

# focus on Patient Safety

A NEWSLETTER FROM THE NATIONAL PATIENT SAFETY FOUNDATION

## From the Annenberg IV Conference Exploring 7 Levels of Safety

BY SUSAN RAEF, EDITOR

*More than 600 professionals—from physicians, nurses and health care administrators, to risk managers, attorneys, government policy makers and patient advocates—gathered in Indianapolis on April 22-24 for the fourth NPSF-sponsored Annenberg conference, "Patient Safety: Let's Get Practical." Internationally renowned British patient safety researcher Charles A. Vincent, MPhil, PhD, Professor of Psychology at University College London, was a keynote speaker, setting the focus for faculty and participants to bring workable patient safety solutions back to their organizations.*

**W**hat are the factors influencing risk and safety in medicine? Charles Vincent, MPhil, PhD, suggests there are seven: patients, tasks, individual staff, teams, work environment, organization and management, and institutional context. Together these factors form a framework for case analysis in search of practical ways to improve patient safety.

Vincent began with a case in point. "A young woman came into the maternity ward of a London hospital one night around midnight," he told the Annenberg attendees. "She was three centimeters dilated. The hospital staff was monitoring the fetal heart and things were going fairly smoothly. About 4:00 a.m., progress was slow; the mother was dilated to about seven centimeters, and the fetal heart was beginning to show some signs of distress. About 6:00 a.m., the physician and midwife decided to administer a drug to augment and stimulate labor. There was still fetal distress; the physician and midwife began to think the baby was too large to be born vaginally, and that they should perform a cesarean.

"The staff began to wonder if the real problem was faulty monitoring equipment; there were a number of less-than-reliable pieces of machinery in the unit. So they changed over to another fetal heart monitor, spending about an hour setting up the new unit and confirming there were indeed problems with the fetal heartbeat. At 9:00 a.m., when the senior consulting physician came on duty, the attending physician and midwife expressed their concerns about the fetal distress. The senior consulting physician—who was new on staff and had not worked extensively with the attending physician and mid-

wife—disagreed that a cesarean was advisable; she said the mother was young, and that she should try to deliver the child vaginally. The senior physician ordered the midwife to administer more of the labor-inducing drug.

### Framework for Analysis of Risk and Safety in Medicine

1. Patient factors
2. Task factors
3. Individual staff factors
4. Team factors
5. Work environment
6. Organization and management
7. Institutional context

"The attending physician and midwife were very unhappy with the senior physician's decision. As the midwife administered more of the drug to the mother, she saw the fetal heart rate decelerate. The protocol in this instance was to stop the drug immediately, which she did. But after a while, since she had been ordered to keep administering the drug, she started it again—with the same results. This continued several more times until another consultation with the senior physician mid-day. The senior physician still felt things would be OK. At 1:00, a young midwife came into the unit to take over for a short while and quickly realized the case was beyond her experience. She ran to get the senior midwife, who saw that a cesarean was needed very quickly.

"The senior midwife knew if she went to the consulting physician, there would be endless problems, so she increased the drug to the point where the fetal distress was so great that she felt justified in bypassing the consulting physician and arranging an emergency cesarean through another physician by herself. In essence, she put the baby's life at risk in order to save it. The baby was born at 4:00 p.m. after many

CONTINUED ON PAGE 2

#### IN THIS ISSUE

Exploring 7 Levels of Safety

Communication Can Mean the Difference Between Life and Death

Mediation Breaks the Wall of Silence

NPSF Names Robert E. Krawisz Executive Director

*Charles A. Vincent, MPhil, PhD, is a Professor of Psychology at University College London, and an internationally renowned patient safety researcher.*

more delays. It was a near-disaster, and everyone on the staff was very shaken.

"Most people will say the key point of the story is that the consulting physician didn't listen to the medical team," Vincent explained. "You can see this as people doing things that are less than ideal, but in case analysis, what you're really trying to do is to look at the unit that allows these things to happen.

"In this case, there was no demarcation of roles and responsibilities. When there was a crisis between the consulting physician and the other members of the team, people just froze. They didn't know how to resolve it, and it was never resolved. There was poor training; staff assumed for several hours that the problem was faulty equipment rather than a problem with the baby.

"When you assess cases, you start by looking back, but the real point of case analysis is to look to the future—or at least to the present—to say, 'What is this telling us about the system we work in?'" Vincent explained.

"Indeed, this is one of the primary diagnostic methods we have in patient safety."

Vincent used the maternity case to illustrate the need to move from a person-centered view to a system-centered approach to find the conditions that influence errors—the factors that predispose people to make errors.

"There is a tendency in patient safety to jump right over the numbers and go straight to interventions, without thinking about what lies in between," Vincent told the Annenberg attendees. "What's missing are the mechanisms—what you might call the biochemistry and physiology of patient safety—how to understand the organizational processes that might bring us success or failure."

#### How is safety achieved?

Vincent acknowledged there are two contrasting visions of patient safety, which are often at odds. "On one hand, you have an engineering view which points to the fallibility of human beings and the need to replace or support them," he explained. "It's the same view that Dell Computer had when they increased reliability hugely by going from having 20 steps in their manufacturing process where humans were involved to only seven. They tried to eliminate human involvement as much as possible, or at least support people in decision-making through technology.

"On the other hand, some say it's people who create safety

—mindfulness, awareness of hazards, anticipation—very human qualities. You see this in clinical work; people are very aware of their environment and their team, and quick to spot when things go adrift and able to rescue things at the last minute." Vincent referred to a book about Antarctic exploration. "One of the things you have to worry about in Antarctica is going across a surface that looks entirely smooth, but underneath is pitted with crevasses, huge chasms you might fall into," he explained. "That's my image of the practitioners-create-safety view—safety is achieved through your skill at avoiding the crevasses or gaps."

Where is the line between standardizing things and allowing enough autonomy and flexibility to make health systems safe? Behind this division lie human abilities and capacities." Vincent draws a distinction between error as a character flaw—which we're trying to get away from—and error as a limitation of another kind: limits of skill, memory and decision-making. Are we as smart as we think? Do we expect too much of ourselves?

"Underneath these two visions, if you're thinking about replacing human decision-making, you're more impressed by human fallibility," Vincent explained. "If you accept the practitioners-create-safety premise, you're much more impressed by humans' adaptability and flexibility—the ability to make immediate, accurate and brilliant decisions based on sometimes sketchy information, people's ability to work in teams and anticipate problems. Both of these visions have truth. The problem is, we need to look more closely on how they play out in clinical practice.

"We're now beginning to accept the limitations of memory," Vincent acknowledged. "It's inaccurate for detail, vulnerable to circumstances and interruption—particularly with today's information overload.

"Decision-making is much more difficult," he explained.

"Using the expertise vision, there's no doubt that experts build up a rich corpus of cases on which they draw. They become experts at recognizing sample signs and recognizing them more quickly than others. In any environment where you have to make fast decisions, this kind of expertise is invaluable.

"Another kind of expertise comes into play when you have a bit more time and are trying to predict something or combine pieces of information," he explained. Vincent compared two disparate examples: assessing suicide risk and assessing pediatric surgery risk.

"The essential thing is the same: the practitioner knows what the risk factors are. When you have a combination of uncertain information, it's hard to put it together. What we know about this kind of decision-making is that it's almost calculating. Research shows that people are prone to bias and inconsistency in this kind of decision-making, and are vulnerable to time pressure and fatigue. Computers, decision aids and simple rules almost always outperform humans in this kind of decision making. This has been known for a long time, but has not been widely applied to health care.

Vincent likened many health care professionals' use of this kind of decision-making to going to the grocery store, looking at the items in the cart and saying, "It looks like about \$40 worth," rather than calculating an accurate total. "Many clinical decisions, in essence, are really like that. But we don't do them like that—we do them on a "looks like \$40" basis, which is often good enough. But when you're talking about being safe, perhaps human abilities should be looked at a bit more skeptically," he said.

"When we're thinking about ways to improve clinical decision-making and judgment, we need to think about whether it should be automated the way it has been in navigation. Vincent said that when his grandfather, a World War I pilot, got lost, pilots used a system of navigation where they would fly low, try to read the name on a railroad station, and then fly along the tracks. "When my father was doing aerial navigation in World War II, they would set a course, fly around in a triangle to get wind speed, look at markers on the ground, and do various calculations offsetting the magnetic north and compass variations. It was fairly well worked out. Today it's all done by computer," he said. "And we regard that as an improvement in reliability.

"So maybe we should start thinking beyond memory and into decisions about ways humans can be supported. Whether this is a reasonable argument depends on the precise clinical activity. If we're trying to improve decisions, if time is short and there's no time for computer decision aids, we'll obviously have to rely on humans and their capabilities.

"Sometimes in dynamic environments, we can rely on machinery to make very tiny adjustments like drug dosages in intensive care. But in emergency medicine, in the middle of an operation, in a crisis in psychiatry, you're always going to need human beings. So in that case, we go to the expertise side—to enhance people's training to support and enhance their expertise. When time allows, and decisions can be framed, maybe we should start to use decision aids without embarrassment, without considering them an attack on autonomy.

"The great thing about the range of computer decision-making tools is that they're patient-specific," he said. "You can enter information about the patient and allow the computer decision aid to make complex calculations, leaving you to handle more important tasks."

Vincent offered the example of a decision-making tool used by Britain's National Health Service to determine when a chest x-ray is warranted. A computer questionnaire allows the physician to check off the patient's symptoms—cough, shortness of breath, signs of metastases, etc. On the final screen, it gives advice—it does the calculation aspect. "It supports the weakest aspect of human function, the combining of information," he said. "Notice that you need a lot of expertise to use this system well; you have to frame the problem from the start. That's not something computers are good at—getting a general idea of what the problem is. You also have to interpret the information by talking with the patient."

#### Choosing interventions: 4 diagnostic questions

1. How safe is your workplace? The most appropriate interventions are based on where your organization is now.
2. Which of the seven levels should you target? Are the foundations in place? What do you need to do before you can get into some of the more subtle interventions? Where do the problems lie in your organization?
3. Stand back from what you do and ask, "Where do we rely unnecessarily on human beings?" You can improve decision-making by using simple things, such as checklists.
4. Ask, "How can we make life easier?" "It's a question not often asked in medicine," Vincent admits. "But taking the pressure off people can help improve safety."

Vincent also stressed the need for the research agenda to move toward a study of the work process. "If interventions aren't targeted properly—if they aren't aimed correctly at either replacing human beings or supporting their decision-making—they're not going to work," he said. "If they succeed, we won't know why. If they fail, they'll fail for the wrong reasons. The question of how to target interventions is very important.

#### Both views of patient safety are needed

"Finally, the two visions of the safety movement depend on each other," said Vincent. "We need both views. The problem is not to argue about them, but to decide which one is appropriate. The real purpose of standardization is to free clinicians. The most important aspect is talking to patients and their families." [NPSF](#)

# Communication Can Mean the Difference Between Life and Death

BY GARY D. MINER, PhD

*Communication—between physicians and patients as well as among medical care providers—plays an integral role in patient safety. The following story illustrates how a series of medical communication breakdowns can end in tragedy.*

In January 1994, a physician in Mankato, Minn. diagnosed my 79-year-old mother, Mildred J. Miner, with bullous pemphigoid, a rare chronic autoimmune blistering skin disease. Her physician prescribed prednisone, and my mother continued to live alone, with her property renters checking on her daily.

Two months later, my mother was found lying on the floor at home, weak from a very large, inflamed bullous pemphigoid lesion. She was taken to the hospital, where the staff discovered that the prednisone had induced diabetes. After her diabetes was brought under control, it was thought that a nursing home would be the best living situation.

I arranged to bring my mother to a respite care center near my home in Oklahoma in May 1994. There, my mother chose a local dermatologist who brought her condition under control with minimal prednisone and topical treatments.

The nurses from the home health service gave the dermatologist reliable information so my mother's condition could be well managed without frequent trips to his office. For six years, she stayed alert, taking care of her own financial affairs and living a fulfilling life at the respite care center. Then, in April 2000, a few new bullous pemphigoid blisters appeared.

This time, a new home health nurse became the conveyor of information to the dermatologist. This turned out to be the beginning of seven errors in medical communication that ultimately led to my mother's death.

## **1. The new home health nurse did not understand bullous pemphigoid. Rather than admit her lack of understanding, she communicated incorrectly to the dermatologist.**

In late September 2000, my mother's skin lesions had gotten so bad that the respite care center took her to the dermatologist, who was "aghast and taken aback" at her condition and apologized for not having insisted on seeing her earlier. My mother had lesions around her entire chest and back, as well as on her head, neck and feet. One foot had swelled to nearly three times normal size and was almost entirely covered with lesions. I had questioned my mother many times over that several-month period as I saw the

lesions worsen, but her answer was always, "It is under the control of [the dermatologist] and the home health nurse, and they know what they are doing." I should have followed my intuition that told me something was not right.

My mother was put on 60 mg of prednisone per day—a high dose that induced shingles and sciatica so painful that it confined her to bed. Because the respite care center, by law, could not keep patients in bed for more than a few days, she was admitted to a hospital in mid-November.

## **2. Incorrect medical information was conveyed from the hospital to the respite care center.**

After having been off duty over the four-day Thanksgiving weekend, the hospitalist in charge of my mother's treatment phoned me and said, "Your mother is walking 100 steps on her walker, needs no assistance in getting up to her walker or in walking. Call me to see about a discharge back to the respite care center."

"A miracle must have happened," I told him. "I've been there every day and to my knowledge she has walked no more than 25 steps and needs help with all of her activities of daily living." The hospitalist checked the nurse's notes and said, "These notes are difficult to read, but you are absolutely right; she does need assistance and is walking no more than from her bed to the bathroom with assistance." The hospitalist admitted that my mother could not be released to the respite care center, and we agreed another week or so of physical therapy was needed.

The next day, a social worker from the hospital's skilled nursing area phoned me and said, "Your mother is walking by herself and we have telephoned the respite care center with this information; they are ready to accept her release." When she was transferred back to the respite care center, the main therapist said, "Your mother is not in the condition the hospital told us about earlier today." I had personally delivered the sheet of the hospitalist's orders. The respite care center discovered that a large number of my mother's regular medications were not included. I contacted her primary care physician, who reordered the missing meds.

## **3. Chest congestion and "racing heart" symptoms prompted re-hospitalization, apparently due to failure to continue a blood pressure medication after prior hospital release. ER misdiagnosed condition as pneumonia.**

Back at the respite care center, my mother developed what appeared to be chest congestion and a racing heart. This became so serious that by Dec. 16, she was sent to the ER,

diagnosed with pneumonia and readmitted, this time under the care of a different hospitalist. After numerous tests, the hospitalist could not detect pneumonia or chronic heart disease, and added a blood pressure medication. Apparently, on her hospital release two weeks earlier, they had forgotten to put her blood pressure medication on the list. This caused the racing heart, and appeared to have been the only reason for the second hospital admission.

My mother's condition no longer warranted remaining in the hospital, and our family contacted several nursing homes, none of which had a bed available. A social worker arranged for her to be transferred to a rehab center.

**4. The dermatologist prescribed a drug—methotrexate—that can be fatal if not monitored properly and an antidote administered within 72 hours of a toxic reaction. The dermatologist apparently failed to alert the rehab center's physicians and nursing staff to the potential dangers of this drug.**

My mother's dermatologist prescribed methotrexate, which was administered by the rehab center staff. The day after receiving methotrexate, my mother complained of nausea and was barely eating and drinking. She said to my wife and me, "I feel like I'm dying; get me out of here!"

I immediately notified the nurses that something was wrong and it appeared related to the methotrexate. Not yet knowing the seriousness of methotrexate, I mentioned to the attending physician that my mother appeared depressed, was sluggish, and was not in her normal vibrant, mentally alert state. He gave her an antidepressant.

My mother received a second dose of methotrexate on Jan. 5, about a week after the first. The following day, my family and I noticed my mother was in very poor condition. I asked the nurses if my mother's dermatologist had been called, and they said he had not.

"You need to do this immediately, and we'll do it if you can't," I told the nurses. They said they would, but I overheard them arguing about the protocol of contacting the attending physician first. I didn't see them call the attending physician, nor hear them talking to the dermatologist.

**5. The dermatologist and attending physician failed to inform the family about the risks of methotrexate.**

I had personally informed the attending physician who administered the methotrexate that something was going horribly wrong 48 hours after my mother received the first

dose. Only when I consulted *Physicians Desk Reference* (PDR) did I discover there is a 72-hour window where an antidote for methotrexate can be given to reverse one of its potential side effects: stoppage of blood platelet production.

In my mother's case, the antidote was administered 19 days after the methotrexate treatment, and only after I questioned the physician as to whether it had ever been given. Had the physician even read the PDR's warning about methotrexate?

**6. The rehab center's attending physician failed to provide a treatment history—specifically the use of methotrexate—when my mother was transferred back to the hospital.**

The hospital admitting records state, "The patient's history was vague," and it took the hospital staff several days to discover that methotrexate had been administered.

On Jan. 11, I was on my way home from the west coast. My wife had stayed at the hospital for four hours that morning; my sister was there all day. There were three calls on my home phone caller ID from the hospital; the nurses told me a doctor was calling to get signed permission to give blood platelets and whole blood. Where was the communication between the doctors and nurses? The nurses knew my wife and sister were in the hospital room with my mother and could have given that permission.

My mother was finally given blood platelets and whole-blood transfusions on Jan. 12 in a last-ditch effort to build up her blood's clotting ability. She was bleeding to death from her mouth to her rectum; her gastrointestinal tract was being sloughed off due to methotrexate poisoning.

**7. The admitting physician for my mother's last hospitalization failed to convey the need for leucovorin—the antidote to methotrexate—even though the 72-hour window of opportunity had been missed. My wife and I requested that this be tried, as did the dermatologist.**

The antidote was finally given on Jan. 18. My mother died the next day at 8:05 p.m. The hospital autopsy report states methotrexate poisoning as the probable cause of death.

What can be done to prevent tragedies like this? A pilot project in Winona, Minn. is offering to put patients' individual health management information online. "The Winona Health Online project foreshadows a not-too-distant time when many Americans will have personalized health details at their fingertips in an electronic format," says the Apr. 16, 2001 issue of *The Scientist*. While it's too late for my mother, this technology may help prevent potentially deadly errors. **NPSF**

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*For details on the Winona Health Online project, visit [www.winonahealthonline.org](http://www.winonahealthonline.org).*

## Mediation Breaks the Wall of Silence

BY JOAN E. ROOVER, JD, MSW, EXECUTIVE DIRECTOR AND DAWN D. EFFRON, JD, SENIOR MEDIATOR,  
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A new era of patient safety has begun. Never before have medical errors received more attention in the media—or precipitated more dialogue in the medical community. This openness is good news for all patients. It can ultimately be good news for health care professionals as well.

Hospitals are looking at medical errors in markedly different ways than ever before. As the Institute of Medicine's landmark report, *To Err is Human*, focuses national attention on the number of errors causing the deaths of thousands of Americans each year, hospitals are seeking ways to identify and correct flawed internal systems and procedures that contribute to error.

Many hospitals are developing blame-free reporting policies to identify faulty internal systems or procedures that contribute to error. They are reporting sentinel events to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and developing a root-cause analysis for each factor that contributed to the error. Through these analyses, hospitals are better understanding the root of medical errors and fixing them rather than erecting a wall of silence after the hospital learns of an error or adverse event.

The latest extension of this open examination of medical errors is directed squarely at the relationship between health care professional and patient. Health care professionals, for the first time, are being encouraged to talk openly with patients about medical errors that occur in their care. According to the NPSF's Statement of Principle, "When an error contributed to the injury, the patient and the family or representative should receive a truthful and compassionate explanation about the error."

As of July 1, (year?), JCAHO will require hospitals to have a system or organizational practice in place that assures that "patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."

While the prospects for improved patient care are enormous, this new era of openness is fraught with danger. Imagine how difficult it will be for doctors, nurses and health care administrators to sit down to give patients and/or family members this troubling news without any training in having these conversations.

Although many patients will be able to have constructive conversations with their health care professionals and resolve their concerns without further conflict, others will not. The danger is that these others will be left feeling they have nowhere to turn but the legal system. The already-overloaded legal system is not the appropriate venue to fix the system or address the deep concerns of the human beings—patients and professionals alike.

There is, however, an alternative to engaging in an adversarial, time consuming and costly malpractice lawsuit: mediation.

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**'Mediation provides for a confidential, privileged meeting between patients or family members and the institution and health care professionals.'**

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Just as mediation is being used to better serve the interests of parties in divorce, labor and employment disputes, it is an excellent vehicle to serve the interests of patients, health professionals and hospitals in the aftermath of medical error. Mediation provides for a confidential, privileged meeting between patients or family members and the institution and health care professionals.

The Massachusetts mediation privilege statute provides confidentiality for the mediator's statements, notes, files and other work product, and for communication by any person, including the parties to the complaint, made while in the presence of a qualified mediator.

With this confidentiality protection, the patient, family and physician talk with the help of a neutral, impartial mediator skilled in facilitating a discussion about both the facts and the emotions surrounding the incident.

Used appropriately, mediation allows the parties to identify

their interests and generate options to satisfy those interests. Experience suggests that when patients and providers work out their differences face to face, they often generate better solutions to problems. Patients feel they have more influence over the health care system, and providers emerge with a stronger commitment to implementing corrective action. Mediation can be used to resolve even the difficult issue of financial compensation for the patient or family in the event of serious injury as a result of medical error.

Mediation complements—but does not replace—strong and decisive action by regulatory agencies chartered to protect the public. Litigation may continue to be the most appropriate alternative for some people. Those contemplating litigation should, be aware however, that an award derived from the civil justice system does not require corrective action on the part of the doctor or medical system.

Litigation provides only a transfer of money—and few patients achieve even that. Mediation, when appropriate, can accomplish the transfer of money, corrective action and so much more, all without the added emotional and financial costs of litigation.

While this is a national debate, in Massachusetts we are clearing the path for this emerging alternative. In working with patients and health professionals, The Center for Health Care Negotiation, a Lexington, Mass. not-for-profit organization, brings together physicians and patients in mediation. In the experience gained from this process, three recurring needs of injured parties were identified.

1. Patients and their family members want an explanation of what happened and why it happened;
2. They want an apology or acknowledgement from the provider; and
3. They want to know a change has been made to ensure that what happened to them would not happen to someone else.

Physicians, even when initially skeptical, often leave mediation feeling they have learned something significant from seeing their practice through the eyes of the patient. They often make changes in their practice to create a safer, more sensitive patient care experience. Physicians appreciate the

opportunity to explain what happened and why, express their feelings about the error and convey an acknowledgment or apology to the patient. Litigation cannot accomplish any of this. Mediation can.

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This new openness—with patients, in hospitals and with the media—marks a fundamental shift away from the “wall of silence” that has characterized the aftermath of medical error. Our current system too often creates adversaries of patients and their health care professionals in the wake of medical error out of fear of a lawsuit. This wall of silence separates the patient and family from their professional caregivers, those who can be most helpful and informative at the time of crisis.

This new era of openness creates the opportunity to reconsider how we negotiate through the difficult terrain following medical error. Mediation is more responsive to the human dimensions of problems in the system, more geared to correcting the factors that contribute to the injury and can be an ideal process to satisfy the interests of all who are affected by medical error. [NPSF](#)

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Focus on Patient Safety  
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The opinions expressed in this publication are not necessarily those of the National Patient Safety Foundation or of its Board of Directors.

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## NPSF Names Robert E. Krawisz Executive Director

On April 17, NPSF appointed as its new executive director Robert E. Krawisz, formerly director of business development at the American Society of Quality (ASQ) in Milwaukee.

Krawisz brings executive management, marketing and quality improvement skills and insight to the NPSF. While at ASQ, he was responsible for business development and strategic planning. This included deployment of the Six Sigma breakthrough strategy in the health care, manufacturing, government and financial services industries and development of new programs aimed at improving organizational performance.

He has extensive experience in successfully leading change management initiatives, and managed the ASQ health care initiatives that propelled the organization to increased growth and further expansion of patient safety initiatives.

Prior to his tenure at ASQ, Krawisz served as assistant vice president of marketing and production at the National Safety Council in Itasca, Illinois. He significantly expanded the council's membership and revenues, helping organizations improve occupational safety and health and comply with OSHA standards. He also created an international subsidiary to improve safety in several major global regions.

Krawisz has also held senior management positions with Comprehensive Accounting corporation, United Equitable Insurance Group and Illinois Central Gulf Railroad.

"I am delighted to welcome Bob to the NPSF," said Carol A. Ley, MD, MPH, chair of the NPSF Board of Directors. "His integrity, experience, and astute sense of safety and leadership issues will drive NPSF's mission and objectives ahead." **NPSF**

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