

focus on Patient Safety

A NEWSLETTER FROM THE NATIONAL PATIENT SAFETY FOUNDATION

AHCPH's Research: Working to Reduce Errors in Health Care

BY JOHN M. EISENBERG, MD

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A YEAR AGO, THE PRESIDENT'S Advisory Commission on Consumer Protection and Quality in the Health Care Industry recommended that the health care system make reducing medical errors a top priority. The Commission noted that "a system of continuous quality improvement committed to preventing errors and correcting them when they do occur is a vital step in improving the quality of care in the United States."

Beginning with the landmark work of Lucian Leape and his colleague David Bates, the Agency for Health Care Policy and Research (AHCPR) has helped build that system of continuous quality improvement. AHCPR supports and conducts research to identify why errors occur, tests systems and processes for avoiding preventable errors and develops measures for evaluating and improving error rates.

The American Medical Association and The National Patient Safety Foundation (NPSF) are making an important contribution by helping the nation's health care leaders and providers—as well as the public—to recognize that errors exist, that we can learn from them and thereby reduce them.

The Quality Commission and NPSF have gone beyond blaming the individual clinician for an error, and have looked at the failure of the system in which the clinician operates as the root of the problem. AHCPR-supported research reveals that errors can occur at several points in the health care delivery system:

- **Medication errors.** In one study of inpatient care in two tertiary care hospitals, errors in ordering and administering medicines accounted for 56 and 34 percent, respectively, of preventable adverse drug events. Another study showed that dosage errors, in particular, were primarily due to the physician's lack of knowledge about the drug or about the patient for whom it was prescribed.
- **Diagnostic inaccuracies.** Incorrect diagnoses may miss serious conditions or lead to unnecessary additional

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testing, which may be costly and sometimes invasive. Inexperience with technically difficult procedures can also affect the accuracy of results. One study showed that physicians who performed 100 or more colonoscopies (a test used to follow up on abnormal Pap smears) per year had more accurate findings than those who performed the procedure less often.

- **Inaccurate information recall.** Patients sometimes fail to recall pertinent health facts, and treatment decisions made without accurate health-related information can have unfavorable consequences. For example, when researchers in one study asked patients to recall their cholesterol readings, participants, on average, recalled their levels as being lower than they actually were.
- **System failures.** Investigators in a major study discovered that failures at the system level were the real culprit in more than 75 percent of adverse drug events. The researchers concluded that any effort to reduce medical errors in an organization would require making changes in system design, including commitment of resources by top-level management.

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AHCPR is working to translate these research findings into practical solutions to correct system-wide failures. For example, the Agency is supporting several initiatives to develop computer-assisted decision-making tools and reminder systems for clinicians, such as a statistical correction factor to help clinicians more accurately choose between two diagnostic technologies for a particular condition—such as an MRI or a CT scan. The National Guideline Clearinghouse (www.guideline.gov) is a new web site that provides evidence-based information to assist decision-makers.

AHCPR is also working in partnership with NPSF to co-sponsor conferences and forums creating awareness of the issue of medical errors and patient safety in the health care industry. These conferences are eliminating the culture of secrecy that often surrounds medical errors, and fostering a more collaborative atmosphere among health professionals aimed at reducing errors and improving health care quality. AHCPR also recently sponsored the first Executive Session on Medical Errors and Patient Safety, a meeting of key individuals to lay the groundwork for future research on the role of systems redesign in addressing medical error.

Earlier this year, AHCPR launched a new initiative, the Centers for Education and Research in Therapeutics (CERTs). The CERTs will conduct research to increase understanding of ways to approve the use of pharmaceuticals and other interventions and to avoid adverse drug events. The CERTs will also add to our knowledge of possible risks of new uses of drugs and drug combinations as they are prescribed in everyday practice.

AHCPR is pleased that research it has supported and conducted, and its partnership with the NPSF have fostered a broader understanding of the nation's safety problems, where they occur in health care delivery, and how we can best address them. However, this is only the first step. This collaboration can also ensure that policy makers and care providers use the research findings to reduce medical errors and improve the quality of health care services.

It would compound medical error to make the researcher's error of declaring success when research is published. Publication is only one step toward impact; translating research into practice is AHCPR's highest priority. The Agency looks to its partnerships to put research to work for improved health care—and through improved health care, improved health. **NPSF**

Annenberg Center President Mark Eppinger, 52

Mark Eppinger, president of the Annenberg Center for Health Sciences at Eisenhower Medical Center and a driving force behind its growth and development, died Feb. 21. He was 52.

Eppinger died at Eisenhower Medical Center in Rancho Mirage, California following a long battle with cancer.

He had been with the Annenberg Center for Health Sciences since its founding by the Hon. Walter H. Annenberg in 1981. Eppinger was a leader in developing the Center into America's premier facility for providing health care education to consumers, medical practitioners and other health care providers throughout the world.

As Annenberg Center President, Eppinger was involved in strategic planning, educational programming and business development. He was dedicated to the Center's vision to be a leader in using communications technology to assist science, research, education, government and industry in addressing issues vital to health and science.

He brought to the Annenberg Center far-reaching conferences, teleconferences and educational programs affecting the future of health care, including: the "Apnea of Infancy" international conference (16 consecutive years); "Visiting Faculty in Interferons;" "Women and Heart Disease;" "Alternative and Complementary Therapies;" "Caring for an Aging America," the "Annenberg Forum on Senior Health Care," and "Enhancing Patient Safety and Reducing Errors in Human Care."

Eppinger believed strongly in exhibiting kindness and support for his staff and employees. Under his leadership, the Center developed into a major force in health care professional education, public wellness, patient education and improving the economics of care.

He is survived by his wife Colette and son Bennett of Palm Desert; his mother and stepfather, Virginia and John O'Steen of Palm Desert; and his sister Jane Walter of Atlanta.

A memorial service was held on Feb. 25 at the Annenberg Center. Donations may be made to a trust established for his son. For information, contact Donna Lavoie at the Annenberg Center at 760-773-4553. **NPSF**

Researching Errors in Surgery:

Five Analytical Tools Borrowed from Industry BY KENNETH A. KERN, MD

NPSF RECENTLY ANNOUNCED five \$100,000 research grants offering opportunities in injury and error prevention. These research grants are of great interest to surgeons, since they are in a unique position to address these issues. Indeed, surgery itself can be defined as a controlled injury to the patient.

Surgical adverse events and errors remain a constant source of patient morbidity, excess cost and litigation. While the total frequency of adverse events involves less than 4 percent of hospital admissions, their impact on the patient and supervising physician may be of enormous magnitude. A review of jury verdict reports from August 1998 reveals a wide range of surgical errors resulting in profound patient injuries and high compensation payments. Examples:

- Complete severance of the cervical esophagus during correction of a Zenker's diverticulum due to incorrect use of a surgical stapler (\$3 million verdict in Georgia).
- Abdominal abscess, fistulization and bowel necrosis resulting from retained sponge after abdominal surgery (\$1.7 million verdict in Kentucky).
- Hernia operation under general anesthesia performed on the wrong side, requiring the patient to be awakened from anesthesia to discuss the correct hernia location (confidential settlement in Utah).

While such events result in costly and time-consuming negligence suits, a more ominous movement has begun toward criminalizing medically negligent physicians by prosecuting them as perpetrators of criminal homicide. Clearly, preventing errors and adverse events in surgery should be a high priority for surgeons.

Prevention efforts begin with a systematic, objective and quantifiable analysis of how surgical adverse events and errors occur. Traditionally, surgeons have expressed interest in understanding adverse outcomes through discussions at morbidity and mortality conferences. While these conferences have educational value, the clinical information discussed is limited in scope, confidential (protected by peer-review standards), and thus rarely used to address broad changes needed to prevent errors in everyday practice.

Prevention efforts begin with a systematic, objective and quantifiable analysis of how surgical adverse events and errors occur.

Given these inherent limitations, the American College of Surgeons (ACS) has long advocated systematic, hospital-wide programs designed to improve patient care and reduce preventable patient risks. The College's approach to patient safety has been outlined in two publications available to surgeons: *Patient Safety Manual* (1979 and 1985) and *Professional Liability/Risk Management: A Manual for Surgeons* (1991). The strategies envisioned by the College emphasize a collaborative effort between a hospital's management staff and its surgeons to identify, evaluate and reduce or eliminate preventable patient risks. This type of risk reduction program falls under total quality improvement (TQI) or continuous quality improvement (CQI).

TQI or CQI is now a nationally recognized standard for ongoing, broadly based quality assurance in patient care. Until recently, however, analysis of specific adverse events and errors in surgery has not drawn on the vast body of work in human and system error analysis from other industries such as airline safety or nuclear regulation. These safety-oriented industries have drawn on scientific work and analytical tools to understand sources of error in human performance and systems operations.

Adverse event analysis has its earliest roots in evaluating combat performance during World War II. These performance evaluations have evolved into complex research programs now applied in an attempt to understand industrial and aviation disasters such as the nuclear power plant failure at Three Mile Island or the Challenger launch explosion.

Five research tools used by other industries to analyze adverse events and error hold much promise for improving patient safety in surgery:

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Adapted from "The National Patient Safety Foundation: What It Offers Surgeons," Bulletin of the American College of Surgeons, November 1998; 83:24-27,46.

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Improving the Quality of the Medication Use Process: Error Prevention and Reducing Adverse Drug Events

EDITED BY ALAN ESCOVITZ, PHD, DEV S. PATHAK, DBA, PHILIP J. SCHNEIDER, MS, FASHP
REVIEWED BY SHARON CONROW, DR.PH

book review

John Iglehart recently noted that expenditures for prescription drugs are the fastest-growing component of personal health costs in the US, representing 8.2 percent of total expenditures or \$78.9 billion in 1997. Not surprisingly, the risks of being harmed as a result of pharmaceutical use have also increased, becoming a national policy issue for legislators, accreditors, federal agencies and purchasers.

Against this backdrop, *Improving the Quality of the Medication Use Process: Error Prevention and Reducing Adverse Drug Events* (Haworth Press, Inc., Binghamton, NY, 1998, ISBN 0-7890-0458-5) is a timely addition to the bookshelf. It contains chapters on a broad range of issues and topics, including etiology of drug events, reporting systems, preventing errors, external regulatory and oversight programs, use of computerized error reduction strategies, and roles for professionals and consumers in reducing drug events.

The origin for this book was the 42nd Annual Ohio Pharmaceutical Seminar, held at Ohio State University in 1997. While there is growing literature on the identification, reporting and prevention of drug events, this volume is unique because it also examines public policy and regulatory issues in some depth.

Henri R. Manasse, Jr., for example, chronicles the rocky road of medication safety public policy. He notes, "Altruistic societal interests that lie at the heart of governmental programs and objectives are sometimes at loggerheads with marketplace agendas of the private sector." His candid and wry observations about the politics of change and the vested interests delaying drug safety improvement efforts challenge policy makers, regulators and professionals alike. While the public is often awed by gains in medical technology, Manasse points out that it is a two-edged sword.

He asserts that public safety cannot be assured because growth in new technologies "... vastly exceeds our current ability to assess, on a premarketing basis, the products' full effects and their deadly interactions with other medications."

Later chapters examine the roles and responsibilities of

federal regulatory agencies, accreditation organizations, voluntary oversight bodies and the pharmaceutical industry. Taken as a whole, some disconnects are evident. For example, the chapter describing the US Pharmacopoeia (USP) medication error reporting system notes that approximately one quarter of the errors reported to USP involve similar-sounding names; many examples are cited. In his chapter, Lucian Leape notes that in 1960, there were 650 approved drugs—compared to 9,000 in 1996. As new drugs are introduced, names are proposed by manufacturers, and reviewed and approved by the FDA. The question remains, why do easily confused drug names continue to cause injuries to patients in the US?

The editors examine the bedside origins of adverse drug events from several perspectives. Lucian Leape provides an excellent summary of weaknesses inherent in the medication use process and, more importantly, the failure of traditional "blaming" approaches to injury prevention. He chides the health care industry for its complacency regarding error rates that would be wholly unacceptable in industries such as banking, manufacturing or aviation.

Dr. Leape is a champion of applying safety practices from other industries to health care. He offers several compelling examples of errors caused by human factors including fatigue, information overload and memory lapses. Human factors are often ignored in health care—often with predictable and tragic results for both patients and professionals. Dr. Leape takes a pragmatic approach; he advocates acquisition and dissemination of information on root causes of errors, redesign to minimize reliance on human performance, and automated systems when they demonstrate superior error prevention properties.

Several authors comment that improving medication safety is often a challenge because of delayed problem detection or fear of reprisal for disclosure. Professionals are embarrassed by errors, often preferring to find fault elsewhere, or to argue that the incident is an isolated event. In his oft-cited *Harvard Business Review* article, "Teaching Smart People How to Learn," (May-June 1991:99-109), Chris Argyris identifies this response as a particular vulnerability of professionals. He argues that because professionals are usually successful, they don't develop skills for dealing with

or learning constructively from errors. Rather, they are much more likely to attribute the problem elsewhere. Lucian Leape, echoing Argyris, comments that doctors, nurses, pharmacists and health care people in general do not deal well with errors, preferring to blame or to punish. Important systems issues are overlooked and left uncorrected. Too often, investigation of errors can become a cycle of blame between physicians, nurses and pharmacists, or attributed to staffing patterns, reimbursement practices, non-compliant patients, etc. While there are elements of truth in these assertions, what's often missing is joint or shared accountability that involves all parties in designing and implementing the medication use system. Charles Myers, in his chapter on reducing adverse events, argues that interdisciplinary teams promote shared accountability and avoid or minimize some of these pitfalls.

This book describes the detection, reporting and analysis of drug errors from several perspectives. The FDA's MedWatch program, the USP medication errors program and the still-evolving JCAHO sentinel event reporting policy are described. Barriers that decrease the effectiveness of these surveillance and monitoring programs include individual and institutional concerns about discoverability of data, confidentiality, and protections from retaliation or prosecution. While some protections currently exist, several authors call for expansion of laws providing immunity to individuals and institutions filing error reports to encourage full and early disclosure of errors.

The patient's voice is heard in the chapter by Victor Cohn, former science editor for the *Washington Post*. While he decries the often incomprehensible "patient information" inserts from pharmaceutical manufacturers, he also brings a refreshingly practical perspective to the issue of responsibility for preventing errors. Along with professionals and the pharmaceutical industry, Cohn holds patients and their friends, relatives and companions accountable for preventing drug errors. He argues that these individuals need to have a basic understanding of which drugs are being taken and why, their possible side effects, and what should be done if side-effects are observed. Cohn advises patients to question when they are offered medications that look unfamiliar, and to request an explanation. In effect, he proposes a "Patient Bill of Rights" for medication safety, spreading the burden of responsibility for safety to *all* parties involved in the process.

Medical informatics is a dynamic field. Intermountain Health Care's (IHC) computerized medication and disease management system brings hope that dramatic improvements can be realized through this mechanism. One of its designers, Stanley L. Pestotnik, describes the evolution of this system and the heartening improvements it has produced. The system, designed with and by clinicians, has

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evolved into a disease management tool, as well as a medication error detection and prevention program. It is able to trace each event back to its root cause, including the cost of treating the patient as a consequence of the error.

Pestotnik reports reduced lengths of stay and hospital costs, as well as substantially lower numbers of ADEs (adverse drug events) and ADRs (adverse drug reactions). He notes that before the system was introduced, 42 percent of ADEs were due to excessive dosages in patients with renal dysfunction. Medical informatics reduced this type of error by 60 percent. IHC's system is one of the best in the country, and represents a substantial investment of capital and human talent. One large California purchaser coalition is calling for incorporating this type of computerized physician order entry system into California hospitals as part of its ambitious quality improvement platform. The full benefit of medical informatics systems will not be realized, however, until they are horizontally integrated to create unified profiles of drugs received by patients from *all* sources.

In discussing the role of pharmacists in preventing adverse effects, Susan Winkler identifies two additional issues:

1. The industry lacks a standard set of criteria identifying when the pharmacist needs to be alerted. Consequently, different systems alert or edit on different issues. If more than one set of criteria are operating, redundant or conflicting alerts may be received for the same prescription.
2. A related issue is that there are no standards for prioritizing these edits or alerts—so the pharmacist may be flooded with alerts and begin to routinely ignore them. Winkler calls this the "right-hand syndrome."

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To order a copy of *Improving the Quality of the Medication Use Process: Error Prevention and Reducing Adverse Drug Events*, call Haworth Press at 1-800-429-6784.

Improving the Quality of the Medication Use Process CONTINUED FROM PAGE 5

book review

Despite these limitations, computer applications hold great promise for reducing adverse drug events and reactions, as shown by the results reported by Pestotnik, Leape and others in the literature.

The editors have created an interesting, informative volume certain to be of interest to a broad audience.

This book is notable for the range and variety of presentations included in its 15 chapters. In the rapidly expanding literature of medication error prevention, it is particularly useful for understanding the evolution of public policy, professional roles and responsibilities, approaches to error reporting, and policies of regulatory and voluntary oversight agencies. **NPSF**

Researching Errors in Surgery CONTINUED FROM PAGE 3

1. The Critical Incident Technique is a standard qualitative research methodology comprising a set of procedures for obtaining descriptors of human behaviors critical to outcomes in a defined area of interest. For instance, in studies of critical incidents in anesthesia, investigators defined critical incidents as human errors or equipment failures that could have led or did lead to an undesirable outcome ranging from increased hospital stay to death. Interviews of physicians were conducted by non-anesthesiologists who derived data without patient and physician identifiers. This innovative and non-confrontational technique produced a set of descriptors of critical incidents and associated factors; their analysis and integration allowed the investigators to establish a set of strategies for preventing anesthesia-related mishaps.

2. The Sentinel Event Investigation analyzes unexpected patient outcomes using "root cause" methodologies. Objective: to uncover latent conditions in a system which lead directly to adverse events, independent of specific human performance. According to psychologist and human factors expert J. Reason, human beings contribute to organizational accidents in two distinct ways: (1) by committing errors and violations of well-defined rules and performance standards—termed "active failures;" and (2) as a passive consequence of poorly designed and inherently unsafe management and organizational processes—termed "latent conditions." Active failures have an immediate impact on patient safety; latent conditions lie dormant in the system until activated. Once latent conditions are identified, they can be corrected before they lead to mishaps.

Root-cause analysis seeks to uncover latent conditions through a variety of analytic tools, such as taxonomies of causal factors. Examples: the Events and Causal Factors Chart developed by the National Transportation

Safety Board for reporting airline accidents, and the Failure Mode and Effect Analysis required by the FDA to investigate adverse drug events and failures of medical devices. Root-cause analysis objectifies the principle that all systems and organizations create errors as an unwanted by-product of routine activities.

3. The Human Factors Process. Following the nuclear reactor accident at Three Mile Island in the late 1980s, the Nuclear Regulatory Commission began to recognize human error as central to the events leading to the catastrophe. This episode led nuclear plant operators to develop a systematic analysis of human errors, the Human Factors Process (HFP). HFP is based on the idea that human error is simply a deviation in operator performance from an accepted or agreed-upon standard. Human error is seen as the result of a mismatch between a system's human performance requirements and what humans can reasonably be expected to accomplish. Human factor problems are defined as tasks which humans in a system are not likely to perform to the level required by the system itself. HFP identifies errors due to lack of components in the system needed to support the expected performance. Example: the absence of sufficient training to allow operators to reach a high level of relatively error-free performance.

4. Error Management Strategy. The FDA has taken the approach that it cannot prevent people from making errors—so it will attempt to reduce or eliminate the opportunity for a particular error to occur. In error management strategy applied to medical devices, specific design requirements are instituted to prevent the possibility of errors. The goal is to eliminate the possibility of a critical error. For example, modern anesthesia machines cannot have all oxygen turned off; they always deliver at least 21 percent oxygen. This error-management strategy

CONTINUED ON BACK COVER

How Do Patient Safety, Quality Improvement and Consumer Participation Interact?

BY SUSAN WAGNER, MPH, CHES

LAST NOVEMBER, the NPSF board of directors held an educational session during its meeting at the Annenberg Center for Health Sciences. The objective: to map the interface among three movements in health care—patient safety, quality improvement and consumer participation. The dialogue moved into uncharted territory, provoking lively discussion on many complex issues. There was not necessarily agreement among all panelists on each of the following points:

Information in consumers' hands does make a difference.

To help consumers make informed decisions, we must:

- Elevate the level of public discourse and availability of information to consumers;
- Increase public attention to and involvement in discussion of health care quality, allowing consumers to use information both at the policy level and as patients on the personal level;
- Change the underlying tone and content of the dialogue among providers, patients and insurers;
- Create an environment of candor, pushing back barriers to honesty and patient involvement; and
- Recognize consumers as full partners in health care.

Unlike all other industries, the health care market

seems not to be driven by quality. By imparting information to consumers about the quality reputations of health care systems, can we expect quality to become a driving force in the health care market? There are potential flaws in depending on consumers to drive quality improvement:

- Many consumers do not have a choice in who provides their health care. Do we risk creating a two-tiered system—one of high quality for those with choice and one of lesser quality for those without it?
- For those who do have a choice, the choice is at the health plan level, not the medical institution or physician level. Health plans cannot directly improve processes related to quality and safety.
- The health care industry does not fully understand what consumers perceive as quality indicators—and has not fully investigated what is important to consumers because there is no economic incentive to do so.
- Is the number of people who use information about health care quality sufficient to drive the market?

'The level of energy and commitment to quality and error reduction at the grassroots level is awesome.'

A pursuit of quality, spurred by professional incentives, will positively affect the type of care that all patients receive. The most important reason to reduce errors is not to contain costs, but because health care providers are to "first, do no harm."

The level of energy and commitment to quality and error reduction at the grassroots level is awesome. Physicians, nurses, pharmacists and others at the sharp end understand the systems approach to safety, and are capable of redesigning those systems where necessary. The will to change and improve is there. The knowledge base, ideas and technical issues for improving systems exist and continue to grow. What's lacking: support from the top.

How do we drive out mediocrity in health care? What can we learn from other systems that engage in processes to avoid or eliminate mediocrity?

- There is much more to be gained by focusing on systems rather than individuals. Focusing on individuals leads to a blaming culture.
- Institutional processes must be adopted and implemented to help all health care professionals avoid making mistakes.

To the extent we can use organizational models that bring professionals together in collaborative ways toward excellence, there is potential to improve quality for all. A recurrent design characteristic found in safer systems is a high level of cooperation and teamwork—such as involving pharmacists centrally in the processes related to dispensing medication.

To continually improve, the patient safety agenda must include the two-thirds of the health care work force who are not physicians or nurses. The health care and patient safety community must continue pursuing patient safety on two fronts: knowledge and the will to improve. **NPSF**

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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.

To submit articles to, or publications for possible review in, Focus, please direct materials to: Lorri Zipperer, Managing Editor, Focus on Patient Safety, National Patient Safety Foundation at the AMA, 515 N. State Street, Chicago, Illinois 60610. Materials, inquiries and subscription requests for the publication will be accepted electronically at npsf@ama-assn.org or via fax at 312-464-4154.

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resulted from instances of anesthesiologists mistakenly shutting off oxygen flow valves instead of the nitrous oxide valves at the end of a general anesthetic.

5. Crew Resource Management draws on the airline industry's experience in developing effective teamwork to improve safety. Its focus: improving communication methods among primary and secondary team members. In applying this methodology to patient outcomes in an intensive care unit (ICU) setting, one study concluded that part of the difference in mortality between patients in ICUs was directly related to the level of interaction and involvement between physicians and nurses.

Research Example:

Does fatigue lead to increased critical incidents in surgery? The role of fatigue in causing human error has been the focus of several recent studies using some of the analytical tools listed above. Bates and colleagues evaluated adverse drug events in an ICU setting. (*JAMA* 274:29-34, 1995) They documented that medication errors did not recur due to individual fatigue, stress or distraction. Rather, medication errors resulted from latent errors in the dispensing sys-

tem itself, such as lack of a discernible difference between bottles of highly concentrated or dilute potassium chloride.

In contrast, Rosekind and colleagues have documented the important role in error prevention of an educational program on sleep deprivation, fatigue-related degradation of performance and countermeasures. (*Journal of Behavioral Medicine* 21:166-70, 1996) The divergent results of these two studies alone document the controversy surrounding the significance and possible contribution of fatigue to human errors in medicine. Given that resident workloads in teaching hospitals are being reduced on the assumption that fatigue alone—and not latent system errors—is directly causing errors in surgery, the need for further research on this topic is critical.

Error Prevention: Awareness is the Key

Research in error prevention has clearly shown that technology itself may trigger human error if machine and system designs do not account for characteristic "error-prone" human behaviors. A new awareness of error prevention as a science, with research opportunities as offered by the NPSF, will hopefully lead to important advances in preventing patient injury in clinical medicine. **NPSF**

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