the nursing staff can show the value of this work in three ways: providing better care for patients, making physicians' jobs easier, and saving lives and money. The ability to make a difference in improving patient care has reinvigorated nurses working at participating ICUs, such as Porter. This helps prevent employee burnout in an often stressful working environment. Some institutions involved in the initiative now have waitlists of nurses who want to work in the ICU.

Replication and related results. The "ventilator bundle" of evidence-based practices is one of six high-impact interventions promoted by the Institute for Healthcare Improvement (IHI) as part of its 100,000 Lives Campaign (Berwick et al. 2006). Between July 2002 and January 2004, 35 ICUs participating in an IHI collaboration reduced the incidence of ventilator-associated pneumonia by an average of 44.5 percent; outcome improvement was proportionate to the degree of adherence to ventilator bundle processes. These ICUs found that the use of multidisciplinary teams and daily goals (Case Study 6) were critical to implementation. Study authors concluded that: "The goal-oriented nature of the bundle appears to demand development of the teamwork necessary to improve reliability" (Resar et al. 2005).

VHA is building on the success of TICU with a new sepsis care improvement initiative (Pronovost and Berenholtz 2004). In the first year of the program, 19 participating ICUs have improved performance on a bundle of eight evidence-based processes of care, from a range of 36–77 percent compliance before the intervention to 62–91 percent compliance after one year, resulting in a 69 percent reduction in patient mortality and a 36 percent decrease in average ICU length of stay (Schilling 2004).

Implications. The ability to apply best practices in community settings challenges the assumption that high-quality care can be found only in large academic centers. "There isn't an institution in the country that doesn't have the ability to make the changes we did," said Terri Gingerich, R.N., critical care educator at Porter, which cut its mortality rate by two-thirds through participation in TICU. Collaborative learning allows an institution to identify promising approaches and "modify them to fit your own house," Gingerich said.

In the current environment, which is characterized by a shortage of skilled nurses, hospitals are learning that it just as important to retain experienced staff as to recruit new employees (Chan et al. 2004). Enlisting nursing staff as equal partners with physicians in improving patient safety—such as by setting expectations that nurses can speak up for safety—sends a strong signal about the value of both nursing and patient safety in a hospital. This connection suggests that doing the right thing for patient safety can produce contingent benefits like improving quality of work life and reducing burnout and turnover among nursing staff (Gifford et al. 2002).

Case Study 8. Perfecting Patient Care at Allegheny General Hospital and the Pittsburgh Regional Healthcare Initiative*

Organization. Pittsburgh-based <u>Allegheny General Hospital</u>, with 829 beds, is part of the six-hospital West Penn Allegheny Health System and a partner in the <u>Pittsburgh Regional Healthcare Initiative</u> (PHRI). PHRI was organized in 1997 under the leadership of former Alcoa chairman and U.S. Treasury Secretary, Paul O'Neill, to achieve "measurable and sustainable improvements in health care on a region-wide basis" (Sirio et al. 2003). PRHI partners include 44 hospitals, four insurers, 32 health care purchasers, organized labor, and civic leaders.

Objective and intervention. PRHI seeks to engage hospital CEOs and physician leaders to endorse one guiding principle to alter the way people work: health care delivery must focus on providing perfect care to every patient.

Date of implementation. The Perfecting Patient Care System was piloted to improve patient safety in the medical ICU and coronary care unit at Allegheny General Hospital beginning in July 2003.

Process of change. PRHI adapted the Perfecting Patient Care System for use in health care from the principles of the Toyota Production System, a widely admired model for high-quality manufacturing at the Japanese car maker. The Toyota Production System consists of two essential concepts, according to the company's <u>Web site</u>:

- *Jidoka* or "automation with a human touch," which means that "when a problem occurs, the equipment stops immediately, preventing defective products from being produced."
- Just-in-time, which means "making only what is needed, when it is needed, and in the amount needed." This concept further implies "the complete elimination of waste, inconsistencies, and unreasonable requirements on the production line."

These principles can be roughly translated and applied to health care, as follows (Shannon 2004):

^{*} This case study is a synthesis of information obtained from a personal interview with Richard Shannon, M.D., chairman of internal medicine at Allegheny General Hospital, and from a review of supporting publications (PHRI 2004a; 2004b; 2004c; Sirio et al. 2003) and presentation materials supplied by the interviewee (Shannon 2004).

- The standards for performing work activities (such as intravenous line placement and maintenance) should be highly specified (not simply assumed), based on best practices, so that problems or variations from standards are immediately apparent.
- When problems (such as nosocomial infections) are encountered, they should be solved, in real time by the people doing the work, to determine root causes and employ countermeasures—or corrective actions—to prevent them.
- When workers cannot solve a problem, they invoke the "help chain" of expert support to solve the problem.

Under this approach, organizations create improvement teams (called "learning lines") in hospital units that work with team leaders to design solutions in real time. To support this effort, PRHI provides intensive education on the Perfecting Patient Care approach and has created a National Clinical Improvement Network to connect those working on patient care improvement through site visits. PHRI has also established safety event reporting using the U.S. Pharmacopeia MedMarx system for standardized medication error reporting and analysis, and a modified version of the Center's for Disease Control and Prevention's National Nosocomial Infections System to monitor nosocomial infection trends region-wide (Sirio et al. 2003).

After attending PHRI education, Richard Shannon, M.D., chairman of internal medicine at Allegheny General Hospital, challenged his hospital to adopt the Perfecting Patient Care approach, with an ambitious goal of completely eliminating a specific type of hospital-acquired infection—central-line-associated bloodstream infections (CLABs)—within 90 days in two ICUs. In order to achieve this goal, staff members would need to monitor the rates, root causes, and complications associated with CLABs and implement countermeasures to prevent CLABs based on evidence-based infection control guidelines and observations of central line placement and care.

Specifically, the steps in the process were to:

- cultivate the unit's medical and nursing leadership as champions for change;
- review past cases of infection to search for clues and common threads in causation;
- investigate the root cause of an infection as soon as it occurred;
- go to the frontlines to observe actual practices;
- generate improvement based on observations;

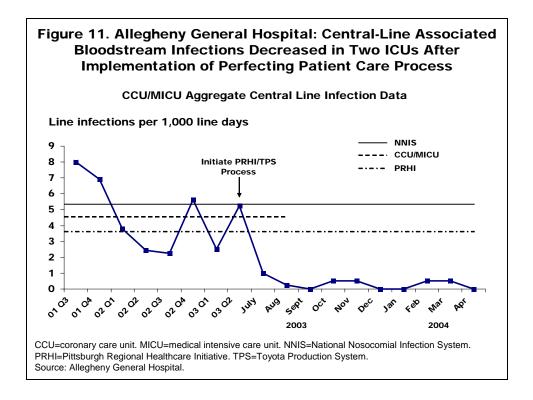
- standardize the process and communicate it to staff immediately;
- commission every clinician as a patient guardian;
- monitor for infections daily; and
- share success.

Root cause analysis found that femoral intravenous lines (i.e., inserted into an artery near the groin) had higher rates of infections than other sites, consistent with the findings of a randomized controlled trial (Saint et al. 2002). Countermeasures developed to reduce CLABs included:

- using subclavian approach (insertion near collarbone) whenever possible;
- removing femoral lines within 24 hours;
- prohibiting the rewiring of dysfunctional catheters;
- removing existing lines on patients transferred from other facilities; and
- asking whether the central line was still necessary.

The team also adopted other best practices, such as a standardized dressing change kit, and is starting to use an antimicrobial dressing when catheters remain in longer than two weeks.

Results. CLABs were nearly eliminated, falling 76 percent from 49 infections in 37 patients (5.1 per 1,000 line days) in the year before the intervention to six infections in six patients (1.2 per 1,000 line days) during the intervention year (Figure 11). Among patients with CLABs, the number of deaths decreased 95 percent and the death rate decreased 69 percent, from 19 of 37 patients (51%) to 1 of 6 patients (16%). Of the six CLABs that occurred, four were attributed to failures to follow specific guidelines.



A case-study analysis was conducted of the revenues and expenses associated with the care of six patients with CLABs, which found an average loss of \$14,572 per case. This analysis suggests that the intervention saved over \$500,000 and could save \$1 million by eliminating the remaining 72 CLABs cases hospital-wide. Likewise, eliminating CLABs, ventilator-associated pneumonia, and antibiotic-resistant infections caused by methicillin-resistant *Staphylococcus aureus* could save a total of \$10 million.

Lessons learned. Critical success factors included the following lessons: hospital-acquired infections are preventable; prevention is everyone's business; favor real-time observation over retrospective review; do not settle for the current best practice—strive for perfection; and progress can be achieved rapidly and continuously using a scientific method.

The intervention showed staff that nosocomial infections are not inevitable and therefore not acceptable. "Where there is a will and a method, we can achieve transforming results," Dr. Shannon said. The hospital's management has been convinced of the efficacy of this approach after seeing the improvement in outcomes and the effect on the bottom line. Although not all physicians are fully engaged with the effort, "data is a powerful tool for overcoming that myth that physician independence is okay," Dr. Shannon said, referring to the teamwork approach that the Perfecting Patient Care approach promotes. Translating the infection rate into actual lives affected gives the numbers greater meaning and impact. As a result of the initiative, the nursing team has developed a can-do attitude toward solving problems. Recently, an ICU nurse called Dr. Shannon to intervene when she could not get the radiology department to install a new intravenous line in a patient whom she feared would develop an infection. "That was the equivalent of pulling the 'andon cord' to stop the Toyota assembly line," Dr. Shannon told the *Wall Street Journal* (Wysocki 2004). Within two hours, the hospital's chief of radiology, Paul Kiproff, installed the new line himself.

Dr. Shannon believes that the same evidence-based approach can be applied to managing other diseases. "Making patients well is a lot more complicated than building a Toyota, but there is still a lot we can learn from the lessons that Toyota and others have built their success on," he said. Yet, efforts like Allegheny's remain "islands of success" and there is a long way to go before anyone can claim organization-wide excellence. He attributes lack of greater progress to failure of hospital leaders to claim the goal of eliminating nosocomial infections as a condition of meeting their commitment to operating a safe hospital.

Replication and related results. The Perfecting Patient Care approach is currently being adopted in all of Allegheny General Hospital's ICUs, which have already seen substantial reductions in CLABs and ventilator-associated pneumonia in the first three months of the intervention. Regionally, PHRI convened a group of infection control experts and other practitioners who developed a regional guideline, shared best practices, and recommended use of a kit of standardized supplies for safe central line insertion.

Recent findings and related efforts in this field include:

- Among the 29 PRHI member hospitals submitting data to a regional database, the rate of CLABs has decreased 55 percent, from 4.2 to 1.9 per 1,000 line days from 2001 to 2004. Hospitals have adopted approaches such as "zero tolerance" for handwashing violations and sending daily reports of infections to the hospital's CEO for review (PRHI 2004b).
- At the University of Pittsburgh Medical Center (UPMC) Presbyterian Hospital, physicians in the medical ICU receive simulator-based training on safe central-line insertion, carried out using torso simulators in the University's simulation center. Residents may only insert a central line under the supervision of a simulatortrained physician. The UPMC Health System plans for all residents to receive this training (PRHI 2004b).

• At the Veterans' Administration Pittsburgh Healthcare System, antibiotic-resistant infections caused by methicillin-resistant *Staphylococcus aureus* have been reduced from about one per month to one per year in a post-surgical unit through education, reminders, and other low-tech strategies, like making hand disinfectant readily available, that remove barriers to complying with infection control guidelines (PRHI 2004c).

Implications. In a recent invited commentary on hospital quality improvement case studies, Paul O'Neil and his colleagues at the PRHI offered these observations based on the experience of other high-reliability organizations that have made safety ubiquitous:

Leaders establish quality and safety as preconditions of serving people and protecting the workforce. They accept responsibility for everything. They ask themselves whether they are getting all the information they need on what has gone wrong every day, and they ensure that the frontline troops have the permission and tools they need to solve each problem. Finally, leaders ask ceaselessly: How far are we from the ideal and what is the next improvement to move us closer to that ideal? (O'Neil et al. 2004).

The Perfecting Patient Care System demonstrates that it is possible to translate the lessons learned from quality improvement in other industries to the health care setting. Using this framework for improvement, Allegheny General Hospital has replicated the results of Johns Hopkins Hospital and others who have significantly reduced or eliminated CLABs (see Case Studies 6 and 7). These experiences demonstrate that it is possible to meet the goal of providing safe health care so that patients are free from harm.

MEDICATION SAFETY AND ADVERSE DRUG EVENTS

Up to 25 percent of hospitalized patients may experience an adverse drug event, an injury resulting from medication use (Rozich et al. 2003). These events are associated with longer hospital stays, increased risk of death, and increased costs (Bates et al. 1995a; 1997; Classen et al. 1997). Across studies, about one-third of adverse drug events are associated with preventable medication errors (Kanjanarat et al. 2003). The medication use process in hospitals is complex, involving numerous steps in which errors might occur. As a result, medication errors are common, occurring in 19 percent of the medication doses administered at 36 hospitals (Barker et al. 2002). While up to half of medication errors have the potential to harm patients, only about 1 percent actually result in harm (von Laue et al. 2003; Bates et al. 1995b).

Luther Midelfort Hospital of the Mayo Health System in Eau Claire, Wis., found that 60 percent of medication errors occurred at transition points including admission, transfer between units, and discharge (Rozich and Resar 2001). Studies comparing medication orders to the medications that patients are already taking, or to which they are allergic, have found discrepancies or inconsistencies in 44 percent to 94 percent of the orders (Marino et al. 2002; Pronovost et al. 2003b). One study found that 22 percent of discrepancies identified in medication orders could have resulted in patient harm and another 23 percent would have required patient monitoring to prevent harm (Gleason et al. 2004).

To ensure safe medication use in the hospital, accurate information is needed about medications patients take at home. In addition, accurate transfer of medication information must occur at all transition points. Patients must leave the hospital with a clear understanding of what medications they will continue to take. Luther Midelfort developed a <u>methodology</u> that hospitals can use for this purpose (Rozich and Resar 2001), freely available at the Institute for Healthcare Improvement (IHI) Web site (IHI 2004f) (Case Study 9). Case Study 10 describes the experience of a multi-hospital system that used medication reconciliation and other strategies to significantly reduce the rate of adverse drug events.

Another targeted approach to preventing adverse drug events involves designing systems for safe use of high-risk medications—those most frequently associated with adverse drug events or that cause the most serious harm when misused. Hospitals can use lists of common high-risk medications developed by other organizations, such as by the Institute for Safe Medication Practices, or they can measure the occurrences and types of adverse drug events in their own institutions.

More than a decade ago, David Classen, M.D., and his colleagues at LDS Hospital, part of Intermountain Health Care, in Salt Lake City, Utah, developed a method for detecting potential adverse drug events using computerized triggers (Classen et al. 1991). Building on this work, IHI, in partnership with Premier, Inc., an alliance of more than 200 not-for-profit hospitals and health care systems, developed a trigger tool to measure and characterize adverse drug events based on a manual review of patient records (Resar et al. 2003). This tool is freely available on the IHI Web site (IHI 2004e). Case Study 9 describes this tool as an introduction to the principles of measuring adverse drug events, while Case Study 10 describes the practical application of this tool as part of a broader effort to reduce adverse drug events at OSF HealthCare.

Case Study 9. Using a Trigger Tool to Measure Adverse Events*

Organizations. The <u>Institute for Healthcare Improvement</u> (IHI) is a Boston-based not-for-profit that works with health care organizations worldwide to spread quality improvement. <u>Premier, Inc.</u>, of San Diego, is an alliance of more than 200 not-for-profit hospitals and health care systems across the United States. Roger Resar, M.D., senior IHI fellow at <u>Luther Midelfort, Mayo Health System</u> in Eau Claire, Wis., developed the tool with assistance of IHI colleagues Carol Haraden, Ph.D., and Frances Griffin, R.R.T., M.A.

Objective. The trigger tool allows organizations to simply measure the incidence and types of adverse events occurring within the institution. This information can be used to prioritize areas for improvement, design appropriate actions for prevention, and track the impact of changes on the occurrence of adverse events over time. The trigger tool is designed to overcome the limitations of other methods like voluntary reporting systems.

Date of implementation. IHI, in partnership with Premier, developed the trigger tool for measuring adverse drug events as part of the Idealized Design of the Medication System collaborative, which began in 2000. Four additional trigger tools have since been developed to detect adverse events globally in the hospital and in intensive care units, specific kinds of adverse events such as those associated with anticoagulation treatment, and adverse events that occur as part of "life events" in the outpatient setting, such as a new diagnosis of cancer or an emergency room visit for an adverse reaction to medication.

Description. The trigger tool uses an efficient sampling technique to identify potential adverse events through a periodic audit of medical records. Each tool includes a limited number of triggers that signal the most common types of adverse events or those that are likely to cause serious harm. Triggers were included based on a literature review, expert opinion, and testing for feasibility. For example, triggers for a potential adverse drug event include orders for antidotes, abnormal laboratory values, abrupt medication stop orders, transfers to a higher level of care, and development of a rash.

The tool is applied to a small, random sample of patient records (e.g., 20 hospital charts per month for patients with a hospital stay of at least 24 hours). When a trigger is found, the chart is reviewed to determine whether an adverse event has occurred. Adverse events are defined from the perspective of the patient and require clinical judgment to

^{*} This case study is a synthesis of information obtained from a personal interview with Roger Resar, M.D., Luther Midelfort, Mayo Health System, Eau Claire, Wis., and senior fellow with the Institute for Healthcare Improvement, Boston, Mass., and from a review of relevant publications (Rozich and Resar 2001; Rozich et al. 2003; Resar 2003; Resar et al. 2003; Neveleff 2003; IHI 2004e).

distinguish those that occur as a natural course of disease process versus complications of treatment. Level of patient harm is classified using an objective scale—the National Coordinating Council for Medication Error Reporting and Prevention Index. To make the process reliable and efficient, the tool developers recommend that chart reviewers be trained by experienced users, that an initial double review be conducted to standardize the process, and that a time limit of 20 minutes be set for reviewing a single chart.

To gain maximum benefit from the trigger tool, Dr. Resar recommends the following approach:

- use the trigger tool monthly for a period of six months to one year to observe trends;
- place identified adverse drug events into "buckets" or clinically meaningful categories to determine the most common types of events occurring within the institution; and
- direct resources to understand the potential causes of commonly occurring events and design countermeasures to prevent them.

Results. A total of 86 hospitals in four medication safety collaboratives tested the original trigger tool (Rozich et al. 2003). There were 720 adverse drug events identified among 2,837 patient charts and 268,796 medication doses, yielding an adverse drug event rate of 25 percent of patients and 2.68 events per 1,000 doses. A low level of variation among hospitals (2.47 to 4.81 per 1,000 doses) suggests that the tool can be used consistently in different settings. Only 2 percent of the adverse drug events detected using the trigger tool were identified using traditional methodologies such as incident reports, pharmacy interventions, and billing codes. Commonly identified high-risk medications associated with adverse events include anticoagulants, narcotics, insulin, sedation and patient-controlled analgesia, and intravenous pumps.

Lessons learned. The trigger tool directs attention to issues that are not otherwise obvious when using traditional reporting mechanisms. By focusing on adverse events rather than the larger universe of errors, the trigger tool "eliminates wasted effort directed towards quantifying errors," noted James Rozich, M.D., Carol Haradan, Ph.D., and Roger Resar, M.D., in a journal article (2003). "Organizations that fail to recognize the difference between medication errors and [adverse drug events] may concentrate their efforts on systems that improve the accuracy of drug administration but that produce only marginal reductions in patient harm," they wrote.

The trigger tool does not assess the preventability of adverse events, because opinions differ regarding those kinds of judgments, noted Dr. Resar. "Some events are more preventable than others, but that can change tomorrow" with advances in medical technology, he said. Dr. Resar suggests that it is more productive for hospitals to focus on driving the adverse event rate as low as possible. "There's probably a basement level below which we can't go today, but we haven't found it yet," he said.

In a previously published interview with the *QualityIndicator* online newsletter (Neveleff 2003), Dr. Resar explained the implications of this philosophy using a hypothetical example in which a patient is mistakenly given acetaminophen.

'The chance that the acetaminophen will cause harm is virtually zero,' Resar notes. 'But that is still considered an error. As a contrasting example, if a patient is given morphine for pain and vomits for three hours afterwards, he or she may not be able to eat, which will delay recovery. Even though the morphine was not given in error, the patient is harmed by the drug, and this harm could have been mitigated by standardized antinausea protocols. Physicians and organizations should strive to prevent or mitigate situations that actually cause harm to patients, whether the harm is caused by an error or a faulty or inefficient process.'

The trigger methodology can be adapted to an automated process, although manual review of the triggered charts or events is still generally required to apply clinical judgment about adverse events. Electronic approaches can also be used as a means of detecting and mitigating potential errors in real time. Because of the time required to review all the positive triggers generated for every patient, those using automated triggers tend to limit their use to a smaller number of conditions related mostly to adverse drug events, according to Dr. Resar.

The manual trigger methodology "has the advantage of being cheap, readily available to all institutions whether they have [information] technology or not, and a real learning experience for those who do the reviews," Dr. Resar says. He sees the manual and automated approaches as two different, but complementary, tools: a retrospective sampling tool to measure the rate at which adverse events occur at given points in time, and a prospective tool to detect and mitigate potential adverse events as they occur in real time.

Implications. Measuring adverse drug events is key to their prevention. Using a trigger tool to review medical records can identify up to 50 times more adverse drug events than traditional incident reporting systems.

Case Study 10. Preventing Adverse Drug Events at OSF HealthCare*

Organization. <u>OSF HealthCare</u> is an integrated health care network that includes six acute care hospitals in Illinois and Michigan, ranging in size from 42 to 710 beds. It is owned and operated by the Sisters of the Third Order of St. Francis, based in Peoria, Ill. <u>OSF St. Joseph Medical Center</u>, is a 165-bed facility located in Bloomington, Ill.

Objective and intervention. OSF HealthCare, and its OSF St. Joseph Medical Center, sought to improve patient safety by fostering a culture of safety characterized by the widespread reporting of errors, systems thinking about error prevention, and a spirit of collaboration for making improvements. Medication errors were targeted as an opportunity to impact the most patients. Specifically, OSF aimed to reduce adverse drug events by improving the process of medication reconciliation, the safe use of high-risk medications, and the reliability of medication dispensing.

Date of implementation. OSF St. Joseph Medical Center joined the Institute for Healthcare Improvement's (IHI) Quantum Leaps in Patient Safety collaborative in May 2001, sending a multidisciplinary team of participants to IHI-sponsored training. At that time, all six OSF hospitals formed a parallel internal improvement collaborative.

Process of change. To promote a culture of safety, OSF instituted several interventions, including the following:

- Hospital executives regularly engage in walk rounds (Frankel et al. 2003), during which they meet with frontline staff in each work unit to obtain input about safety practices and concerns and elicit ideas for needed improvements.
- Nursing units conduct safety briefings at shift changes to elicit conditions that did or could cause patient harm and ways that harm was prevented.
- To encourage physician involvement, patient safety issues identified in safety briefings and root cause analyses are discussed with physicians during departmental meetings.

^{*} This case study is a synthesis of information obtained from personal interviews with John Whittington, M.D., patient safety officer and director of knowledge management for OSF HealthCare System, Peoria, Ill., and Kathy Haig, R.N., director of quality resource management, risk manager, and patient safety officer for OSF St. Joseph Medical Center, Bloomington, Ill., and from a review of publications (Haig 2003; Whittington and Cohen 2004). Some of the actions described were taken system-wide while others were initiated at the St. Joseph Medical Center.

A medication reconciliation process was instituted, which included the following steps:

- A nurse obtains the best possible information on home medication use by interviewing the patient or the patient's advocate at hospital admission. If the patient or advocate cannot remember all the medications the patient is taking, the nurse attempts to contact the patient's primary care physician and pharmacy, if the patient consistently uses the same pharmacy.
- When patients are transferred between units, medications that the patient was taking on the prior nursing unit are compared to orders on the new unit. Likewise, when patients are discharged from the hospital, medications that the patient was taking in the hospital are compared with those that the physician orders to be continued upon discharge.
- Any discrepancy between medications ordered and those currently being taken at hospital admission, transfer, or discharge must be reconciled by the patient's physician within four to 24 hours, depending on the type of medication in question.
- A pharmacist reviews home medication use and physician orders to detect and avert any medication errors in dosing or other problems such as potential drug interactions.

A standard medication reconciliation sheet doubles as the medication order sheet for review and approval by the physician at admission, which saves time and prevents transcription errors. The medication reconciliation sheet was subsequently automated to save time and prevent transcription errors at patient transfer and discharge. A computerprinted form lists all prescribed medications with check-off boxes for the discharging physician to indicate which should be continued, along with doses, amounts, and schedules. A duplicate copy is generated for the patient to take home and another copy is sent to the patient's referring physician.

Other strategies—adopted either OSF system-wide by OSF or at the OSF St. Joseph Medical Center—use human factors principles, such as standardization and redundancies, to reduce complexity and unnecessary variation in processes that can lead to errors and patient harm, as follows:

• Standardized order sets or dosing services are used for certain high-risk medications, such as anticoagulants, narcotics, and insulin. Order sets were

developed through an iterative process in which users gave repeated feedback, thus easing implementation.

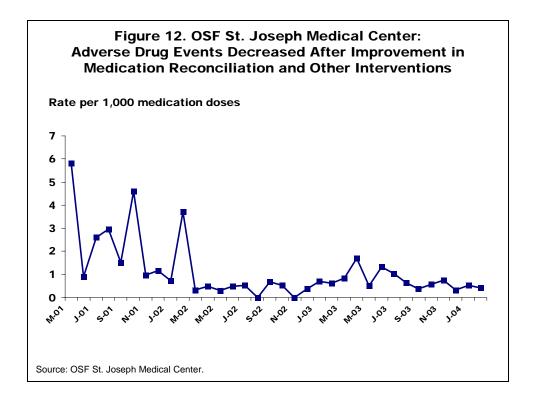
- Adult intravenous (IV) medications were standardized, nonstandard doses are only prepared by the pharmacy, and an IV Drug Administration Reference matrix was developed with dosage guidelines and monitoring information for nursing staff.
- Pharmacists on nursing units perform independent double checks while entering medication orders, which permits them to detect dosing errors or potential drug interactions and to immediately contact physicians for resolution.
- Anesthesia staff standardized epidural-safe pumps with color-coded tubing to prevent confusion and errors when multiple infusion pumps are used for the same patient.
- Patients (and their advocates) are given forms to list their medications and are encouraged through posters and brochures to question any unfamiliar medications.

OSF uses failure modes and effects analysis (IHI 2005a) to examine and objectively score the risk associated with vulnerabilities in the medication dispensing process. This assessment drives the design of process improvements and countermeasures. For example, to prevent reuse of leftover medication when it is discontinued for a patient, the floor nurse places it in a plastic bag, which is picked up by pharmacy technicians during hourly rounds on the floor.

At the corporate level, patient safety is one component in a balanced scorecard approach to performance management (Kaplan and Norton 2000), which includes broad indicators for hospital-wide goals related to the workforce, quality, safety, service, and finance. All hospital staff work toward achieving the organizational goals directly and through supporting departmental goals. Employees are eligible to receive a monetary team award based on results, provided that the hospital meets its financial goals.

Results. Along with greater collaboration among OSF HealthCare hospitals, the initiative increased the rate of proposed ideas for safety improvements. At OSF St. Joseph Medical Center, staff perceptions of the hospital's safety culture improved, from 3.96 to 4.28 on a 5-point rating scale, as measured by the University of Texas Safety Climate Survey (Sexton and Thomas 2003).

Medication reconciliation increased dramatically across OSF HealthCare and was associated with a decrease of 52 percent in the rate of detected adverse drug events (as measured using the trigger tool) system-wide within the first 20 months of the initiative, from 3.84 to 1.39 per 1,000 doses (Whittington and Cohen 2004). OSF St. Joseph Medical Center experienced a 91 percent decrease in detected adverse drug events, from 5.8 to 0.5 per 1,000 doses during a similar period (Haig 2003) (Figure 12).



Lessons learned. Medication reconciliation is essential to preventing adverse drug events. This lesson was reinforced when a glitch in automating the process caused medication reconciliation to fall off for a short time, during which the adverse drug event rate noticeably increased at OSF St. Joseph Medical Center. Given the dispersed nature of medical record-keeping, obtaining accurate information on home medication use can be challenging, said John Whittington, M.D., patient safety officer for OSF HealthCare System. The goal is to obtain the best possible information under the circumstances, recognizing that this results in far better information than what is available when no such effort is taken.

Process improvement projects that cross multiple boundaries, such as those designed to reduce adverse drug events, have the potential to change the organizational safety culture, said Dr. Whittington. Frontline staff must see that management takes patient safety seriously and that everyone will be held accountable for achieving it. Patient safety is a "long-term walk . . . the further you are along the journey, the more you see how far there is to go," Whittington said. Kathy Haig, R.N., patient safety officer at the OSF St. Joseph Medical Center, agreed. "Culture change is not something you do in a

year," she said. Three years of concerted effort have reached a tipping point where "true understanding and passion are coming through" from both leadership and frontline staff.

The tools and techniques that Whittington and Haig say have been most valuable to patient safety improvement at OSF hospitals include:

- enhancing root cause analysis (or use of critical event analysis) to encourage deeper thinking about human factors issues and latent causes of safety incidents;
- using failure modes and effects analysis to examine system vulnerabilities and to assess planned changes to help ensure that they decrease rather than increase the risk of harm;
- training to improve teamwork and the use of structured communication skills, such as the Situation-Background-Assessment-Recommendation technique (Case Study 3);
- creating a simulation laboratory to practice teamwork skills, evaluate critical thinking, and learn—through videotaped debriefings—how processes enable errors;
- engaging in collaborative learning among staff at OSF hospitals, which provides ideas and support for improvement;
- making rapid tests of change using the Plan-Do-Study-Act method (Berwick 1998), which minimizes the risks of failure by involving staff in giving feedback at incremental stages of the implementation;
- planning for a measurement strategy, such as the trigger tool to track and understand adverse drug events, and providing monthly reports to management on safety incidents and actions taken to address identified issues.

OSF recently installed electronic health records and automated medication dispensing in the pharmacy. In Haig's experience, technology can be helpful but it is not a cure-all. "People think technology will solve all their problems," but that is not realistic, she said. It requires a lot of up-front work to create a "clean process" to automate. Underlying process failures will show up in "big bright lights" and workarounds will be required to fix them.

Currently, OSF is engaged in efforts to comply with National Quality Foundation-endorsed Safe Practices for Better Healthcare, which are being highlighted through a voluntary hospital survey conducted by the Leapfrog Group, a collaboration among large employers to promote high-impact patient safety practices. OSF expects further regulation and pay-for-performance initiatives to center on these practices. The current voluntary approach to compliance is appealing because it permits hospitals to determine the priority of particular practices and the preferred order for mastering them, Dr. Whittington says.

Dr. Whittington believes that a business case for patient safety can be made when avoidance of adverse events, such as hospital-acquired infections, results in shorter lengths of stay and increased throughput and effective capacity. In other words, efficiency is enhanced when the same facilities serve more people.

Replication and related results. Medication reconciliation is one of six high-impact interventions promoted by the Institute for Healthcare Improvement as part of its 100,000 Lives Campaign (Berwick et al. 2006). The Joint Commission on Accreditation of Health Care Organizations designated medication reconciliation as one of the 2005 patient safety goals required of all accredited hospitals in 2006.

After Luther Midelfort, of the Mayo Health System, in Eau Claire, Wis., implemented a systematic, hospital-wide medication reconciliation process, adverse drug events declined 60 percent from 7.6 per 1,000 doses in 1997 to 3.1 per 1,000 in 2001. A standardized process reduced the amount of time that staff spent on medication reconciliation by half or more, saving an estimated 20 minutes per patient at admission, 30 to 45 minutes at patient transfer from the coronary unit, 35 to 50 minutes at hospital discharge, and 30 minutes per nursing shift (Rozich and Resar 2001). Other related improvements undertaken by the health system have included the following (personal communication with Roger Resar, M.D., 2004):

- developing a standardized protocol for sliding scale insulin, which reduced hypoglycemic events and insulin errors by half (Rozich et al. 2004);
- limiting the number of drug types in a class, such as having one standard narcotic except in case of a patient allergy; and
- improving process reliability by using midlevel practitioners for tasks that do not require a physician's order, such as monitoring and communicating dose changes to the patient.

Implications. Adverse drug events can be substantially reduced through a multifaceted approach that applies human factors principles to reengineer processes through techniques

such as the standardization of processes and equipment and the implementation of independent double checks to avert errors.

An effective medication reconciliation process provides more accurate information for safe prescribing and can prevent 15 percent to 20 percent of adverse drug events in a hospital, according to Roger Resar, M.D., a patient safety consultant at Luther Midelfort (Tokarski 2004). If hospitals do not have a systematic process for reconciling medication use at all transition points from admission through discharge, nurses and pharmacists can spend significant time engaged in ad hoc reconciliation as patients move through the hospital, resulting in repeated work and potentially serious errors from incomplete information (Rozich and Resar 2001). Nursing and pharmacy staff have critical roles to play in improving the medication reconciliation process, but "the ultimate reconciliation is the responsibility and duty of the physician, with the appropriate knowledge," Dr. Resar told *Medscape Medical News* (Tokarski 2004).

Well-designed computerized physician order entry and clinical decision support systems can prevent many serious medication errors with the potential to cause harm (Kaushal et al. 2003). However, these systems cannot eliminate errors caused by incomplete or inaccurate information on home medication use (Bobb et al. 2004). Without a change in the underlying methods of collecting and recording medication history, computerized medical records systems can exhibit the same kinds of inaccurate or incomplete medication information as their paper-based counterparts (Kaboli et al. 2004). Hence, hospitals will continue to need a systematic medication reconciliation process until such time as there are reliable, interoperable electronic health records that faithfully capture a patient's complete medication history.

METHODS

Ten cases were selected from more than 20 identified by several experts and leaders in patient safety whom we consulted for this project. (For a full list of these individuals and organizations, see <u>Acknowledgments</u>.) These experts were asked to name five to 10 innovations, including tools, programs, and best practices, that had made the most difference in improving patient safety since the Institute of Medicine report or those that had the potential to make a major difference (Tables 2 and 3). Additional innovations were identified from examples noted by experts in the literature.

The cases focus on the hospital setting because that has been the focus of most patient safety improvement efforts to date. We did not examine expensive hightechnology innovations, such as computerized physician order entry systems, because we wished to focus on approaches that are broadly applicable regardless of an institution's readiness to make expensive capital investments. Some description of intermediate-level technology, like computerized mannequins used in simulation, are included.

Information presented in the cases was synthesized from telephone interviews and written communications with key change leaders in each organization and a review of relevant reports, publications, and presentations. The cases are not meant to be templates for replication, but rather a highlight of these leaders' experiences. Each case includes examples of related work in the field to provide wider a perspective.

The case study or studies included in this Fund report were based on publicly available information and self-reported data provided by the case study institution(s). The aim of Fund-sponsored case studies of this type is to identify institutions that have achieved results indicating high performance in a particular area, have undertaken innovations designed to reach higher performance, or exemplify attributes that can foster high performance. The studies are intended to enable other institutions to draw lessons from the studied organizations' experiences in ways that may aid their own efforts to become high performers. The Commonwealth Fund is not an accreditor of health care organizations or systems, and the inclusion of an institution in the Fund's case studies series is not an endorsement by the Fund for receipt of health care from the institution.

Table 2. Selected Innovations to Improve Patient Safety:*Programs and Initiatives Noted by Patient Safety Experts

- Veterans Administration (VA) National Center for Patient Safety: creating a culture of safety through the innovative use of multiple tools and approaches.
- Institute for Healthcare Improvement (IHI): promoting collaborative learning with methods, tools, and approaches to develop and spread best practices for improving patient safety.
- Pittsburgh Regional Healthcare Initiative (PRHI): application of Toyota Production System model to Perfecting Patient Care, as exemplified in Allegheny General Hospital's initiative to eliminate nosocomial infections in all ICUs.
- Johns Hopkins Hospital, Comprehensive Unit-Based Safety Program: integrates multiple approaches to improve and create a culture of safety, now being replicated through collaborative projects with several state hospital associations.
- VHA Transformation of the Intensive Care Unit national collaborative: evidencebased improvement program to reduce and eliminate nosocomial infections and improve sepsis care in the ICU.
- Vermont Oxford Network: multi-hospital reporting and collaborative learning programs to improve patient safety and quality in the Neonatal Intensive Care Unit.
- Centers for Medicare and Medicaid Services (CMS), Surgical Infection Prevention program: collaborative and state pilots to reduce surgical site infections (being rolled out nationally as part of the Surgical Care Improvement Project).
- Leapfrog Group: consumer education using hospital profiles of compliance with the National Quality Forum's 30 Safe Practices for Better Health Care; incentives to spur adoption of computerized physician order entry systems, safe practices, evidence-based hospital referral, and intensivists in the ICU.
- Statewide patient safety coalitions, such as the Massachusetts Coalition for the Prevention of Medical Errors, that bring together stakeholders to educate, promote, facilitate, and support patient safety improvement across institutions.

^{*} Experts were asked to name five to 10 innovations (tools, programs, best practices) that had made a difference in improving patient safety since the IOM report, or that had the potential to make a difference in the future. Additional items were derived from examples noted by experts in the literature.

Table 3. Selected Innovations to Improve Patient Safety*Tools and Techniques Noted by Patient Safety Experts

Measurement and Analysis

- Non-punitive internal and external safety event reporting (VA)
- Safety culture assessment/climate surveys (Johns Hopkins, others)
- Trigger tool for measuring adverse events (Mayo/Luther Midelfort Hospital, OSF)
- Institute for Safety Medication Practices, Medication Safety Self-Assessment (VHA)
- Failure modes and effects analysis (VA)
- Observation of behavioral markers (Kaiser Permanente)

Improvement: Human Performance

- Behavioral-based expectations (Sentara Norfolk General Hospital)
- Teamwork and communication skills development and training (Kaiser Permanente, MedTeams Consortium, Beth Israel Deaconess Medical Center)
- Safety briefings/debriefing (Kaiser Permanente)
- Collaborative rounds (Concord Hospital)
- Daily goals (Johns Hopkins Hospital)
- Simulation for teamwork and procedural skill building (Stanford, Harvard)

Improvement: Leadership, Incentives

- Patient safety leadership walk rounds (Partners Healthcare)
- Executive adopt-a-unit (Johns Hopkins Hospital)
- Safety coaches and champions (multiple)
- Pay-for-performance (Leapfrog Group)

^{*} Experts were asked to name five to 10 innovations (tools, programs, best practices) that had made a difference in improving patient safety since the IOM report, or that had the potential to make a difference. Additional items were derived from examples noted by experts in the literature. Organizations in parentheses represent case examples (not necessarily the originator of the innovation).

Table 3. Selected Innovations to Improve Patient SafetyTools and Techniques Noted by Patient Safety Experts (continued)

Improvement: Process

- Perfecting Patient Care (PRHI/Allegheny General Hospital)
- Medication reconciliation (Mayo/Luther Midelfort Hospital, OSF HealthCare)
- Rapid response teams/medical emergency teams (Baptist Memorial Hospital-Memphis, Pittsburgh Medical Center, Missouri Baptist Medical Center)
- Computerized physician order entry (Brigham & Women's Hospital)
- Medication bar coding (VA)
- Checklists as forcing functions for hand-offs (Kaiser Permanente)

Improvement: Patient Involvement and Disclosure

- Consumer education and support (Leapfrog)
- Patient advocacy programs (Kaiser Permanente, Dana Farber, VA Lexington)

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<u>Mirror, Mirror on the Wall: An Update on the Quality of American Health Care Through the Patient's</u> <u>Lens</u> (April 2006). Karen Davis, Cathy Schoen, Stephen C. Schoenbaum, Anne-Marie J. Audet, Michelle M. Doty, Alyssa L. Holmgren, and Jennifer L. Kriss, The Commonwealth Fund. Focusing on adults with health problems, the authors of this cross-national study find the U.S. ranks at or near the bottom on a number of indicators of health care quality, patient safety, patient-centeredness, efficiency, and equity.

<u>Stories from the Sharp End: Case Studies in Safety Improvement</u> (March 2006). Douglas McCarthy and David Blumenthal. *Milbank Quarterly*, vol. 84, no. 1 (*In the Literature* summary). The authors highlight promising techniques for stimulating cultural change within health care organizations.

<u>Nurse Staffing in Hospitals: Is There a Business Case for Quality?</u> (January/February 2006). Jack Needleman et al. *Health Affairs*, vol. 25, no. 1 (*In the Literature* summary). The authors report that an "unequivocable business case" can be made for increasing the level of nurse staffing in hospitals—a move that can pay for itself in fewer patient deaths, shorter hospital stays, and decreased rates of medical complications.

Five Years After To Err Is Human: What Have We Learned? (May 2005). Lucian L. Leape and Donald M. Berwick. *JAMA*, May 18, 2005 (*In the Literature* summary). Five years after the landmark IOM report, *To Err Is Human*, two of the authors note that while the book has not yet succeeded in creating comprehensive, nationwide improvements, it has made a profound impact on attitudes and organizations. First, it has changed the way health care professionals think and talk about medical errors and injury, with few left doubting that preventable medical injuries are a serious problem, according to the authors.

<u>Physicians' Views on Quality of Care: Findings from The Commonwealth Fund National Survey of</u> <u>Physicians and Quality of Care</u> (May 2005). Anne-Marie J. Audet, Michelle M. Doty, Jamil Shamasdin, and Stephen C. Schoenbaum. This companion report to the *Health Affairs* article, "<u>Measure, Learn, and Improve</u>," provides additional survey findings on information technology, coordination of care, and strategies for improving the quality of care.

<u>The End of the Beginning: Patient Safety Five Years After To Err Is Human</u> (November 30, 2004). Robert M. Wachter. *Health Affairs* Web Exclusive (*In the Literature* summary). In this article, the author assesses the impact of the landmark IOM report and advancements of the past five years, giving a 'C+' to U.S. efforts overall.