

FORUM

VA HEALTH SERVICES RESEARCH & DEVELOPMENT

OCTOBER 2001

DIRECTOR'S LETTER

As FORUM goes to press, the nation mourns for the victims of the tragic events of Sept. 11. We know that our country will respond and that the brave men and women of our military will be called upon to serve. They will be tomorrow's veterans. For all of us within VA, it is our honor and privilege every day to serve America's veterans and their families with dignity and compassion. Through our work, we too serve America.

Enhancing our capacity for this work, I am pleased to announce several new HSR&D Centers: the Rehabilitation Outcomes Research Center for Veterans with Central Nervous System Damage at the North Florida/South Georgia VAMC, which is the first Center jointly funded by HSR&D and the Rehabilitation Research Service; the Center for Health Equities Research and Promotion, affiliated with the University of Pittsburgh and the University of Pennsylvania; and a new QUERI Coordinating Center based at the Minneapolis VAMC that will focus on colorectal cancer.

In addition, five Research Enhancement Award Programs have been funded: ■ Patient Safety: Safe Mobility for Frail Elderly and Persons with Disabilities, Tampa VAMC ■ Center for Quality Improvement Research, Cleveland VAMC ■ Program for Interdisciplinary Research in Health Care Organization, Iowa VAMC ■ Information Management for Patient-Centered Treatment, Roudebush (Indianapolis) VAMC ■ Enhancing VA Health Services Research in Patient Centered Care, VA San Diego Healthcare System.

I believe each of these centers will make important contributions to the health care of our veterans.

John G. Demakis, M.D.
Director

COMMENTARY

Promoting Patient Safety at VA: Learning from Close Calls

By James P. Bagian, M.D., P.E., Director
VA National Center for Patient Safety

Patient safety is a fundamental tenet of VA care. The goal is to ensure that patients experience optimal outcomes — without unintended consequences or side effects that undermine their health or security. While patient safety has always been a priority for VA, during the past few years we have refocused our approach. We have shifted the VA's emphasis from punishment to prevention, and, in doing so, have engaged VA health care professionals who are eager to provide better and safer care for their patients.

Patient safety gained a national spotlight in 1999 with the release of a landmark report, *To Err is Human: Building a Safer Health System*, by the Institute of Medicine (IOM). This report attributed tens of thousands of hospital deaths per year to medical error. These figures became the subject of considerable debate, but the point was clear: Patient safety, by any measure, is a substantial problem that requires immediate attention.

Fortunately, VA had a head start in addressing the issue. More than two years before the IOM report, VA established the Patient Safety Improvement Initiative, which had at its core an internal reporting system designed to capture reports of sentinel events, close calls, and other adverse events.

After less than a year, it became obvious that this reporting system was not identifying VA's vulnerabilities and necessary preventive actions as well as had been hoped. In 1998, VA convened the Expert Advisory Panel for Patient Safety System Design and charged it with the task of finding ways for VA to better identify system-level vulnerabilities and use this information to reduce or eliminate these vulnerabilities.

Learning from Close Calls

Perhaps most importantly, the Panel concluded that reports alone do not improve patient care. The actions we take based on what we glean from reports are what make a difference. The Panel also identified the importance of looking at "close calls" — events or situations that could have resulted in accidents, injuries or illnesses, but did not, either by chance or through timely intervention. Close calls are important because they present opportunities to learn without the pain of an actual mistake.

Consider this example: Mr. Jones is admitted to a VA hospital to have an arthroscopy on his right knee. Hospital staff prep and drape his left knee. Fortunately, someone catches the mistake and Mr. Jones receives the correct pro-

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COMMENTARY

Commentary

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cedure. Staff may discuss the close call briefly, but the incident won't be investigated or reviewed. Three months later, this same mistake actually happens — that is, an arthroscopy is performed on the wrong knee of another patient. The staff members involved discover that their colleagues nearly made the same mistake with Mr. Jones. But because Mr. Jones wasn't injured, everyone simply breathed a sigh of relief. The event wasn't recognized as a systems problem — and a learning opportunity. Nothing was learned, and the next patient suffered instead.

Close calls present opportunities to learn without the pain of an actual mistake.

If the staff taking care of Mr. Jones had taken the time to address possible system-level issues — such as appropriate patient and surgical site identification — raised by their close call, this second incident could have been prevented. The lesson is that close calls offer the best opportunities for learning because they occur more frequently than sentinel events, people don't get hurt, and staff members can discuss them more freely than adverse events where someone actually suffered. The old saying that experience is the best teacher has a flip side — experience is also the most expensive teacher, and our patients bear the brunt of the cost when we make a mistake.

The Panel recommended building a patient safety system with learning — not accountability — as its core purpose. Accountability has an important role in any organization, but it is not an effective way to accomplish learning.

Prevention, Not Punishment

Accordingly, we focused our efforts on creating a system that promotes personal responsibility and professional respect and engages health care professionals in a cooperative, participatory learning process aimed at preventing adverse events. The approaches we devised are designed to encourage health care professionals to report adverse events and close calls without fear of reprisal and with the assurance that the information they report will be used to improve patient care.

We revised the internal reporting system, adding to it a well-defined analysis process with a number of cognitive aids and computer-assisted tools for preventing adverse events through systems-level solutions. We also provided intensive training and mentoring throughout the program rollout and beyond. As a result of these efforts, the number of close calls reported has skyrocketed. More significantly, the solutions developed by analyzing these incidents have had a tremendous impact — worldwide in some cases.

Despite these efforts and results, it was clear that fear of reprisal remained a barrier to full reporting. That is why we created a complementary system administered outside VA.

In May 2000, VA partnered with the National Aeronautics and Space Administration (NASA) to develop a voluntary, external system based on NASA's highly successful Aviation Safety Reporting System (ASRS). This collaboration ultimately resulted in the VA-NASA Patient Safety Reporting System (PSRS), which is currently being rolled out nationwide in the VA. NASA, acting as an objective external third party, is responsible for administering the PSRS, which has been designed as a completely confidential reporting system that permits VA staff to report a range of incidents without fear of repercussion. This system supplements

the internal system and acts as a safety valve so that vulnerabilities that would otherwise go unknown can be identified. Unlike VA's internal system, the PSRS is not designed to come up with systems-level solutions but to catch those otherwise unknowable vulnerabilities. Solutions must be formulated through activities separate from those of the PSRS.

Two crucial features of the PSRS assure staff confidentiality and promote learning:

■ **Confidential Reporting.** It is important to note that reports are not submitted anonymously because NASA may follow up with the reporter to get the most accurate picture possible of the systems-level vulnerability. But because NASA administers the system for VA, no VA personnel are involved in the processing, analysis, or handling of these reports before they are stripped of *all* identifying information.

■ **Narrative Reporting.** Unlike checklist reports, narrative reporting by users provides more information and permits a richer understanding of the context in which the event occurred. This helps identify system vulnerabilities.

Reports supply the fuel that powers VA's patient safety improvement effort. If vulnerabilities aren't recognized, they can't be addressed, and it is in mitigating these flaws that we produce true value. If we fail to convert the information we gather from events reporting into preventive actions, there is little point in continuing reporting these events at all.

Next Steps

Where do we go from here? Within the next year, we are embarking on several exciting initiatives, including the Failure Modes and Effects Analysis (FMEA), aggregated reviews, and national Root Cause Analysis (RCA) software rollout. These activities get us into prospec-

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RESPONSE TO COMMENTARY

VA's Approach To Ensuring Patient Safety Is Responsible — and Realistic

By Rodney A. Hayward, M.D., HSR&D Center of Excellence, Ann Arbor

Ensuring patient safety is an ethical and moral obligation for all health care providers and organizations. Although some statistics about the number of deaths due to medical errors are undoubtedly exaggerated, no one should doubt that the problem is very real.

Efforts to ensure and improve patient safety are still in their early stages. Among the questions yet to be fully answered: What are the definition and scope of patient safety? How should patient safety initiatives interface and overlap with quality monitoring and improvement? What is the best way to implement a coordinated patient safety program?

To remain a leader in patient safety, the VA is continuing to refine its approach to safety monitoring and to learn from its early experiences. Most importantly, it is adapting its methods based on what appears to work best. For example, the VA National Center for Patient Safety is currently soliciting information on "close calls," rigorously evaluating safety concerns, and seeking out research partnerships with HSR&D. These developments reflect the VA's emphasis on understanding the nature of serious safety problems and on the need to carefully evaluate the merits of proposals designed to decrease preventable adverse events.

At the same time, we must be cognizant of the difficulties and risks involved when intervening in a complex system like medical care. It is much easier to identify problems with the current approach than it is to design a better system. We must carefully consider whether a proposed system or policy change will truly decrease the risk of patient harm — without excessive costs, complexity, disruption, and, most importantly, with-

out creating new problems that may be worse than the original problem.

Defining Feasible Goals

Analogies frequently are drawn between patient safety and air traffic safety. In some cases, where the error under question is egregious or catastrophic, these analogies are on target. For example, we must try to reduce to zero instances of amputating the wrong leg or administering a fatal dose of medication. These represent the type of rare but unacceptable events sometimes encountered in air transportation safety.

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However, many of the safety problems that we face in medicine are more analogous to ground transportation safety. Although preventable adverse events are common, it is unrealistic to think that they can be eliminated completely. Yes, setting the speed limit to 5 miles per hour could probably prevent most motor vehicle deaths, but that solution is simply not feasible.

Similarly, some of the most common safety problems found in large medical studies can be substantially reduced, but they cannot feasibly be eliminated. Most studies evaluating patient safety have identified patient vulnerabilities related either to very high-volume practices or complex issues that could make pursuit of zero errors virtually impossible and even counterproductive. Common problems that lead to preventable mortality and morbidity include delays in medica-

tion dispensing, confusion during cross-coverage of patients, decisions involving patient transfer or discharge, diagnosis, and choice of treatment. To address these types of complex problems, collaboration and coordination among the National Center for Patient Safety, the Office of Quality & Performance, and HSR&D are likely to be very important.

The first step toward improving safety and quality is to recognize and accept achievable safety goals. Given the resources that we have available, we must try to reduce these problems, but we must also realize that pharmacists, nurses, clerks, and physicians are already working extremely hard, and that whatever patient safety systems we develop must consider this fact. The most effective systems will be those that make it easier for people to avoid serious mistakes without disrupting their busy days. If we create redundant or reminder systems that make it substantially harder for health care professionals to do their jobs, these systems will probably be ineffective and possibly even harmful.

The patient safety movement represents a wonderful opportunity for us to improve medical care. We should all be proud of the leadership and innovation that the VA has provided in this area. However, participating in patient safety is everyone's responsibility. No patient safety or quality improvement system will work unless we help foster a culture of quality and safety. The new emphasis on prevention, rather than on punishment, allows us a better opportunity to actively help each other improve health care. No one should be persecuted for making a mistake, but each of us has a moral responsibility to try to make health care better and safer.

R ESEARCH HIGHLIGHT

Using Indicators To Prevent Hospital Medical Errors: Case Study Illustrates the Importance of Validation

By Timothy Hofer, M.D., M.Sc., VA Ann Arbor Healthcare System

In order to prevent medical errors, we must know where we as providers of health care services are vulnerable. Indicators for monitoring the delivery of health care services allow us to do that — to see where there are flaws or problems in the system and address them before a patient is hurt.

Unfortunately, although we have managed to produce reams of guidelines and, in some cases, retrospectively explore the reasons for bad outcomes, we have been less successful in developing indicators that alert us to potential process-of-care problems. There is a simple explanation for this. In order to develop a reliable process-of-care indicator, you need clear, research-based evidence of a link between process and outcome. Little such evidence exists. In addition, there is a need for more generic indicators that assess quality of care across diagnoses for some of the sickest patients seen in hospital settings, where the intensity of care raises the risk of problems in the process of care.

Examining Adverse Outcomes

Our goal in the Laboratory Abnormalities Project was to develop a set of indicators for efficiently identifying and monitoring five preventable, hospital-acquired adverse events. More broadly, we sought to delineate a general methodology for developing and validating new indicators of hospital quality of care and to identify the challenges to developing indicators for the many clinical areas where experimental evidence on relationships between process and outcome is lacking.¹

Our study had three components:

(1) Based on the literature and a pilot study, we selected adverse

events that could be considered indicators of poor quality care and measured how frequently they occurred.

(2) An expert panel identified and ranked the importance of a comprehensive set of specific process measures causally related to the development of the adverse events. We then developed a list of key processes to look for when these events occurred.

(3) Using a matched case control design, we tested the association between specific processes of care and specific adverse events.

Effective quality indicators must either directly measure or be clearly linked to definable processes of care.

We selected five hospital-acquired adverse events where poor monitoring or inattention play key roles: hypokalemia, hyperkalemia, hyponatremia, acute renal failure, and digoxin toxicity.

Iatrogenic electrolyte disorders and drug toxicity occur frequently, at rates ranging from 0.3 percent to 2.8 percent of hospitalizations. The frequency of these adverse events increases substantially — fivefold to fifteenfold — among patients in the highest quartile of relative treatment intensity. However, even controlling for treatment intensity, less frequent monitoring of drug or electrolyte levels and measures suggesting inadequate response to milder levels of electrolyte disorders were highly predictive of these adverse outcomes.

A case control study showed that

failure to perform key processes of care was associated with a twofold to threefold increase in the rate of developing an adverse event. Looking at our results, the process problems that occur most frequently involve inadequate response to milder degrees of hyperkalemia and hypokalemia. This finding suggests that alerting providers to these milder events could help prevent the more serious events. More centralized interventions — like stop orders for medications and automatic consultation by clinical pharmacists or specialty services — might also be effective.

Validating Indicators is Key

However, we also found that the process indicators for prevention of renal failure were *not* associated with hospital-acquired renal failure. This finding may be even more instructive because it underscores the importance of conducting validation studies before disseminating quality indicators. We identified several process problems that appear on clinical grounds and in the view of a national expert panel to be critical to the development of hospital-acquired renal failure. Yet these problems occurred as frequently in a group of control patients who did not develop renal failure in the hospital.²

This example clearly shows that developing quality indicators may be a complete waste of time unless they are validated. At this point, we still have no evidence that higher rates of hospital-acquired renal failure or digoxin toxicity are associated with more in-hospital process problems in the management of drugs, fluids, and electrolytes.

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R ESEARCH HIGHLIGHT

Adverse Drug Events: The Harder You Look, the More You Find

By John F. Hurdle, M.D., Ph.D., and Jonathan Nebeker, M.S., M.D., VA Salt Lake City Health Care System
Geriatric Research, Education, and Clinical Center

Late in 1999, the Institute of Medicine (IOM) released its now famous report, *To Err is Human*. This document caused an uproar, focusing physicians, politicians, and patients alike on the staggering number of medical misadventures that occur routinely in this country. It underscored with dramatic and convincing data how universally under-appreciated medical errors were.

The VA has been consistently well ahead of the curve on patient safety, as evidenced by the fact that fully two years before the IOM report hit the streets, the VA's HSR&D was preparing a call for proposals on patient safety research initiatives.

In response to that call, a team at the Geriatric Research, Education, and Clinical Center in Salt Lake City proposed to mount an epidemiologic and economic study of inpatient adverse drug events (ADEs), in order to characterize the extent of the problem and to define clinically rational intervention schemes.

The key outcome of this work lies in its ability to pinpoint prevention strategies.

The research team began with a thorough literature review of pertinent articles from the past 10 years (with some exceptions for often-cited articles). This review made it clear that inpatient ADEs were a problem; what was not clear was the extent of the problem. A report by the U.S. Government Accounting Office on ADE incidence (GAO/HEHS —00-21) issued

in 2000 is illustrative: It cites articles that determined ADE rates ranging from 0.56 per 100 admissions to more than 30 per 100.

There are few clinical syndromes where the literature routinely offers a fifty-fold variation in incidence. The research team recognized three confounders that accounted for this variation:

- 1) Little consistency in how ADEs were *defined*.
- 2) Little consistency in how ADEs were *detected*. (There are five main categories of detection techniques: spontaneous reporting; computer-based screening; case review by a pharmacist, physician, or nurse; patient interviewing; medical records/ICD9 review; and various miscellaneous techniques. The studies reviewed by the research team used one or more techniques simultaneously for ADE detection.)
- 3) Little consistency in how the ADEs were *classified and described*.

The research team's goal was to remedy each confounder in ways that were explicit, consistent, and clinically sound. The researchers adopted the World Health Organization's *definition* of an ADE and modified it by adding criteria that emphasized clinical significance, as well as by adding explicit inclusion and exclusion rules to deal with the dozens of common variations not easily accommodated by the standard definition.

The researchers then put in place a *detection* scheme that stressed the most sensitive ADE detection techniques described in the literature, emphasizing clinical pharmacist case review, patient interviewing, computer-generated alerts, and retrospective ICD9 code review.

Each suspected ADE was reviewed by a panel of two physicians, two clinical pharmacists, a Ph.D.-trained nurse, and a Masters-level interviewer. This panel reviewed each component of the *classification* form, an eight-page instrument that lists more than 120 data items (covering drugs involved, clinical syndrome, clinical response to the ADE, causality, severity, preventability, and error analysis).

This combination of explicit definition, multiple-detection signals, and thorough classification and analysis is unique in the study of ADEs.

The researchers turned up far more ADEs than they had expected. They reviewed 939 admissions (out of 2,036) from Aug. 14, 2000, through Dec. 31, 2000.

Observation and research study patients were excluded. Using their definition of an ADE, which favors clinically significant events, the researchers found that:

- only a small percentage of the ADEs were mild;
- most were moderate (not self-limited and requiring treatment); and
- a significant portion were severe (required additional hospitalization or led to a hospitalization or caused permanent harm or death).

The researchers found no systematic bias by gender or race. Complete results will be published later this year. While it is important to know that ADEs are more common than expected, the key outcome of this work lies in its ability to pinpoint prevention strategies. Since each adverse event is thoroughly characterized,

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LEGAL PERSPECTIVE

Patient Safety at the VA: Five Lessons in Prevention from Tort Claims Experience

By Suzanne C. Will, Regional Counsel, San Francisco

In fiscal 2000, the U.S. government paid more than \$185 million for settlements and judgments to claimants in medical malpractice cases, including \$68 million paid out by the VA. In many cases, a serious or tragic result for a patient can be traced to a failure to follow VA's patient safety rules. A disproportionately large number of these failures involve nursing homes and mental health units.

The Regional Counsel offices investigate tort claims involving VA medical facilities throughout the country. Following are some observations concerning five common types of safety violations that we have encountered during the past five years. The cases cited here could easily have been prevented; indeed, we think of them as lessons in prevention. *(To protect the privacy of patients and others, the facts of the following cases have been liberally modified and are based on composites of several claims that illustrate specific safety issues.)*

#1 Lifting Rules. A local nursing service lifting policy required at least two staff members to assist in lifting, transferring, or turning a heavy or immobile patient. This safety rule has a dual purpose: It prevents the ubiquitous back injury for staff and ensures that the patient will not end up on the floor. People in a hurry tend to forget these rules, which is what happened with a licensed VA nurse (LVN) who couldn't wait until a second person was able to join him. The patient had quadriplegia secondary to advanced multiple sclerosis and was considered an immobile patient. The LVN knew that the patient was light and thought that he could easily handle him alone. He didn't take into consideration, however, that the patient's

advanced disease made his body stiff and unwieldy. The nurse lost his grip on the helpless patient, who fell solidly on his head, resulting in the patient's death several days later. *Lesson learned: Never second-guess a patient safety rule.*

Lesson learned:
Never second-guess a patient safety rule.

#2 Spills. The "slip and fall" case is extremely common in hospitals and underscores the need for scrupulous maintenance. In one instance, a patient's wife came to visit him, bearing numerous gifts piled high in her arms. She also was carrying a large vase of flowers. These objects naturally obstructed her view of the floor. To make matters worse, she was focusing her attention on the room numbers of the patient rooms. As a consequence of all these factors, she slipped on spilled water and broke her ankle. *Lesson learned: Maintenance and other staff must be ever-vigilant in keeping floor surfaces dry, clean, and safe — particularly on rainy or snowy days — and entrances, corridors, and dining areas free of debris, obstructions, and spillages.*

#3 Protecting Patients from Other Patients. In a particularly alarming case, a combative patient in a mental health unit became angry and started choking his vulnerable roommate. Fortunately, a nurse was walking by and saved the victim's life. The attorney investigating the case was surprised when he found that the combative patient's medical record documented numerous physical altercations with patients and

other staff in a short time period prior to the incident. Even worse, the room that the two patients shared was in the farthest possible location from the nurse's station. Aside from the medical mismanagement of the combative patient, the decision to put a defenseless, incompetent patient together with a known batterer defied all logic. *Lesson learned: Take affirmative measures to protect patients and staff from physically abusive patients.*

#4 & #5 Misplacement of Restraints and The Unattended Patient. A combination of safety failures resulted in a patient's death by exsanguination. An ICU patient had a catheter sutured to his left femoral vein. The patient was disoriented, agitated, and unable to respond to questions. Because he had attempted to pull out the catheter, soft wrist restraints were necessary. When the ICU nurse on duty applied the soft wrist restraints, she left too much slack in the left restraint. She then positioned the patient on his left side, and the excess slack enabled him to pull out the catheter that had been inserted in his left groin area. Had he not been able to reach the catheter, he would not have been able to remove it. *Lesson learned: Double-check safety restraints; they are useless if not applied properly.*

The patient would not have bled to death, however, if not for a second safety violation. In fact, if the nurse had not left the patient to go to the other side of the ICU area, where she ate an apple and talked to another nurse for about 30 minutes, the patient might have survived the first mistake. The nurse also neglected to ask any of the other nurses on duty to watch her

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patient while she was away. When she returned, the monitor showed a flat arterial line tracing. No alarms had sounded. Later, it was discovered that the EKG lead wires were defective — yet another contributing cause to the patient's death.

Lessons learned: Follow a policy of continuous assessment in an intensive or critical care situation.

Require each nurse to alert another nurse when he or she is going to be away from a patient — even if only for a few minutes — and ensure that the patient is being attended.

Never rely on mechanical monitors. Finally, have a solid, well-documented maintenance plan in place to identify and repair defective equipment.

Improving compliance with patient safety rules is essential to reducing risk of harm to our patients; it can also save VA millions of dollars in tort claim payments. Working together as partners, VA managers, clinicians, and the Regional Counsel offices can prevent common safety violations.

Hurdle*continued from page 5*

the researchers are already able to mount specific measures to reduce the most common ADEs (such as complications due to opioid analgesics or loop diuretics).

When the study is complete, standard regression techniques will be used to build patient profiles that indicate high-risk patient categories. Prevention schemes will then be tailored to improve patient safety for patients in these categories. Findings to date also suggest a critical need to mount a correspondingly thorough outpatient ADE survey, as a surprisingly large fraction of hospital admissions were related to outpatient ADEs.

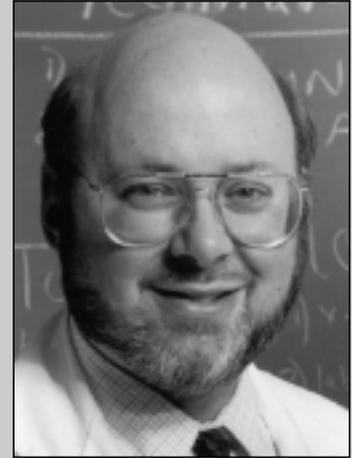
In Remembrance of Mark Moskowitz

Health services researchers across the United States lost a true mentor and colleague when Dr. Mark Moskowitz died on Sept. 1, 2001. It is difficult to express just how much Dr. Moskowitz has meant to VA's HSR&D Program and staff because he contributed his expertise and consultation on so many levels for so many years.

A talented clinician and admired faculty member at Boston University's School of Medicine, Dr. Moskowitz was a trusted advisor and champion of quality health services research in VA. He was a member of HSR&D's Scientific Review and Evaluation Board for 10 years and Chair for a number of those years, contributing significantly to quality improvements in the review process and in health services research proposals. He served on the HSR&D Subcommittee of the National Research Advisory Council for the past three years and added his keen perspective to our Quality Enhancement Research Initiative's Research and Methodology Committee since its inception in 1998.

In 1990, he became one of the original Steering Committee members for HSR&D's Center for Health Quality, Outcomes, and Economic Research located in Bedford, Mass. He has since worked on numerous health services research projects with staff there. For the past two years, he also chaired the Steering Committee for HSR&D's Center for Chronic Disease Outcomes Research in Minneapolis, providing exceptional guidance to that Center's strategic direction.

Dr. Moskowitz's commitment to ensuring high-quality health care and health services research was matched only by his commitment to interacting in a meaningful way with the people of health care and health services research and the humor and value he brought to those interactions. We are deeply grateful for all that he has shared with us.

**HSR&D's 20th Annual Meeting
Feb. 13-15, 2002**

Celebrating the Past: Shaping the Future is the theme of the next HSR&D annual meeting, to be held in Washington, D.C., Feb. 13-15, 2002. This event will mark HSR&D's 20th annual meeting and the 25th anniversary of VA funding for HSR&D.

To celebrate the occasion, we will feature several special events and displays recognizing the accomplishments of HSR&D through the years, as well as many competitively selected workshops, presentations, and posters on current and innovative health services research in VA.

For more information about the meeting and registration, visit the HSR&D web site at <http://www.hsr.d.research.va.gov>.

Invited Commentary

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tive risk assessment and analysis, as well as aggregate-data driven analysis for certain high-frequency events, such as missing patients, falls without serious injuries, close calls associated with medication-related events, and suicide attempts. Our program will continue to leverage the efforts of the RCA teams over the coming year through mining of information, analysis of trends, and sharing of important evidence-based results.

We also anticipate increasing our collaboration with VA researchers during the next few years. At NCPS, we are interested in developing solutions and tools that can be adapted to address local problems and situations. Some interventions can be applied to solve broader problems, and in those cases we would welcome the opportunity to work with VA researchers to design prospective effectiveness studies. This type of research would help us identify a best practices base for common and difficult problems.

Hofer

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Effective quality indicators must either directly measure or be clearly linked to definable processes of care. Only through this linkage can providers figure out how to fix problems. Likewise, these quality indicators and processes must be clearly linked to outcomes that are important, through experimental evidence in the literature or a large body of observational studies. Both ends of the bridge are important. Although the current trend to use process measures as indicators appears to obviate the need to conduct validation studies such as this one, the number of process measures with clear evidence of a link to outcomes of care is limited. Many intermediate outcomes — such as level of glycemic control, blood pressure measurement, lipid levels, and so forth — continue to be popular indicators. In that light, the cautions supplied by this study take on added importance for the development and use of future such indicators.

(1)Hofer TP, Bernstein SJ, Demonner S, Hayward RA. *Validating Quality Indicators for Hospital Care. Jt Comm J Qual Improv.* 1997; 23(9):455.

(2)Hofer TP, Bernstein SJ, Demonner S, Hayward RA. *Developing new quality indicators: A case study of electrolyte disorders and drug toxicity acquired in the hospital. (manuscript in preparation)*

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