focus on Patient Safety

A NEWSLETTER FROM THE NATIONAL PATIENT SAFETY FOUNDATION®

Full Disclosure Is More Than Saying "I'm Sorry"

BY TIMOTHY MCDONALD, MD, JD, AND COLLEAGUES, UNIVERSITY OF ILLINOIS MEDICAL CENTER AT CHICAGO

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Transparency related to unexpected adverse outcomes, including the full disclosure of medical errors, is central to the current patient safety movement. Improving patient outcomes while reducing medical errors depends on learning from unanticipated outcomes and associated failures.

Candidly disclosing unexpected outcomes and providing an appropriate apology for medical errors should facilitate learning and foster the improvement process. From the professionalism perspective, maintaining the ethical imperative of honest and open communication with patients should help maintain trust between provider and patient.[1] If coupled with the appropriate rapid remedy, the properly designed disclosure process should maintain that bond.

Building an effective disclosure program

The following elements are the foundation of a comprehensive disclosure program, implemented at the University of Illinois Medical Center at Chicago (UIMCC), designed to rapidly respond to unexpected adverse events involving patient harm:

- Reporting
- Investigation
- Communication
- Apology and remedy
- Improvement

Early reporting is key

The response to any "unexpected adverse event" begins with a report to the organization's department in charge of patient safety or risk management. Reporting can occur in a variety of ways. Prompt reporting is paramount to a successful adverse event response system. Triggering early quality committee oversight, preservation of data, and timely interviews with all providers are benefits of early notification.

Another important benefit of early reporting is the opportunity to immediately hold all patient bills related to medical services while the root cause analysis (RCA) determines if error had a role in the adverse event. This provides a first remedy to patients who have sustained harm from a medical error and will play an increasingly important role as the US Centers for Medicare and Medicaid Services (CMS) rolls out its plan to withhold reimbursement for preventable events in October 2008.[2]

The new requirements state that facilities "cannot bill the beneficiary for any charges associated with [any of the 8] hospital-acquired complications."[2] Holding bills at the outset of an unexpected adverse event will facilitate this process.

> "Early reporting is paramount to a successful adverse event response system."

There are multiple barriers to reporting unexpected adverse events that should be addressed in any disclosure program, including:

- Attitudes of legal counsel in a litigious environment and predictions of runaway financial costs of disclosing.
- Fear of retribution or "shaming." Medical directors must eradicate the "shame and blame" mentality that plagues many institutions.
- The assumption that nothing will come from reporting the event.[3]

Conducting a root cause analysis

Investigations of unexpected adverse events causing patient harm must employ an RCA tool. This investigation must explore possible contributory causes of the error—issues such as policies and procedures, environment of care, equipment, medication, and personnel. A comprehensive RCA investigation requires objective content experts from

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patient care disciplines involved in the error.[4] Conflicts of interest are recognized and mitigated while the investigatory team examines the facts. During these inquiries, the team must decide whether the standard of care was breached, through either an error of commission or omission. The team must also determine whether any breach of care led to patient harm.

In addition to establishing whether an error caused patient harm, the RCA identifies process breakdowns and opportunities to improve practices or individual performance, and seeks to support those involved who struggle emotionally with what happened.[5]

Maintaining open communication

Following any adverse event, maintaining communication and the bond between care providers and patients and their families is essential while the adverse event is undergoing RCA. At this point, patients and families want to know:

- What happened?
- Will we be abandoned now that something unexpected has happened?
- Who is going to care for us or our loved one?
- Who will our contact person be on an ongoing basis?
- How and by whom will the event be investigated?
- When will someone be able to share further information with us?[5]

A patient liaison is designated to communicate regularly with the patient and family. If communication will occur over several days, there is an appropriate communication hand-off to maintain ongoing constructive contact. After each communication encounter, the parties involved debrief and reflect on the positive and negative aspects of the interaction.

Apologizing and offering a remedy

From the transparency perspective, the RCA seeks to obtain enough information to meet the expectations of the patient and/or family during the disclosure discussion. If the adverse event was the result of an error, these expectations may include:

- An apology
- An explanation of what happened in layperson's terms, including the error, if one occurred, and how it caused harm
- Assurances that high-quality care will continue
- Processes being implemented to prevent recurrences
- Accountability for the error
- A remedy or benevolent gesture

The RCA helps organizations meet these expectations during a full disclosure. A handful of organizations have implemented disclosure initiatives with a compensation component. The experiences from the Veterans Affairs Hospital in Lexington Kentucky, the University of Michigan Health System, and COPIC, a physician-directed liability insurer in Colorado, provide some encouragement to the healthcare community regarding the financial viability of a disclosure process.[6,7]

Improving the system

The true value of transparency rests with organizations' ability to rapidly learn and make changes from investigation and analysis of the errors. Organizations should consider whether to invite patients or families into the improvement process following an unexpected adverse event. This can assist in maintaining the bond between patient, family, care provider, and hospital. Potential process improvements identified should contain specific practice changes with measurable quality or safety indicators for long-term tracking of effectiveness.

Learning from mistakes

Each error disclosure provides an opportunity to improve future interactions with patients or families. Based on feedback from UIMCC patients, providers, and resident physicians, common communication mistakes that occur include:

- Incomplete disclosure
- Misleading or incomplete information prior to family/patient meeting
- Failure or difficulty in clearly explaining medical terms and events
- Not ensuring "right" persons are present for the discussion
- Finger-pointing
- Inadequate cultural sensitivity or foreign language assistance
- Failing to provide proper follow-up

Once an organization has decided on a transparent process for handling unexpected adverse events, personnel must be educated and trained. At UIMCC, a group of individuals trained in patient communication is deployed once an adverse event is reported. This interdisciplinary team undergoes regular specialized training using role-play and standardized patients to practice the art of communicating bad news and medical errors to patients and families.

Standardized patients (SPs) are actors and actresses trained to simulate clinical scenarios with pre-scripted answers to questions and to play the role of the patient while care providers are trained and assessed in communication. SPs are now the standard used to assess all medical students

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Building a Culture of Trust: Improving Relationships with Employees for Patient Safety

BY CHRIS ANDERSON, CHIEF EXECUTIVE OFFICER, SINGING RIVER HOSPITAL SYSTEM, GAUTIER, MS

Ten years ago, the reputation of Singing River Hospital System (SRHS) in South Mississippi was under attack.

The county-owned system, founded in 1931, faced a barrage of criticism from several sources. Employees and physicians at the system's 2 hospital campuses, located about 15 miles apart, often did not understand the organization's priorities or direction. Local newspapers were calling for the sale or lease of the hospital system and there was no formal communications plan addressing the many issues of concern expressed by employees, physicians, and members of the community. Further complicating the situation, the hospital system was in a bad financial position and was experiencing poor patient satisfaction scores.

The hospital system's community-based board of trustees decided the time for change had come, and charged the new chief executive officer and administrative team with the challenge of revamping the organization, overhauling the system's image, and planning for growth and success.

A decade later, SRHS ranks in the top 10% nationally in a 2007 Management Science Associates SRHS Employee Opinion Poll Survey in which employees were asked if they were proud to work at SRHS, if they would bring their families there, and if they understood how departmental success is measured. The hospital system boasts a top 3% ranking in a Press Ganey Associates Annual Physician Satisfaction Survey in which more than 200 SRHS physicians were asked to rate their relationship with administration.

Building a healthy organizational culture

The improvement in SRHS's culture resulted from well-defined strategies with measurable goals. A key strategy was to rebuild the hospital system's image from the inside out by strengthening and improving relationships with employees, physicians, and volunteers. This process can be employed in hospitals that are trying to promote change to drive patient safety work.

When a culture of trust exists in any organization, management and employees will be more likely to share a common vision, be engaged in achieving success, and participate in sharing stories to learn. This element is crucial in supporting a safety vision and the improvements that follow, and will contribute to a more reliable environment for care to

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during the active phases of their board exams.[8]
Training must consider all communication scenarios that may follow an unexpected adverse event. These scenarios may include 2 ends of the spectrum: an event unrelated to an error or an adverse event associated with a clearly preventable error—a "never" event.[5] Communication training is a fundamental part of the disclosure program.

Disclosure: The key to transparency in patient safety

Transparency related to unexpected adverse outcomes, including full disclosure of medical errors, is central to the patient safety movement. The disclosure program at UIMCC continues to evolve as it is informed by each disclosure. This comprehensive disclosure program provides a clear process to follow once an adverse event has been detected and has encouraged the adoption of a safety culture. Specialized training is required for personnel involved in the communication of adverse events to maintain trust between the provider and the patient.

One strength of the UIMCC program is the involvement of patients and their families in the investigation and improvement processes, thereby encouraging an ongoing relationship with them. Patients and their families actively participate in RCA and in designing process improvements.

Disclosure programs, if implemented in a comprehensive manner with appropriate training and education, should lead to improved processes, reduced medical errors, and engendering a safety culture in health care. **NPSF**

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be delivered.[1] If leadership and management have a positive relationship with their employees, they will take care of patients effectively. For example, retention of nurses and their feeling they are part of the team results in better patient outcomes and continued commitment to safety work.[2]

> "Hurricane Katrina helped the system further its relationship with its employees, just as leadership's management of a sentinel event can affect that relationship."

Strengthening communication

A key to strengthening relationships is a commitment to honest, open, 2-way communication throughout the hospital system. SRHS's leadership team put in place a strategic plan that supported this goal. The plan's elements included:

- Development and implementation of a fact-based, measurable communications plan.
- Emphasis by the leadership team on the importance of communications in strategic planning, creating a formal, integrated communications plan that identified metrics to measure success.
- Assignment of responsibilities to each member of the administrative team to meet annual communications goals, including speaking engagements and tours of the hospital system's facilities.
- Use of annual surveys to objectively define the success or failure of the communications initiatives.

The communications plan includes a weekly employee newsletter that highlights organizational activities and priorities, employee accomplishments, birthdays and benefits, and other items of interest. This newsletter is distributed via email, then scrolled continuously on large flat-screen televisions throughout the SRHS hospitals, clinics, and administrative offices. A more formal monthly newsletter, now in its 26th year, is distributed to SRHS's 2,400 employees and mailed to 500 community members, elected officials, and local leaders. A community report is made available to all employees and is released to an extensive community-wide mailing list. A separate community benefit report highlights the not-for-profit system's impact on the community.

Culture supports safety in times of trouble

The culture of an organization can be tested in times of distress.[3] With Singing River's strategic plan, the concerns that had become divisive in the community and the hospital system slowly dissolved. The communication tools and administration's consistent efforts at improving the hospital system's image were helping the organization regain the trust of its employees and the community it serves. Then, in August 2005, the greatest natural disaster ever to hit the United States slammed Coastal Mississippi.

Though horrendous, the disaster had a silver lining when seen in retrospect. Hurricane Katrina helped the system further its relationship with its employees, just as leadership's management of a sentinel event can affect that relationship. Katrina gave SRHS an opportunity to demonstrate trustworthiness. The storm also gave the nurses and physicians a chance to demonstrate their commitment to the community.

The extent of Katrina's impact meant that nearly all of the hospital system's employees were affected by the hurricane to varying degrees. More than 780 employees suffered substantial economic loss and/or loss of property. The hospital system provided food, water, and clothing to employees and their families in the immediate aftermath of the storm.

As basic needs were met, other, more complicated issues arose—child care, laundry, and fuel. SRHS staff drove 30 miles east to Mobile, Ala., bought washers and dryers, and set them up in the distribution and transportation warehouse. The financial services and business office employees volunteered to wash clothes for the clinical staff.

Each of the system's 2 hospitals provided child care (public and private schools were closed for over a month) by establishing an on-site day care center run by volunteer nurses from out-of-state and from SRHS. Singing River obtained 1,000 gallons of fuel from a local refinery, and financial services employees pumped gas for fellow employees. The dietary department fed employees 3 meals a day for 6 weeks for free.

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NPSF Launches Ambulatory Stand Up for Patient Safety® Program

NPSF's new Ambulatory Stand Up for Patient Safety program, launched in January 2008, offers targeted materials and resources to assist with patient safety initiatives in the ambulatory setting. The program's development was guided by expert input, including review by multiple practices and ambulatory experts.

In developing this program, NPSF sought to address the critical need for patient safety materials oriented to ambulatory care. Although recent years have seen a rapid growth in patient safety resources, these materials overwhelmingly target the hospital setting. The nature of care and the types of errors in the ambulatory setting differ qualitatively from those associated with the hospital setting. While some safety issues cut across healthcare settings, it has been argued that the fundamental differences between the inpatient and ambulatory care environments may mean that approaches appropriate for one setting may have limited applicability in the other. The Stand Up Ambulatory program addresses a significant need for patient safety resources tailored to office practices and ambulatory centers.

What are the membership benefits?

Member benefits include: the Ambulatory Member Resource Guide; access to a password-protected member web site; DVDs, brochures, and other tools and resources; access to NPSF's Current Awareness literature alert and *Focus on Patient Safety* newsletter; and free participation in regularly scheduled audio-web conferences presented by national experts and leaders in patient safety. The member web site contains a virtual copy of the guide, additional resources, and a web-based discussion forum.

The Member Resource Guide is organized around 5 sets of competencies:

1. Making the case for implementing and sustaining an ambulatory patient safety program

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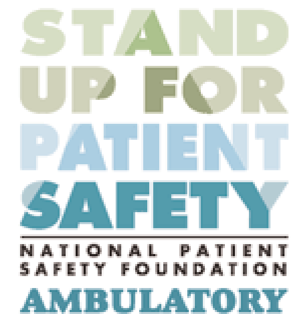

Building a Culture of Trust

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The Human Resources Department went to places where relief was being offered—the American Red Cross, FEMA, the Salvation Army—and collected all of the necessary paperwork. They then set up consultation tables at each campus so employees could stay at the hospital to complete the applications. A member of human resources submitted the paperwork as needed, thereby allowing SRHS employees to avoid hours-long waits in lines for relief.

The collective efforts of the health system employees produced valuable results that went far beyond the direct benefits provided. Collectively, SRHS built on its culture of trust as staff members cared for one another in a safe, healing environment. This, in turn, helped the staff provide care to every member of the community in their time of crisis.

The significance of SRHS in the community's recovery from Katrina has been heralded publicly. However, hospital leadership received little direct feedback from patients or their families about the services the hospital provided in the days, weeks, and months following Katrina. This may be due to the fact that there was never an interruption in those services. From the patients' perspective, Singing River's commitment to service never changed. Ultimately, that consistent commitment to the employees of SRHS has had a similar lasting impression on their morale and on the quality of care in each hospital. Creating a culture of trust is just another way of saying that an organization is continually and aggressively working to strengthen relationships and build a learning environment that supports improvement.

A recent *JAMA* commentary noted that "[U]ltimately, patient safety must be based on trust—trust between patients and their physicians and between patients and their health care teams across settings of care—trust that the system will 'first (and last) do no harm.'"[4]

The Jackson County, Mississippi area and its patient base have clearly benefited from SRHS's effort to build a culture of communication and trust. If another catastrophe should strike, regardless of size or scope, it will be met head-on by employees who are more committed than ever to maintaining a superior level of care because they know their employer will maintain the same level of commitment to them. **NPSF**

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as I see it

The Silence of the Night: A Lost Opportunity for Learning and Partnership

BY BECKY STEWARD, BSN, MANAGER, PATIENT SAFETY LEARNING COLLABORATIVE, ILLINOIS HOSPITAL ASSOCIATION

In the silence of the night, when our senses are most finely tuned to whispers of change, we—a family of caregivers—struggled with a different role: that of family to a patient, Julie. We were simultaneously allies and adversaries, qualified to assess and observe, but no longer in an environment where we were authorized to act on our knowledge.

> "We were in an unfamiliar place, trying—almost desperately—to balance our fear of losing Julie because of her injuries with our fear of losing her because of our silence."

When we were seen as allies, our presence was encouraged, our observations were explored, and we were part of the team. We could discuss the plan for management of near-fatal, multi-system trauma, and were accepted as advocates when Julie could neither speak her thoughts clearly nor retain information presented to her. When alert, she reinforced to all clinicians that we were to be fully involved.

Lost in the Sunday night shuffle

Sunday nights in a hospital have earned a reputation for being the worst time to become critically ill. Residents are committed elsewhere, and less-experienced nursing staff accept that on Sunday night, you don't call anesthesia to establish IV access—not even for a multi-trauma patient 3 days after a near-fatal accident and surgery, after which a ventilator was used for a day and a half to maintain her breathing.

Although Julie was breathing on her own, her body was holding on to 35 pounds of excess fluid, some of which was filling her lungs. The nurse contacted the physician and received orders, but Julie was not assessed by a physician—not for her crushing chest pain, shortness of breath that increased even though she was receiving oxygen, and 4 failed attempts to draw blood to determine if she was having a heart attack. Julie's nurse had no answers for us and seemed to avoid coming into the room. We sought her out to emphasize Julie needed to be seen by a physician as hourly dressing changes failed to contain drainage, chest pain persisted as color and mental activity deteriorated, and respirations could be counted by watching the trajectory of the pelvic fixators as they oscillated between Julie's knees and her ribs. Vitals could be done only as ordered, continuous pulse oximetry was not part of floor protocol, and only a physician could tell us the results of the portable chest x-ray done earlier.

Aching to partner

We sought out the RNs and communicated our observations while praying Julie's condition would be recognized. In our hearts, we knew we should call for assistance, but no official mechanism was in place for us to "sound the alarm." We wanted to be viewed as partners, not as adversaries trying to direct care based on our education, clinical experience, and professional roles.

We were in an unfamiliar place, trying—almost desperately—to balance our fear of losing Julie because of her injuries with our fear of losing her because of our silence. We were walking a fine line to honor and respect other professionals while asking for timely intervention when none was forthcoming and whispers of the need for change became a roar.

A trip to x-ray for a repeat ankle film delayed evaluation until mid-morning. Residents familiar with Julie's care commented on her improvement over the past 24 hours despite the observations we had shared. Blanket reassurances were given that someone would have acted had she really been having a heart attack, had she really needed an IV or labs, or had anything shown up on the chest x-ray.

With Julie now unable to brush her teeth due to air hunger and fatigue, we brought her nurse and a respiratory therapist to her bedside. The day shift nurse, shocked by the physical presentation and alarmed by the lack of response to our concerns, notified the head of trauma.

Within a half-hour—and without additional tests—Julie was transferred to a critical care area where a central line was placed, labs drawn, and multiple diagnostic tests performed with a ventilator ready at the bedside. Within the first hour, the Foley catheter drained 6 liters of urine, and the first of 2 chest tubes removed 1.3 liters of fluid from her lungs.

During this time, communication was non-existent until one of the residents—the same one who had dismissed our concerns that morning—provided a brief summary of the interventions in process. Residents had been tied up in the emergency department all night, she said. After all, while unfortunate that interventions were delayed, our family member did not die because of the delay. As I saw it, a series of system failures delayed the recognition and treatment of her acute respiratory distress syndrome.

Those same system failures let clinicians down, from the nurse locked in by protocol and unwritten rules, to the staff from 3 different areas who could not establish IV access or draw labs, to the resident who did not correlate the x-ray with a physical exam or question the absence of lab results.

The resident said the appropriate staff would be spoken to and disciplined. Our family did not want to punish anyone, but did want the organization to examine what had happened and develop processes to prevent it from happening again.

I asked the resident if she had heard of using a tool called root cause analysis to look at breakdowns like the one that had just happened, and explained how it could be used to prevent other patients, families, and clinicians from repeating our shared experience.

"It sounds useful," the resident said, "but it's not part of the curriculum."

Access denied

Nothing prepared us for what happened next. As a result of that conversation, the head of trauma forbade me to have further contact with any of the residents, and barred me from the ICU. For the next 7 hours, he remained in the ICU to monitor Julie and to prevent my admission to the unit. Other family members were allowed to sit at her bedside; I was not allowed entrance to the unit despite repeated requests to the physician from Julie and other family members.

Eventually, the head of trauma talked with me in a busy hallway, reminding me he was the founder of the trauma program and did not believe in wasting time on root cause analysis. His experience was vast, his residents well-trained, and who was I to challenge his care when the patient was still alive? Wouldn't I want him as my doctor?

While the trauma program and staff had saved a life very precious to us, the combination of arrogance and broken systems almost forfeited Julie's life. Both the clinicians and the organization lost an opportunity to develop an understanding of their current practice and design safer, more effective processes. As a result, another generation of physicians in the trauma program will fail to value working with patients and families as partners in their care.

When asked who I was, I told him I was the nurse and family member he'd want at his bedside if *he* were the patient. As I see it, that says it all. **NPSF**

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Ambulatory Stand Up for Patient Safety Program

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2. Creating a safety culture
3. Engaging patients and families as partners through communication and transparency
4. Managing after an event
5. Developing leaders who actively embrace the principles of a safety culture

The guide includes a comprehensive collection of articles, assessment tools, brochures, DVDs, and other tools and resources. The member web site contains a virtual copy of the guide with downloadable versions of many articles and tools. Members also have access to a real-time web-based discussion forum, and enjoy complimentary registration for regional seminars by AIG Healthcare and NPSF, an annual series addressing crucial risk management and patient safety issues.

NPSF will monitor the literature and available offerings to identify items of interest for Ambulatory Stand Up members. The member guide and the web site will be updated continually to include selected new tools and articles.

Program details and a downloadable enrollment form are available at *www.npsf.org*. For more information, please email *ambulatory@npsf.org*. **NPSF**

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If your qualified physician organization is insured by AIG Healthcare® for medical liability coverage, AIG Healthcare will support your organization's participation in the Ambulatory Stand Up program by providing a malpractice insurance premium risk management credit in the amount of the program enrollment or renewal fee. For details, call (704) 553-5027 or visit *www.aighealthcare.com*.

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Pre-Congress Programs, Wednesday, May 14

Choose from 3 sessions:

Leadership Day—Embedding a Sustainable Safety Culture: Focused Approaches for Leadership. Designed for executive leaders on the board, in the C-Suite, and in senior and mid-level management. This program focuses on the opportunities and challenges leaders face as they create and lead teams to build a culture of safety.

Patient Safety 101. An overview of patient safety theory and practice and an introduction to various approaches and techniques for detecting and reducing adverse events. This program presents essential information for anyone interested in learning the fundamentals of patient safety.

Community Engagement from the Patient and Family Perspective, For healthcare workers, community members, and patient and family representatives interested in learning how to partner effectively to improve patient safety.

For more information on the pre-Congress programs, visit *http://www.npsf.org/npsfac/pf/*.

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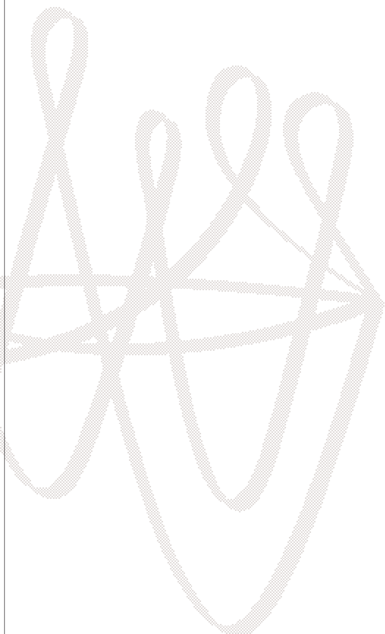

Patient Safety Congress plenary sessions

Thursday, May 15

Through the Eyes of the Patient: The Quality and Safety Imperative for Informed Medical Decision Making. Michael J. Barry, MD • Floyd J. Fowler, Jr, PhD

Lucian Leape Institute at the National Patient Safety Foundation Town Hall Plenary: Transforming Concepts for Patient Safety

Friday, May 16

A Whole New Mind. Daniel Pink, best-selling author

How Leaders Influence Learning, Collaboration, and Innovation: A Dialogue. Amy C. Edmonson, PhD • Lee A. Carter • Gary S. Kaplan, MD, FACP, FACMPE • Gregg S. Meyer, MD, MSc

For more information on 2008 Annual NPSF Patient Safety Congress, including complete Congress program and registration information, visit *http://www.npsf.org/npsfac/* or email *conferences@npsf.org.* NPSF