Healthcare exists in an evolving political landscape. Currently, the new presidential administration is driving demand for accountability. This accountability often takes the form of demands by legislators and third party payers for assurances of patient safety and positive outcomes.

Patient safety is a complex phenomenon encompassing myriad factors and disciplines. Standards of practice must evolve in a manner that keeps pace with reality. Health care leaders must be willing to challenge the conventional wisdom that created sacred cows and to move toward evidence-based practice. Systems must encourage safety in patient care and eliminate opportunities for error. An interdisciplinary approach can refocus organizational goals so that quality and safety drive clinical initiatives. VHA is well positioned to create environments of safety because of such gold standard approaches as the Computerized Patient Record System (CPRS) and Bar Code Medication Administration (BCMA).

Organizational Culture: A Powerful Tool

Organizational culture is a powerful tool that leaders use to create change and to drive operational initiatives. A nexus of safety, medication management, and informatics can set the stage for systems redesign, and creates an organizational culture that is centered on patient safety. With respect to patient safety, the concept of “just culture” has become important. As contrasted with the notion of a “no blame” culture, “just culture” seeks to promote learning through analysis of errors and near misses, as opposed to simply resorting to a disciplinary process.¹

“Systems must encourage safety in patient care and eliminate opportunities for error. An interdisciplinary approach can refocus organizational goals so that quality and safety drive clinical initiatives. VHA is well positioned to create environments of safety because of such gold standard approaches as the Computerized Patient Record System (CPRS) and Bar Code Medication Administration (BCMA).”

Rethinking conventional wisdom provides a basis for creating opportunities for safety. For instance, several generations of nurses have been taught that maintaining four side rails in the upright position provides safety for the patient. Evidence has demonstrated that four side rails can be detrimental to safety and should be avoided in favor of low beds, more frequent comfort rounds to eliminate the most frequent cause of falls, and reducing the incidence of polypharmacy.

Falls incidence is one of the nurse-sensitive measures closely tied to the issue of patient safety. Other measures include pressure...
Director’s Letter

Last January, HSR&D launched its pilot study research initiative. Pilot study submissions are a maximum of 10 pages, one year duration, and $100,000. The goals of the pilot study program are to encourage the collection of data to improve the quality of subsequent Investigator Initiated Research (IIR) proposals, provide a simplified mechanism for investigators early in their careers to obtain funding, and provide initial support for innovative research that might be considered too risky for the IIR mechanism.

Pilot projects will allow investigators to refine research objectives, designs, and methods to better address HSR&D priority areas. For example, pilot projects might be “mini-versions” of a potential multi-center randomized trial, or might focus on refining surveys or questionnaires to strengthen a larger project. Moreover, pilot projects provide opportunities for investigators to explore novel research issues through small-scale initiatives. Areas of HSR&D priority interest include but are not limited to: post-deployment health, traumatic brain injury, mental health, rural health, health services genomics, and the care of complex chronic conditions. For more information about the HSR&D Pilot Project program, visit www.hsrd.research.va.gov/funding/solicitations.cfm.

Over 40 percent of 82 pilot project proposals reviewed at the August Scientific Merit Review Board (SMRB) will be funded. HSR&D looks forward to dynamic research projects from our talented investigators, who strive to improve the quality of health and health care for our nation’s Veterans.

Seth A. Eisen, M.D., M.Sc.
Director, HSR&D

Errors Provide Opportunity for Learning

Realistically, although clinicians and administrators strive to achieve a zero defects outcome, it has to be assumed that errors will occur. Such situations must provide opportunities for learning. Root cause analysis (RCA) provides a venue to learn from clinical errors by dissecting the routes by which the error occurred, analyzing the consequences, and creating hard fixes to prevent future errors. While conventional wisdom would advocate keeping errors confidential, involving front line staff and publishing an abbreviated report of the RCA allows for learning to occur on a wider scale. Thus, evidence-based knowledge is made available to those most intimately involved in error-prone circumstances.

Medication management represents an area of risk for many health care providers, especially nurses, that can provide opportunities for learning. Individual patient risk increases with polypharmacy and the use of high-risk medications. VHA has long been a leader in medication safety with the introduction of CPRS and BCMA. Both of these products are far more than data depositories. Inherent in their creation was the design of safety devices and prevention strategies. Coupled with the performance measure and external peer review programs, it is possible to monitor practice patterns and organizational achievement of targets to determine improvement foci.

Role of Clinical Informatics

Clinical informatics is the vehicle by which safety measures are enhanced and standards of care are refined. Rather than leaving this important endeavor to a centralized “IT” department, clinician-informaticists create systems that reflect the realities of experience at the point of care and address the needs of front line staff. Systems should accomplish much more than record keeping: they must scan for iatrogenic effects of care delivery that are likely results of the increasing complexity of health care. Involving the end user in system redesign can do much to obviate the need for workarounds, which often result from system failures that did not anticipate the demands of clinical reality.

In short, the complexity of contemporary health care is fraught with opportunities for error. This environment demands an interdisciplinary approach that questions conventional wisdom and does not subscribe to the notion that accidents are largely unpreventable. New approaches refine systems of care delivery that build in safety from their inception yet acknowledge that errors provide learning opportunities. Successes and failures are shared with all care providers so that a culture of safety is created. While these efforts require a commitment of energy and resources, the stakes are far too high to gamble with the lives of our patients. Based upon its advantages in systems design and performance improvement, VHA can be a leader in reforming health care for the nation and the world.

Reference

Response to Commentary

Building a Culture of Patient Safety

Maude Rittman, Ph.D., R.N., North Florida/South Georgia Veterans Healthcare System, Gainesville, Florida

As reported by the Institute of Medicine, medical errors are the fifth leading cause of death in the United States and cost a staggering $29 billion annually. Patient safety has become a major concern in the U.S. health care system and the VHA as well. Cynthia Caroselli describes the complexities in the health care arena that affect patient safety, including issues at the point of care delivery as well as political influences that shape the culture of the VHA. She argues that the VHA is well positioned to be a leader in patient safety, and analyzes two critical considerations about patient safety in the VHA to which I would like to respond.

Interdisciplinary Approach

The first consideration is that an interdisciplinary approach is needed to create a culture of patient safety. She provides several examples of contributions from nurses to monitor and improve patient safety and states that patient safety in the VHA can be enhanced by systems such as the CPRS and BCMA. This is all true. The VHA has made some significant contributions to patient safety. However, more information about interdisciplinary collaboration to improve patient safety is needed. More research and program evaluation is needed to evaluate the outcomes of interdisciplinary approaches to patient safety. Patient safety is not discipline-specific and yet, much of the responsibility rests with nurses. Some interdisciplinary strategies have been proposed, however, including the importance of communication.

One example of an interdisciplinary approach that could improve patient safety is developing interdisciplinary patient care standards and evidence-based practices.1 Other examples include interdisciplinary approaches to teamwork, shared governance, and patient rounds—all of which have been found to improve patient safety.2 We also need to develop an effective infrastructure to support interdisciplinary monitoring to reinforce that patient safety is a shared responsibility. These interdisciplinary approaches may help health care organizations create a culture of patient safety, reduce costs, and save lives.

Caroselli’s second point is that not all errors are preventable and that when they do occur, organizations should use these events as learning opportunities. This point is an important one. The challenge for the VHA is to use system re-design methods to convert health care organizations into learning organizations. Organizations that develop into learning organizations have the ability to identify knowledge gaps, trust opposing views, reflect on experiences, and tolerate errors. Bureaucracy and political environment influence the culture of the VHA, which may discourage reporting of errors and unintentionally impose penalties for errors. These influences may decrease the likelihood that errors will be acknowledged.

Learning Organization Tenets

These processes may preclude a culture of patient safety that is based on the tenets of a learning organization. The political environment often creates a protective response from leaders that may shape the organization toward a restrictive system that is hesitant to openly acknowledge and deal with errors. The three building blocks for learning organizations to develop are: 1) a supportive learning environment; 2) concrete learning processes; and 3) leadership that reinforces learning.3 These building blocks provide a structure for assessing performance and identifying areas for improvement to promote a learning organization.

Integrating three powerful processes—developing interdisciplinary approaches to patient safety, creating learning organizations that support a culture of safety, and the research expertise in the VHA—will increase performance and reliability of services in health care. Innovations being developed in patient safety centers of excellence provide a unique opportunity to evaluate structure, process, and patient safety outcomes using research methods. As the VHA continues its strong commitment to system re-design processes, it is more likely to become a true learning organization. However, leaders will have to embrace leadership styles that promote trust and that view errors as learning opportunities. Nursing leadership teams can define strategies for developing interdisciplinary teams to monitor and promote patient safety. The VHA is committed to building a culture of safety across the continuum of care, including home care—an often overlooked area for promoting safe environments for Veterans. The VHA is well positioned to build research programs to test organizational strategies for each of the building blocks of learning organizations and to disseminate research-based information to help leadership teams use these strategies to build a stronger culture of safety in their facilities. Linking the VHA research expertise with evaluation of innovative strategies will make a significant contribution to promoting safe care for Veterans.

References

Research Highlight

The Prescription Drug Facts Box: Helping Doctors and Patients Make Wise Choices

Lisa M. Schwartz, M.D., M.S., and Steven Woloshin, M.D., M.S., VA Outcomes Group, Department of Veterans Affairs Medical Center, White River Junction, Vermont

The views expressed herein do not necessarily represent the views of the Department of Veterans Affairs or the United States Government.

People need accurate, understandable information to make wise decisions about medical care. Yet much of what they receive is marketing designed to generate enthusiasm for new products by highlighting benefit and minimizing harm. Balanced data promoting informed decision making about medical interventions—including the decision to forgo them—is far less common.

Problems with Drug Information

Direct-to-consumer (DTC) advertising for prescription drugs is the most prominent example of how medical interventions are marketed to the public. Industry spent more than $5 billion on these ads in 2007—more than twice the total U.S. Food and Drug Administration (FDA) budget. Although proponents claim they serve an educational purpose, the ads generally fail to relate the most fundamental information consumers need: how well the drug works. No surprise, consumers tend to overestimate treatment efficacy.

DTC advertisements are only one way that patients learn about medications. Theoretically, prescribing physicians summarize drug benefits and harms, although this probably does not occur often in practice. When they fill their prescriptions, patients may receive a variety of information sheets, patient package inserts, or medication guides. A recent FDA survey found, unfortunately, that these information sheets (which provide instructions about use, but rarely if ever quantify benefit and harm) are often illegible and hard to understand. Even the most complete prescribing information—the prescription drug label—written by industry and approved by the FDA—can be incomplete and biased.²

A Practical Idea: The Drug Facts Box

To clearly communicate prescription drug benefits and harms, we developed a single page, standardized format called the “prescription drug facts” box (see example). The box is modeled on FDA’s nutrition facts box, a format already familiar to consumers. Data for drug boxes would come from the studies used in FDA’s drug approval process. Ideally, boxes would be written by FDA’s reviewers during the drug approval process. The reviewers, independent experts with complete access to the relevant published and unpublished data, could ensure that everyone knows what FDA knew at the time of approval.

LUNESTA STUDY FINDINGS

788 healthy adults with insomnia for at least 1 month—sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep—were given LUNESTA or PLACEBO nightly for 6 months. Here’s what happened:

<table>
<thead>
<tr>
<th>What difference did LUNESTA make?</th>
<th>People given PLACEBO</th>
<th>People given LUNESTA (3 mg each night)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did LUNESTA help?</td>
<td>45 minutes to fall asleep</td>
<td>30 minutes to fall asleep</td>
</tr>
<tr>
<td>LUNESTA users fell asleep faster (15 minutes faster)</td>
<td>5 hours</td>
<td>6 hours</td>
</tr>
<tr>
<td>LUNESTA users slept longer (37 minutes longer)</td>
<td>45 minutes</td>
<td>22 minutes</td>
</tr>
</tbody>
</table>

Did LUNESTA have side effects?

No difference between LUNESTA and a sugar pill

Symptom side effects

None reported yet

How long has the drug been in use?

LUNESTA was approved by FDA in 2005 based on studies involving about 1,200 people. As with all new drugs, rare but serious side effects may emerge after the drug is on the market—when larger numbers of people have used the drug.
Drug facts boxes could serve a variety of purposes including: an executive summary of the FDA review documents, a replacement for the current “brief summary” (the FDA required, small print 2nd page) on direct-to-consumer drug ads, and as standalone information sheets for doctors and patients. The approach could easily be used for devices and surgical procedures as well.

**Does the Drug Box Help?**

We have published a number of studies, including two national randomized trials, showing that consumers want the information in the drug box, understand it, and can use it. Most importantly, the box helps consumers make better decisions about prescription drugs. For example, we randomized 231 consumers to see either standard drug advertisements or ads with drug facts boxes for two medications used to treat heartburn. The drugs were selected so that they had similar side effect profiles, but one clearly outperformed the other. We found that the drug box group was more than twice as likely as the standard ad group to choose the better drug: 68 percent vs. 31 percent, p<0.001.

**The Drug Box and FDA Policy**

In a pilot project, we have shown that FDA reviewers can create drug boxes. We worked with 10 FDA medical reviewers who iteratively drafted, critiqued, and revised boxes for a variety of drugs. To develop a transparent, replicable process for creating drug facts boxes, we also developed a handbook to guide subsequent production of drug boxes.

Earlier this year, the FDA’s Risk Communication Advisory Committee voted unanimously in a non-binding recommendation that FDA “should adopt the Drug Facts Box format as its standard for communicating essential information about pharmaceuticals” in the drug label, advertisements, and other consumer materials. Most recently, Senators Reed (RI) and Mikulski (MD) introduced legislation (S. 1142, the Informed Health Care Decision Making Act, May 21, 2009) calling on the Secretary of the Department of Health and Human Services to review the evidence supporting the drug facts box, and if satisfied that the box would improve health care decision making by clinicians and patients and consumers, to “promulgate regulations as necessary to implement such format.” The legislation has been incorporated into the Senate’s health care reform bill, the “Patient Protection and Affordable Care Act” now under consideration.

Helping patients make informed decisions is fundamental to good medical practice and has long been a VA priority. Drug facts boxes—ideally produced by the FDA—would help inform decisions about prescription drugs by providing doctors and patients with access to key information about drug benefits and harms in an understandable format.

**References**

Research Highlight

Suicide Prevention

Marcia Valenstein, M.D., M.S., Research Scientist, Department of Veterans Affairs Center for Clinical Management Research, and the Serious Mental Illness Treatment Research and Evaluation Center, Ann Arbor, Michigan

Recent reports indicate that suicide rates are higher among U.S. Veterans when compared with non-Veterans. Veterans who completed the U.S. National Health Interview Survey (NHIS) between 1985 and 1996 had higher suicide rates than non-Veterans. Data from the National Violent Death Reporting System in 16 states also indicate higher than expected rates of suicide among Veterans living in the community. Suicide rates have been increasing among active duty Army soldiers and now surpass age and gender-adjusted suicide rates in the general population.

Of direct interest to VHA investigators focused on health system safety, the VHA has assessed suicide mortality among its entire patient population—the only large health care organization to do so. In 2001, suicide rates among VHA health care users were 66 percent higher than the age and gender-adjusted general U.S. population. The crude suicide rate among male and female VHA users was 43.1/100,000 and 10.4/100,000 person-years, respectively; whereas, the crude suicide rate among males and females in the general population was 23.2/100,000 and 5.2/100,000 person-years, respectively. The capability of determining and following suicide rates in its patient population gives the VHA unparalleled opportunities for assessing the efficacy of suicide prevention programs.

Suicide Prevention Activities in VA

Because of its high-risk population and the priority placed on suicide prevention, the VHA has worked to improve access to evidence-based mental health services, and to develop and implement comprehensive suicide prevention programs. A Veteran-specific telephone hotline option has been implemented in cooperation with the National Suicide Prevention Lifeline. Veterans who call the Lifeline number can press “1” to be routed to trained VHA mental health employees who have access to patients’ medical records and who work with VHA suicide prevention coordinators to ensure systematic follow-up of Veteran callers.

VHA has placed suicide prevention coordinators at all VHA facilities to provide ongoing suicide training for staff; identify, track, and monitor high-risk patients; coordinate suicide prevention activities with community agencies; develop local prevention strategies; and participate in patient safety and environmental analysis (e.g., assess the safety of inpatient units). VHA will soon initiate additional initiatives to reduce suicide.

Reducing Suicides in Veterans

by Steven Bagley, M.D., M.S., VA Greater Los Angeles Health Care System

Suicide prediction and reduction are pressing issues for VA. Many Veterans have significant risk factors, such as mood disorders, substance use disorders, pain, disabling chronic medical illness, traumatic brain injury, posttraumatic stress disorder (PTSD), and skill in using firearms. Clinical prediction is a challenge because it requires forecasting a single infrequent act of behavior. The low base rate of suicide in the population means that widespread use of screening tests generates many false positives. Therefore, most clinical attention has been devoted to organizing the interventions by risk strata, typically by providing low-intensity interventions, such as suicide awareness programs, to populations, and higher-intensity interventions, such as case management or post-discharge tracking, to those in high-risk groups or with known risk factors such as prior suicide attempts.

VA has already implemented several suicide reduction programs, and much of this has been coordinated through the Center of Excellence in Canandaigua, New York, and the Mental Illness Research, Education, and Clinical Center in Denver, Colorado. As Valenstein mentions in her research highlight, Suicide Prevention Coordinators (SPCs) are now located at each VA facility. Computerized clinical reminders screen patients for depression, PTSD, and alcohol abuse. A suicide risk “flag” aims to close gaps in treatment, expedite access and follow up, and alert non-medical health providers to keep an eye open for signs of depression or decompensation.

Risk stratification requires knowing details about prior attempts. Policy planning and program evaluation requires accurate aggregate statistics on attempts and completions. It is well recognized that ambiguity exists in the informal vocabulary used (such as “ideation” and “attempt”), and considerable work remains to be done to define terms that can be easily used across different disciplines with accuracy and ease. Further work will also be needed to ensure that comprehensive surveillance of suicide attempts and completions in Veterans is routinely conducted and reported. There are numerous research questions about multifaceted suicide reduction programs—even if they are robustly successful, the question remains as to which facets are causally related to reductions in suicides, and whether there are facilitative or synergistic effects among the program components.

continued on page 8
Organizational Profile

New Center of Excellence in Tampa, Florida

Gail Powell-Cope, Ph.D., ARNP, FAAN, HSR&D/RR&D Center of Excellence, Tampa, Florida

Under the leadership of Dr. Audrey Nelson, investigators at the HSR&D/RR&D Center of Excellence (COE) in Tampa, Florida have made significant contributions to both staff and patient safety in VA and in health care across the country.

Over the past 30 years, efforts to reduce work-related musculoskeletal injuries in health care relied on body mechanics classes or training in lifting techniques, both of which have been unsuccessful. At the COE, Dr. Audrey Nelson leads a program of research and research translation in safe patient handling that is now culminating in a $200 million VA-wide implementation program. This program is designed to radically change the way nurses and other direct health care providers move and transfer dependent patients, from manually lifting and pulling to an ergonomics-based program featuring technologies to mechanically move them.

Through studies funded by VA and others, researchers documented that an ergonomics-based program will decrease the number and severity of patient handling injuries, decrease the cost of health care by decreasing workers’ compensation costs, and result in increased comfort and dignity for patients.1

Dr. Nelson works with schools of nursing across the country to implement a curriculum for colleges of nursing co-developed with the National Institute for Occupational Health and Safety.2

Researchers at the COE in Tampa have also made strides in the areas of falls prevention and fall-injury prevention. Patient falls are the most frequent adverse event with injury within the VHA and are the leading cause of injury-related deaths among people age 65 and older. Researchers at the COE are addressing gaps in the literature such as the lack of research on falls among patients who use wheelchairs for mobility, fall prevention in impairment-specific populations, and prevention of fall-related injuries. Key research findings in these areas from recently funded studies include the following:

- People with spinal cord injuries who use wheelchairs have a different fall risk profile compared to other populations. In a prospective epidemiological study, investigators identified six predictors of wheelchair falls: pain in previous two months, alcohol abuse, greater motor function, previous fall, fewer spinal cord injury years, and shorter length of wheelchair. Predictors of injurious falls were: pain in previous two months, greater motor function, previous fall, and inaccessible home entrance. Results are being used to develop a reliable and valid screening instrument, and in the testing of a wheelchair skills training program.

- Using an innovative probabilistic risk modeling method, researchers identified key high-risk behaviors in VA community living centers that contribute to fall injury risk. These behaviors included staff failure to respond to fall alarms in a timely manner, residents’ use of unsafe transfer techniques, and residents’ use of wheelchairs that are not properly maintained. Results are being used to develop a staff training program that targets these three at-risk behaviors.

References

HSR&D Deputy Director Named

Effective August 2009, VA’s Health Services Research and Development Service (HSR&D) welcomed Andrew Guccione PT, PhD, DPT, FAPTA, as its Deputy Director.

In his role as Deputy Director, Dr. Guccione will direct his efforts to ensuring the integrity of the scientific merit review process; developing partnerships to advance HSR&D’s strategic plan; and fostering collaborations across health services, clinical science, and rehabilitation research to enhance the quality of health care for Veterans. Dr. Guccione is no stranger to HSR&D, having served for a year and a half as the Scientific Program Manager for HSR&D’s Mobility, Activity, and Function and Quality Measurement Development portfolios before accepting the Deputy Director appointment.

Prior to joining HSR&D, Dr. Guccione served for ten years as Senior Vice President for the Division of Practice and Research at the American Physical Therapy Association. He also spent six years at Massachusetts General Hospital, where he was Director of Physical Therapy Services for three years, and Director of Quality Assurance, Research, and Education for three years. “I look forward to assisting VA HSR&D investigators in the field through streamlined processes and enhanced communications so we can more efficiently review and fund health services research to improve the quality and cost of health care for Veterans,” Dr. Guccione told FORUM.

HSR&D Deputy Director Named
Evidence for Suicide Prevention Effectiveness

A literature synthesis on suicide prevention was commissioned from the HSR&D Evidence-based Synthesis Program (ESP). This synthesis updated the Mann, et al. review of articles published between 1966 through June 2005 to May 2008 and focused on Veteran and military relevant articles. The synthesis identified seven multifaceted studies of military personnel and three studies of U.S. Veterans. The review also identified twenty controlled trials of interventions for individuals who were post-suicide attempt and a large number of observational studies of restricting access to lethal means. The synthesis determined that the quality of the evidence supporting most suicide prevention strategies is low (i.e., further research likely to have an impact on the estimate of effect) or very low (i.e., any estimate of effect is uncertain). The synthesis found insufficient data to reach any conclusions about the effectiveness of Community-based Suicide Prevention Centers and determined that there are no studies that assessed the specific effectiveness of hotlines, new outreach, counseling, or treatment coordination programs. Restriction of access to lethal means was thought to have an effect on cause-specific suicides although the quality of evidence was low.

Opportunities for VA Research

Given the limited evidence for the effectiveness of most suicide prevention efforts, further research in this area is imperative. The VHA has large patient numbers, a strong mandate to reduce suicide rates among its patients, and coordinated roll outs of suicide prevention programs—making it one of the few health systems in which rigorous research on suicide prevention is possible. VHA researchers are thus poised to lead the way in the area of suicide prevention—to the benefit of both Veterans and the general population.

References