

# focus on Patient Safety

A NEWSLETTER FROM THE NATIONAL PATIENT SAFETY FOUNDATION®

## Lessons from the Sharp End: Critical Components of Successful Patient Safety Work

BY MICHAEL LEONARD, MD, DIRECTOR OF PATIENT SAFETY, COLORADO PERMANENTE MEDICAL GROUP

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Successful patient safety work has to address and incorporate factors related to the culture of medicine, the systems supporting care, and the human factor—how highly trained clinicians work in a highly complex environment.

### Engaging the culture

A basic tenet of medical culture is that well-trained individuals will deliver error-free performance if they are paying attention and trying hard. So deeply rooted is this belief that clinicians link their sense of clinical competence and personal self-image with the absence of error. Even in highly trained individuals, inherent human limitations and the complicated nature of clinical care virtually ensure that mistakes will be made.

Educational perspective around these issues is extremely useful in helping practitioners realize “it isn’t them,” ie, a personal failing.<sup>1</sup> Rather, the problem is that the “game” has changed into a rapidly paced, multitasking environment full of distractions, interruptions, and potential potholes.

### The limitations of human performance—a few examples

- **Limited memory capacity.** The human brain can hold five pieces of information in short-term memory. A busy clinician—with the pager going off, talking on the phone, and trying to talk with two people at once while conveying patient information—can easily exceed the capacity of his or her short-term memory.<sup>2</sup>
- **Negative effects of stress.** Human performance degrades in the face of significant stress. In a relaxed environment, clinicians can choose the correct medication off the shelf 99.9% of the time, but with a “blue” patient on the floor, the error rate may be as high as 25% in performing the same task. Stress also increases the risk of developing tunnel vision—not being able to see the forest for the trees.<sup>2</sup>
- **Fatigue.** Though doctors being on call all night and nurses working double shifts is commonplace, fatigue impairs the ability to process complex information and care for patients. After 24 hours without sleep, cognitive performance is equivalent to a blood alcohol level of .10%.<sup>3</sup>

- **Distraction and interruptions.** Today’s clinical care environment is very fragmented. If a clinician is interrupted during a critically important task, it takes a very formal cue to turn attention back to the original activity.
- **Multitasking.** Humans have limited multitasking ability, as evidenced by the substantial increase in auto accidents seen in drivers talking on cell phones.

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Knowing that human performance will never be perfect, the challenge is to keep the inevitable mistakes from becoming consequential and harming patients and practitioners. Working collaboratively and communicating effectively to keep fellow clinicians and patients safe is the best answer.

### Structuring the conversation on system change

How the conversation on system change is structured has a dramatic impact on the chances of successful implementation.

- **Culture is critical.** Approach the issue of change from the bottom up. Anything perceived as top-down will immediately be rejected. If the culture is not on board, it will do anything necessary to subvert change.
- **Focus on the common goal or desired state.** Keep the conversation de-personalized and non-judgmental.

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- **Rule number one is always “What’s in it for me?” (WIIFM).** The people doing the work need to see an upside. “We’re trying to make your day a little safer, simpler and easier” is a good message.
- **Engage the expertise of the people doing the work.** No one knows it better than they do. If successful, they will “own it”—the critical difference between something being “the flavor of the month” and achieving lasting improvement. If the expertise is seen as externally derived, there’s a substantial risk that the conversation will turn to, “You don’t understand how we do it around here. We’re different.” All politics are local.

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### ‘Rule number one is always “What’s in it for me?” The people doing the work need to see an upside.’

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- **Let’s fix the systems so good people can work safely.** If it were being built today, how should it be done differently? What gets in the way of delivering optimal care?

#### Applying practical skills and tools

The common goal of applying these skills is to enhance communication. Communication failures are not only the most common cause of patient harm, but also detract from the quality of the daily experience for people delivering care. Practical skills and tools include:

- **Briefings**—structured, efficient conversation for effective communication;
- **Assertion**—a model where junior team members can and will speak up if they see something going wrong;
- **Situational awareness**—keeping everyone on the same page;
- **Expert-novice decision making**—acknowledging that experts rapidly problem-solve by pattern-matching against a large library of experience, while novices use a slow and error-prone problem-solving approach;<sup>4</sup> and
- **Debriefing**—an opportunity for individual, team, and organizational learning after delivering care.

Though an in-depth discussion of these skills is beyond the scope of this article, they have been used extensively in safety work.

#### Selecting projects

- **Have a crystal-clear focus and be limited in scope initially.** Otherwise, it is easy to lose focus and become overwhelmed, given the complexity of care processes.
- **Have discrete goals.** Take one bite of the elephant at a time.
- **Obtain a finite time commitment from team members.** It is much easier to get people to “try this for a month” than to agree to permanently change at the start. If it works, they’ll do it indefinitely.
- **Employ frequent measurement and feedback.** People need to see the fruits of their labors.
- **Consider WIIFM**—Make the day a little easier for the people doing the work.

#### What determines implementation success?

- **Is the culture ready for change?** A response of, “How do we make it happen?” is a strong predictor of actual change and success. “Interesting, we’ll think about it,” means the culture is not ready. Spend time and energy where it will be most productive. It’s always possible to come back.
- **Sponsorship is key—from both senior leadership and physicians.** Active physician buy-in is critical for success. If you don’t have it, you’re swimming upstream.
- **Map the landscape for allies and potholes.** Think about the people who will be involved in the change, and whether they will support or hinder the work.
- **Use local solutions for local problems.** Every care area in medicine has a unique culture; the solution has to fit or it will not be accepted.
- **Involve the people doing the work in developing the solution.** Anchor the change using practical skills embedded in what they do every day.

Creating lasting change in patient safety is a complex task. A systematic approach that engages the culture, provides tools and perceived benefits, and skillfully manages the conversation will be most successful. **NPSF**

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# Distinguishing Patient Safety Quality Improvement Activities from Clinical Research

BY TRACEY L. KLEIN, JD, REINHART BOERNER VAN DEUREN, SC, MILWAUKEE

Differentiating between quality improvement studies and clinical research involving human subjects is essential if an institution is to ensure compliance with applicable state and federal laws regulating the conduct of research involving human subjects, as well as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy regulations, or the privacy rule.

Quality studies have become very important in shaping the delivery of healthcare services in hospitals and healthcare systems. These studies are typically designed to improve care provided to patients in a hospital or health system by refining and enhancing clinical guidelines and practice parameters. In the patient safety context, quality studies could include:

- Studies aimed at reducing medication errors in chemotherapy;
- Studies to assess the effectiveness of different approaches for prevention of nosocomial infections; and
- Studies to determine the impact of computerized alerts and reminders on the effectiveness of various clinical protocols.

Quality studies may also involve randomizing patients to different modes of standard treatment. In many contexts, it is increasingly difficult to distinguish quality studies—even in the patient safety context—from clinical research. Alternatively, those needing access to health information for clinical research may choose to use health information that has been de-identified through one of three methods proposed under the privacy rule.

## Compliance with HIPAA's privacy rule requires institutions to distinguish quality studies from clinical research

What are the requirements for conducting quality studies and clinical research involving protected health information (PHI) under the HIPAA privacy rule?

Healthcare providers subject to the privacy rule, referred to as *covered entities*, may use or disclose PHI for purposes of treatment, payment, and healthcare operations after obtaining a patient's written acknowledgement of the covered entity's notice of privacy practices. Use of PHI for any purpose other than treatment, payment, or healthcare operations, with few exceptions, requires the provider to obtain the patient's specific written authorization.

Under the privacy rule, the term *healthcare operations* includes the conduct of quality studies not intended to produce generalizable knowledge. Providers may thus access PHI to conduct quality studies with a patient's written notice acknowledging the covered entity's notice of privacy practices.

In contrast, clinical research falls outside the definition of healthcare operations. After April 14, 2003, researchers or providers who wish to access PHI to conduct clinical research must satisfy a series of burdensome administrative procedures. With few exceptions, PHI may be obtained or accessed for clinical research only in the following circumstances:

- Specific and written authorization has been obtained from the patient; or
- A waiver of the authorization requirement has been obtained from an internal review board (IRB) or a privacy board.

Unfortunately for researchers, in addition to satisfying one of the above-described requirements for accessing PHI for clinical research, covered entities also need to track the disclosure of information used in connection with certain clinical research projects to produce an accounting of such disclosures on the request of an individual.

The significant differences in the HIPAA compliance requirements for quality studies versus clinical research underscores the importance of determining whether an activity involving the use of PHI is a quality study or clinical research before conducting the activity. Given the substantial monetary and criminal penalties associated with privacy rule violations, institutions now have an additional incentive to appropriately regulate the conduct of these types of activities in their facilities.

## HIPAA raises the stakes for compliance liability

While research compliance has been and remains a significant quality concern for institutions conducting clinical research, the advent of HIPAA significantly raises the stakes in terms of compliance liability for institutions. Providers are well advised to evaluate whether their current policies and procedures are adequate to address the need to identify and distinguish between quality studies and clinical research.

## How do government regulations define research?

The US Department of Health and Human Services (HHS)

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# Distinguishing Patient Safety Quality Improvement Activities from Clinical Research

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human subject protection regulations, the applicable Food and Drug Administration (FDA) regulations and the privacy rule all define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Available HHS and FDA guidelines pertaining to the distinction between quality studies and clinical research are similar in that both evaluate the intent of the person conducting the study.

## How are quality studies defined?

Most federal regulators contend that a quality study is an intervention designed to improve the health of a specific patient or group of patients. They view clinical research, on the other hand, as an intervention designed to measure the efficacy of a new approach on a particular symptom or illness with the intent to publish the results to create a generalized standard. In this context, the focus of clinical research is on the impact of the intervention and the sharing of the results, rather than the particular improvement of the health of a particular patient or group of patients.

## What are the guidelines for distinguishing clinical research from a quality study?

How can institutions determine whether an activity should be categorized as a quality study or clinical research? Taken together, HHS and FDA guidelines suggest that any one of the following factors may be sufficient to render an activity clinical research rather than a quality study:

- The goal of the activity is to test a hypotheses or answer a research question to create generalizable results. However, modifying clinical protocols for use internally in a health system based on a quality study does not constitute generalization.
- The activity will primarily benefit people other than those who receive care at the institution in question.
- The intent is to publish the results for public distribution outside the institution conducting the study.
- The researchers anticipate public recognition of the study results.
- The activity requires the patient to undergo additional medical procedures than otherwise would be required.
- The activity requires randomization of patients to different modes of treatment.

- The study involves alteration in dosage level or route of administration of an approved drug or biologic and such alteration significantly increases the level of risk to the patient.
- The intent is to report the results to the FDA as a well-controlled study in support of a new indication for use or in support of a change of labeling or advertising for a drug or biologic.
- The activity alters the timing or frequency of standard medical procedures.
- The activity involves use of a significant risk device for any purpose other than in accordance with its label.

## Are quality studies exempt from federal regulation?

The FDA expressly states that it does not regulate the practice of medicine, even if it involves use of an approved drug or biologic for an unlabeled indication. This position is reinforced to the extent that a physician can point to medical literature that supports the off-label use of the drug or biologic for treatment purposes.

In this context, the FDA equates a clinical therapy intervention used by a physician on a group of patients to the practice of medicine. Consequently, the FDA views quality studies, including those used involving the off-label use of medications, as the practice of medicine and, therefore, exempt from FDA regulations.

## Clinical research requires IRB review and approval

If a study is clinical research, IRB approval is needed. The study will also have to comply with many federal regulations. Determining whether approval is required is always based on the specific facts and circumstances. It is highly recommended that institutions consider establishing a streamlined mechanism for the IRB to review quality studies or categories of quality studies to determine whether conducting them is exempt from the IRB's jurisdiction.

Both the FDA and HHS caution against leaving the determination of whether a study is a quality study or clinical research in the hands of the investigator. It is strongly recommended that health systems educate physicians on the legal distinction between quality studies and clinical research, and establish a mechanism for the institution's IRB to make the final determination. [NPSF](#)

# Fruits of an Early Harvest: NPSF-Funded Research Yields Results

BY JEFFREY B. COOPER, PhD, CHAIR, NPSF RESEARCH PROGRAM

This is a pivotal time for the NPSF Research Program. After five years of sponsoring independent, investigator-driven research grants, 18 projects have been funded and eight completed. More than 500 letters of intent have been submitted to the Foundation, proposing various mechanisms to improve patient safety.

In 2002, NPSF teamed up with the American Medical Association (AMA), the Commonwealth Fund, and the Donaghue Foundation to award nearly \$300,000 for three new research projects aiming to improve patient safety. NPSF recently evaluated 150 letters of intent to conduct research and development in patient safety; 17 finalists have been invited to submit a full proposal for a 2003 research grant.

The collaboration among NPSF, AMA, the Commonwealth Fund, and the Donaghue Foundation demonstrates the deep desire to improve patient safety through support of research—especially in uncertain economic times. This partnership allows the organizations to make a greater impact on patient safety research together than they could as separate entities.

## What has been gained from the Research Program support?

The very nature of research—especially from investigators in the early stages of their careers—is that it is difficult to identify a specific path between one project and an ultimate outcome. Yet, among the eight completed projects and even in several projects still under way, a few important outcomes are finding practical applications.

The completed projects have generated more than 43 journal publications and about as many presentations by the investigators. Researchers have identified at least one important new direction for patient safety research and intervention, and several research tools have been refined. The careers of many new investigators and new patient safety research teams have been established—many of whom are already leaders in patient safety or fast becoming such. This was one of the main goals of the NPSF Research Agenda, and it is satisfying to see it being realized so soon.

Reports of the investigators and testimonial letters show that the Foundation's support has been pivotal to the careers of several individuals and to establishing new centers of research and action in patient safety.

## Research teams increase understanding of patient safety

The Dartmouth Hitchcock Medical Center team, led by George T. Blike, MD, has brought the important topic of pediatric sedation safety to the attention of a large audience of clinicians. Conferences, newsletters, publications, and the now-thriving research effort were catalyzed by NPSF funding.

More recently, the patient safety efforts of some University of Virginia surgeons have created a promising new voice and leader in patient safety—J. Forrest Calland, MD—who is now a third-year surgical resident after having completed a three-year fellowship. Dr. Calland has committed his career to patient safety, spurred by the two NPSF grants on which he is an investigator. That group is doing groundbreaking work on the use of video recording in the operating room to study various aspects of surgical team effectiveness and safety interventions.

Another surgeon, Richard J. Novick, MD, at the London, Ontario Health Sciences Center, has produced what may prove to be seminal work in tracking the learning curve of surgeons performing new procedures. Bruce L. Lambert, PhD, at the University of Illinois at Chicago, has made important contributions to understanding errors due to “look-alike-sound-alike” drug names, as well as developing effective prevention strategies.

The established team led by Colin Mackenzie, MD, and Yan Xiao, PhD, at the University of Maryland Shock Trauma Unit, has made further progress in understanding human performance in the emergency room. They contend that their NPSF support was pivotal in gaining further, much larger funding for their important, widely recognized research.

In a similar vein, Matthew B. Weinger, MD, at the University of California, San Diego, leveraged NPSF support into substantial federal funding on topics related to the basic work being done with NPSF funding.

Management scholar Jenny Rudolph, PhD, of Boston University, is a good example of how this funding has attracted creative research minds from disciplines outside of health care to work on patient safety problems. Her cutting-edge work on understanding fixation error has brought her into a career that promises to yield significant contributions. These and other research award recipients represent the new generation of leaders in patient safety. **NPSF**

*Jeffrey B. Cooper, PhD, is director of biomedical engineering for the Partners Healthcare System, Inc. in Boston, and Associate Professor of Anesthesia at Harvard Medical School. In the 1970s, he led the early studies of human error in anesthesia that helped catalyze that specialty's patient safety movement.*

*He is chair of the NPSF Research Program, founder and executive director of the Center for Medical Simulation in Boston, and a founder and executive committee member of the Anesthesia Patient Safety Foundation. Contact him at [jcooper@partners.org](mailto:jcooper@partners.org).*

# The DeHavilland Moment: Accepting the Need to Embrace Uncertainty

BY JEFF BROWN, PRINCIPAL, SYSTEM SAFETY GROUP

At the age of 20, I worked as a float plane pilot in northern Maine. One calm morning, as I began a take-off run from the cove that my company shared with other float plane operators, a pilot was conducting a pre-flight inspection of a DeHavilland float plane on the west side of the cove.

Abeam of the DeHavilland, I began to shift the floats from a “plow” position low in the water, to a position where the floats could accelerate across the water’s surface like a speedboat. As I did this, the airplane suddenly snapped 90 degrees to the left, heading directly toward the DeHavilland. I cut the throttle, released the water rudders, and kicked the left rudder pedal, barely clearing the DeHavilland’s wingtip.

While embarrassed, what bothered me most was that I didn’t understand why I had lost control during a maneuver I performed daily without difficulty. Clearly, if I intended to survive the season, I needed to figure out why this happened.

My theory, after some research, was that I had attempted to shift the center of buoyancy forward too soon, before the air rudder was effective. I had committed a “knowledge-based” mistake.<sup>1,2</sup> Over the next few years, I had additional opportunities to plumb my knowledge deficiencies, and witnessed preventable accidents and incidents in which inadequate or flawed knowledge, procedures, or skill were a factor.

These experiences ultimately led me to collegiate aviation education where, I reasoned, flight safety could be improved by providing novices with a better foundation in the essentials of their craft. My reasoning proved partly sound, but substantially naïve.

## Foiled by complexity and uncertainty

One summer afternoon during my first stint as an administrator in a college aeronautics program, an instructor lost control and crashed with a student during a sudden change in wind velocity, or shear, on approach to landing. The instructor’s recovery technique failed, in part, because the published approach speed for the aircraft was too low—a misprint by the manufacturer. An error made years earlier, in a distant place, crossed time to subvert an appropriate response to a deadly situation.<sup>3</sup>

A subset of factors in this accident included the manufacturer’s flawed information, instructor inexperience with the aircraft type, and an airport with unusual windshear

potential. Additionally, the instructor had been rapidly upgraded to teach in an advanced aircraft because of an instructor shortage. She had many students and had been working to maximum flight time limits for two weeks. In addition to the fatigue associated with this schedule, she had supervised 32 landings in four hours at the time of the accident.

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**‘The belief that one mind can anticipate and manage all that may happen in complex systems is profoundly dangerous..!’**

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Frequent repetition of any process without a serious glitch can lead to loss of vigilance. While the instructor’s recognition of the windshear and her appropriate response were a testament to her vigilance, the conditions under which she was required to work were nonetheless a setup for error and accident. In this and other mishaps, unsafe conditions often arose as side-effects of decisions about resource allocation, work processes, and technology acquisitions. These decisions were made not only by front-line operators and managers, but by senior leaders responding to a variety of economic and regulatory pressures.

Eventually, I realized that safety is not wholly dependent on the character and competency of one person. The belief that one mind can anticipate and manage all that may happen in complex systems is profoundly dangerous—an artifact of low-technology, craft-based endeavors.<sup>4</sup>

## Coping with complexity and uncertainty

Ultimately, flight safety is shaped by multiple individuals, disciplines, and entities in a broadly distributed system. The functioning and reliability of the humans and machines in such complex systems can never be wholly apparent—operational surprises can come from any quarter at any time, interacting with local vulnerabilities to precipitate failure. If we accept the notion that one mind cannot perceive all that is happening in complex systems, we also accept that we exercise judgment, make decisions, and take actions with substantial uncertainty about what factors may be afoot to

foil our intentions.<sup>5</sup> Perhaps the best we can do is establish the “theory of the situation” we are managing, and develop a plan that includes tolerances and contingencies that help us detect if it isn’t working out, and to adapt our actions.<sup>6</sup>

In the late 1970s, findings shared at a NASA-sponsored conference suggested that airline accidents might be limited if—contrary to tradition—not only captains, but all crew members were engaged in situation assessment and management.<sup>7</sup> Crew Resource Management (CRM) methods were developed for this purpose: to harness intellectual resources and promote effective managerial monitoring and backup.

As CRM techniques evolved, so did administrative controls that probe front-line environments for the emergence of hazards and error-provoking conditions. Confidential safety reporting programs and routine shift debriefings, for example, provide intelligence on front-line performance factors. These programs yield data which can fuel measurable, proactive safety intervention programs.<sup>8</sup>

While the aviation industry is generally perceived as being ahead of health care in managing complexity and risk, like health care, it is prey to endemic economic, legal, and cultural forces that can drive regression to a less-protected, less-reliable state. No complex human endeavor is ever out of the woods.

### What are the implications for health care?

During the six years I have collaborated in patient safety improvement initiatives, I have frequently experienced *déjà vu*. To a striking extent, healthcare professionals are wrestling with safety factors that pose ongoing challenges for aviation. Yet, it would be naïve to assert that health care and aviation are mirror industries evolving at a different pace.

The practice of medicine and delivery of health care are more complex and uncertain than engagement in flight operations. Intervention for the improvement of patient safety requires not only measured adaptation and implementation of methods from other industries, but the development of process and technology innovations unique to health care.<sup>9</sup>

To this end, health professionals in training will require grounding in safety sciences. The recently released Institute

of Medicine report, *Health Professions Education: A Bridge to Quality*, asserts the need to redesign education and training processes for health professionals.<sup>10</sup> Just as professionals are collaborating across industries to develop organizational interventions for the improvement of patient safety, it is desirable for educators to collaborate across industries to co-develop curricular interventions and innovations.

Some aviation educators, for example, have significant experience with methods of establishing error-limiting practices in professional primacy—not as an add-on to traditional education, but as part of the experiential fabric of curriculum.<sup>11</sup> And learning will flow in multiple directions; efforts to improve patient safety will likely inform and transform approaches to safety in all industries. The compassion, ingenuity, and commitment to human welfare embodied by healthcare professionals is what keeps our struggling healthcare system as safe as it is. There is no better collection of minds to advance the science of safety. **NPSF**

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### Sharyn Wilson Woods Joins Staff

Sharyn Wilson Woods is NPSF's new manager of marketing communications. She comes to us after nearly five years of communications consulting, work with A.T. Kearney in marketing communications, and a wealth of other experience from nonprofits and corporations. Sharyn has a degree in journalism from Northwestern University and has taken courses toward an MBA at the University of Chicago.

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### 'Integrity and Accountability in Clinical Research' Conference Rescheduled

The Integrity and Accountability in Clinical Research conference has been rescheduled for Nov. 2-4, 2003 at the Renaissance Washington DC Hotel. Please visit the conference website for updated information and to register: [www.saferesearch.org](http://www.saferesearch.org).

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