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VA PATIENT SAFETY

Initiatives Promising but Continued Progress Requires Culture Change

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VA Patient Safety: Initiatives Promising but Continued Progress Requires Culture Change

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Department of Veterans Affairs' (VA) effort to improve patient safety, an integral part of VA's overall strategy to improve the quality of health care. VA's quality management strategy is multidimensional and includes programs and internal and external review processes to improve health outcomes, to ensure that providers are competent and well-trained, and to optimize the use of technology to achieve health outcome goals. In this overall system, the role of patient safety activities is to prevent injuries related to care and, when they do occur, identify the causes and countermeasures to prevent them in the future.

My comments today will focus on VA's effort to reduce and prevent patient adverse events in VA health care facilities through its new patient safety initiatives, part of its internal review processes.[1] Adverse events, which occur in both public and private health care facilities, can have tragic consequences, including permanent disability and death. A number of studies have shown that serious injuries sustained from medical care are common and often preventable. A 1997 poll of 1,500 Americans conducted for the National Patient Safety Foundation showed that 42 percent felt that they or a close friend or relative had experienced a preventable adverse event.[2] A 1999 report by the Institute of Medicine (IOM) estimated that 44,000 to 98,000 Americans die each year as a result of medical errors.[3] These findings were widely reported in the media, further heightening the public's awareness of the need to improve patient safety in health care.

As you know, in mid-1997 VA began an effort to improve patient safety in VA facilities. Specifically, the effort aims to reduce adverse events by focusing on system weaknesses instead of assigning blame to individuals. A growing body of evidence shows that adverse events are commonly caused by problematic systems and processes rather than human performance problems. Consequently, many experts believe that crafting

[1] VA defines adverse events as untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other Veterans Health Administration (VHA) facility. These include events such as falls, medication errors, missing patient events, and suicides. Adverse events may result from acts of commission or omission.

[2] *Error Reduction in Health Care: A Systems Approach to Improving Patient Safety*, P. L. Spath, ed. (San Francisco, Calif.: Jossey-Bass Publishers, 2000).

[3] IOM, *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, Nov. 1999).

solutions that make it more difficult for human errors to occur holds the most promise for reducing adverse events. In fact, the premise of the systems approach is that human error is to be expected and that errors can be reduced by changing the conditions under which humans work. For example, changing the system of gas connectors can prevent a gas hose or cylinder from being installed at the wrong site, and differentiating similar names and packaging of drugs can reduce the likelihood of giving a patient the wrong medication.

VA has set out to implement this approach so that health care professionals will feel able to openly acknowledge and report adverse events as part of their daily work. VA created the National Center for Patient Safety (NCPS) in 1998 to take the lead in integrating its patient safety efforts and to develop and nurture a culture of safety in VA medical facilities so that adverse events and close calls (situations in which adverse events are narrowly averted) can be reduced and prevented.

Given the importance of VA's patient safety effort and the IOM report highlighting the need to improve patient safety, you asked us for this hearing to (1) determine the status of VA's initiatives to detect and prevent adverse events and (2) describe the challenges VA may face as it establishes a culture of safety. Our work is based on discussions with officials at VA headquarters, the NCPS, and four Patient Safety Centers of Inquiry funded by VA; participation in VA's Patient Safety Improvement Handbook training; reviews of VA's patient safety policies and reports, the IOM study on patient safety, and other relevant literature; and visits to VA facilities in California, Florida, and Washington, D.C.

In summary, VA has developed a number of initiatives that indicate it is moving toward a culture of safety in which systems are developed or revised to better detect and prevent adverse events. Some of VA's systems have been cited as potential models for other health care organizations. For example, VA has established systems that incorporate the use of bar code technology to prevent blood product and medication administration errors. VA introduced bar code technology in operating rooms to ensure that patients receive the correct blood product. Bar code technology is also being used when medications are administered to inpatients to verify that the right patient is receiving the right drug in the right dose at the right time. VA is currently completing its implementation of a revised mandatory adverse event reporting and prevention process, which will allow VA to identify systems and processes that require redesign. This initiative is perhaps the most challenging because its success is dependent on VA establishing a culture in which employees feel safe to openly report actual adverse events as well as close calls.

In implementing its initiatives, VA used strategies that mirror some of those suggested by IOM for creating a culture of safety. However, we believe VA can benefit if it increases its emphasis on several leadership strategies cited by IOM. In fact, VA agrees that it is appropriate to measure its progress against the IOM recommended strategies. These include making patient safety a more prominent goal, establishing clear responsibilities and expectations, and communicating the importance of patient safety to all staff. VA's interim draft strategic plan for fiscal years 2001 through 2006 better highlights patient safety as a goal than the current strategic plan, but does not yet include outcome measures for determining the effectiveness of its patient safety initiatives. VA could also better ensure success if it prepared a detailed implementation plan that identifies how and when VA's various patient safety initiatives will be implemented, how they are aligned to support improved patient safety, and what contribution each initiative can be expected to make toward the goal of improved patient safety. In addition, VA could raise staff awareness and understanding of the importance of this effort by better communicating its commitment to establishing patient safety as a top priority. Taking such steps should help VA progress further in the development of its patient safety culture and convey the commitment necessary to sustain a lasting change.

Background

In 1996, a conference on Examining Medical Errors in Health Care brought together for the first time leaders from medicine, nursing, pharmacology, and hospitals as well as accreditors and regulators to talk and learn more about medical errors—a subject usually not openly discussed in health care organizations.[4] At the conference, it was acknowledged that there was a need to improve patient safety by addressing medical errors. In 1997, VA's Under Secretary for Health initiated a revised risk management policy that he believed "would place VA at the forefront of efforts everywhere to provide safer medical care." According to the Under Secretary, VA's modified program was based on research findings showing that preventable medical errors resulted from poorly designed systems or processes and that analyses of systems could often lead to process or system redesign that would reduce the likelihood of errors.

Before VA's new patient safety effort, adverse events were investigated by the health care facilities where they occurred and the findings were

[4]Annenberg Center for Health Sciences, *Examining Errors in Healthcare: Developing a Prevention, Education and Research Agenda* (Rancho Mirage, Calif.: Oct. 1996).

submitted to regional quality management staff for their review; they forwarded the results to headquarters officials. In 1997, VA required that reported events that resulted in serious injury or death be included in a registry maintained by VA's chief network officer. In 1999, VA's Office of the Medical Inspector analyzed the adverse events reported to the registry over a 19-month period beginning June 1997. In its report, issued in December 1999, the Medical Inspector found that VA's registry data showed wide variation in the number and types of events reported by VA's 22 Veterans Integrated Services Networks (VISN).[5]

In an effort to help ensure adequate oversight of its investigation and reporting procedures, VA established the NCPS in 1998 to lead and integrate VA's patient safety effort. Under NCPS' direction, VA's Patient Safety Improvement Handbook was revised to include new adverse event investigation and reporting procedures and tools.[6] In November 1999, NCPS began training representatives from VA facilities to use the new procedures and tools. Adverse events are now reported to NCPS, which enters them into VA's new mandatory adverse event reporting system database, replacing the system maintained by the chief network officer.

Patient Safety Initiatives Are at Various States of Development and Implementation

Since VA began its patient safety effort in 1997, it has taken a number of important steps to reduce and prevent adverse events by evaluating and then modifying or redesigning the systems that allow them to occur. These initiatives are at various stages of development, and only a few are fully implemented.

VA reports that it has fully implemented two patient safety initiatives—each of which eliminates identified hazards that can have fatal consequences. First, to ensure that a patient will not receive the wrong blood type during surgery and die, VA requires that blood products administered to patients in an operating room be verified through independent computer bar code technology. This check is made in addition to VA's standard verification procedure of having two people visually match information about the patient's identity and information on the blood product. VA's second initiative eliminated an identified lethal

[5]Office of the Medical Inspector, VHA, *VA Patient Safety Event Registry: First Nineteen Months of Reported Cases Summary and Analysis, June 1997 through December 1998.* The Office of the Medical Inspector is currently reviewing the causes of underreporting and the reasons for variations in reporting.

[6]The Patient Safety Improvement Handbook, developed in January 1998, effectively replaced VA's risk management policy.

medication error. Specifically, VA reports that it has removed concentrated potassium chloride and other concentrated injectable solutions from patient care areas—such as patient wards, intensive care units, and surgical suites—and instead now requires that a facility's pharmacy dilute concentrated injectable solutions before sending them to patient care areas for administration. This system change virtually eliminates the possibility for human error to result in accidental administration of a lethal dose of concentrated potassium chloride.

Several other major initiatives addressing adverse events are under way in VA health care facilities. These include using bar code technology when administering medications; implementing a new internal mandatory process for analyzing and reporting adverse events; and collaborating with the National Aeronautics and Space Administration (NASA) to develop an external voluntary adverse event reporting system.

In October 1999, VA began implementing a bar code medication administration (BCMA) system for inpatient medications. BCMA is designed to help caregivers avert potential medication administration errors by verifying that the right patient is receiving the right drug, in the right dose, at the right time. The system also screens for other potential problems such as drug interactions. VA reported that during a BCMA pilot test at the Topeka, Kansas, VA medical center, medication errors were reduced by about 70 percent. Systemwide implementation of BCMA was scheduled for June 30, 2000. However, only 79 of 137 facilities have fully implemented BCMA in all inpatient care areas excluding intensive care units; 9 facilities have not implemented BCMA in any area.[7] According to VA officials, these delays are due to technical and administrative difficulties, including computer hardware being delivered damaged or late; the need for hardware upgrades; and renegotiations of union labor agreements, which do not include BCMA use. VA expects the BCMA system to be fully operational in all inpatient care areas except intensive care units by September 2000.

VA's Patient Safety Improvement Handbook specifies new processes that VA staff at health care facilities must use when reporting adverse events and close calls that pose safety risks to patients. The handbook details the use of the Safety Assessment Code matrix, a tool facility staff can use to assess the actual and potential probability and severity of the adverse event or close call—measured on a scale of one through three, with three

[7]As of July 7, 2000.

reflecting the highest severity. An adverse event or close call with a score of three requires that a team be assembled to conduct an analysis to identify the root causes of the event. Once the causes have been identified, the team makes recommendations for reducing or eliminating the occurrence of such an event in the future. Representatives from each medical center must receive 24 hours of training in the use of the new approach before the facility can begin using the revised reporting and analysis system outlined in the handbook. According to VA's schedule, training of facility staff in the use of the new procedures is scheduled for completion by the end of August 2000.

To complement its internal mandatory reporting system, VA is also establishing an external voluntary adverse event reporting system that will allow VA employees to report errors confidentially. Specifically, at the end of May 2000, VA signed a 4-year, $8.2-million agreement with NASA to develop a voluntary Patient Safety Reporting System (PSRS), which will be modeled after NASA's Aviation Safety Reporting System (ASRS).[8] PSRS will collect and analyze voluntarily submitted reports of adverse events or close calls that occur in VA health care facilities. To ensure confidentiality, reports will be stripped of any identifying information—that is, all personal and organizational names and dates, times, and related information that could be used to infer an identity—before they are entered into the database. Some organizations expect a system that protects the identity of the person reporting a potential or actual adverse event to yield more complete data because it helps remove the fear of reprisal. However, it will take time to determine if a system similar to ASRS will be successful in a health care setting. PSRS is scheduled to be fully operational sometime in 2001.

VA Faces Challenges as It Implements Its Patient Safety Initiatives

VA's initiatives to improve patient safety mirror some of those suggested by IOM, but VA will face significant challenges to ensure the success of its patient safety effort. In particular, establishing a culture of safety using strategies such as ones described by IOM will be unprecedented in a health care system of VA's size and will require sustained commitment to effect permanent change. After reviewing lessons from aviation, nuclear power, and other high-risk industries—as well as reviewing evidence of practices that can improve health care safety—IOM identified various strategies related to five principles for achieving safe health care (see table

[8]ASRS was established in 1975 under an agreement between the Federal Aviation Administration (FAA) and NASA. NASA administers the program and sets its policies in consultation with FAA and the aviation community.

1). These strategies essentially lay out a framework within which VA's progress can be monitored as it attempts to create a patient safety culture.

Table 1: IOM's Five Principles and Strategies for Achieving Safe Health Care

Principle	Strategy
Leadership	Make patient safety a priority corporate objective
	Establish clear responsibilities and set expectations for safety
	Make patient safety everyone's responsibility
	Provide resources, human and financial, for error analysis and system redesign
	Develop effective mechanisms for identifying and dealing with unsafe practitioners
Respect human limits in process design	Design jobs for safety
	Avoid reliance on memory
	Use constraints and forcing functions
	Avoid reliance on vigilance
	Simplify key processes
	Standardize work processes
Promote effective team functioning	Train in teams those who are expected to work in teams
	Include the patient in safety design and the process of care
Anticipate the unexpected	Adopt a proactive approach: examine new technologies and processes of care for threats to safety and redesign them before accidents occur
	Design for recovery—make errors visible
	Improve access to accurate, timely information
Create a learning environment	Use simulation whenever possible
	Encourage recognizing and reporting of errors and hazardous conditions
	Ensure no reprisals for reporting errors
	Develop a working culture in which communication flows freely regardless of authority gradient; improve verbal communication
	Implement mechanisms of feedback and learning from error

Source: IOM, 1999.

Because VA is just beginning its initiative to create a culture of safety, we conducted our assessment by comparing its efforts to the IOM leadership principle. Successful leadership strategies create the foundation on which all other patient safety strategies are built. Experts agree that a culture change can take several years to effect, and VA officials have estimated 5 to 7 years are needed to implement their effort. Moreover, such profound change is largely dependent on leadership and staff having a common understanding and unequivocal commitment to the goal of improved patient safety. Our review identified several strategies under IOM's leadership principle that could help VA better achieve such a common

understanding and commitment in this early phase of the culture change. These include (1) making patient safety a priority organizational goal (with measurable outcomes); (2) developing a detailed and integrated patient safety plan with clear lines of responsibility and expectations; and (3) ensuring, through effective communication, that all employees understand that patient safety is their personal responsibility as well as a collective responsibility. While VA has made significant strides so far toward improving patient safety through the implementation of its various initiatives, emphasis in these three areas would assist them in creating a culture of safety throughout the organization.

VA is three years into its patient safety effort and it has dedicated approximately $478 million over 3 years to support its national patient safety initiatives. Although its fiscal year 1998-2003 strategic plan did not include patient safety as a specific goal, VA's draft interim fiscal year 2001-2006 strategic plan takes an important step in the right direction by articulating improved patient safety as an objective. However, the plan does not yet identify measurable outcomes so that progress can be assessed.[9] For example, VA's strategic plan does not incorporate outcome measures related to reducing medication administration errors through the use of BCMA. Outcome measures are another way to emphasize the importance of patient safety because collecting the data to measure outcomes underscores the importance of the goal for all staff.

VA has not yet developed an overall implementation plan that establishes clear responsibilities, sets expectations, and explains linkages between the offices accountable for patient safety. Such a plan would help VA explain how and when VA's patient safety initiatives will be implemented, how they are aligned to support improved patient safety, and how each initiative is expected to contribute to improved patient safety. Currently, primary responsibility for patient safety improvement is distributed across NCPS and two headquarters offices—the Office of Quality and Performance and the Office of the Medical Inspector. NCPS was created to lead and integrate VA's patient safety efforts, the Office of Quality and Performance coordinates the design and implementation of performance measures related to patient safety, and the Office of the Medical Inspector explores how and why patient care systems failed and resulted in an

[9]The fiscal year 2001-2006 plan includes what VA calls "6 for 2006"—referring to six strategic objectives that represent the highest priorities for providing health care to veterans. One objective refers to patient safety. Specifically, the objective "put quality first until first in quality" lists "improve the safety of the care environment for patients and employees" as a strategy for achieving this objective.

adverse event. The three offices' physician leaders are core members of VA's Patient Safety Improvement Oversight Committee, which meets at least once a month to review national trends in adverse events and analyses that have implications for department policy development. During our discussions with these officials, they told us that the linkages between the three offices were still being developed. For example, prior to 1998, patient safety was under the purview of the Office of Quality and Performance. When NCPS was created, many patient safety functions were realigned, but VA has not yet finalized how the two offices will work together.

An overall implementation plan could also clarify the role of the four Patient Safety Centers of Inquiry, which VA created to function as learning laboratories for the development and dissemination of evidence-based patient safety practices. The plan would also lay out linkages between the four centers and either NCPS or the Office of Quality and Performance. The centers all concentrate on identifying and preventing avoidable adverse events and each has a different focus. The primary areas include but are not limited to reduction in medication errors, risk assessment for falls, issues related to human-machine interfaces, and anesthesia/operating room simulation training. Although NCPS and these Patient Safety Centers of Inquiry have developed informal relationships to work on projects of mutual interest, such as the pilot testing of the new adverse event analysis and reporting procedures at one of the Centers, each of the four centers formally reports to a VA medical center or network director. Establishing formal linkages could facilitate rapid and systematic dissemination of findings that could improve patient safety across the entire VA health care system. In addition, as the patient safety effort matures, VA could consider whether linking the results of the centers' findings to national performance measures would help send a clear mandate to improve patient safety throughout VA.[10]

In addition, IOM reported that ensuring that all employees understand that patient safety is their responsibility is key to a successful effort. Although VA has issued policies regarding many of its patient safety initiatives, it has not communicated its commitment to establishing patient safety as a top priority to all of its employees. Clear and unambiguous communication from leadership that patient safety is a serious priority of the organization is crucial to gaining the trust and support of employees, which IOM

[10]VISN 1 Patient Safety Center of Inquiry, *VA Collaborative Breakthrough Series on Reducing Adverse Drug Events, September 1999 to April 2000* (May 25, 2000).

identified as an important component of a successful patient safety program. A physician with the Institute for Healthcare Improvement—which contracted with VA to help coordinate its patient safety education efforts for one Center of Inquiry—similarly describes a successful management system for safety as needing processes for encouraging and maintaining a participative culture.[11] Moreover, some employees voiced the opinion that VA medical center management staff could benefit from a better understanding of the new adverse event reporting and review process as well as the need to move from a culture of blame to a nonpunitive environment. When we asked VA officials about the leaderships' exposure to the new adverse event reporting and analysis process, they did not have a plan to ensure that all VISN and medical center leaders would receive the information needed to understand the shift in paradigm. We believe VA leadership could do more to build agency management and employee awareness of and support for the patient safety effort by communicating openly and frequently about the effort.

In conclusion, it is too early in VA's implementation of its various patient initiatives to predict if it will be successful in creating a patient safety culture. Doing so could be of significant benefit to veterans and could lead the way for private sector health care providers to improve patient safety. The patient safety objective VA outlines in its draft interim strategic plan is a critical step toward making patient safety a more prominent goal in the organization. Articulating ways to measure progress toward reaching this goal, developing an explicit implementation plan, and stepping up communication with staff should further advance the coherence and visibility necessary for an effort of this magnitude.

[11]Donald F. Phillips, "New Look Reflects Changing Style of Patient Safety Enhancement," *Journal of the American Medical Association*, vol. 281, no. 3 (Jan. 20, 1999).

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of the Subcommittee may have.

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