PATIENT SAFETY AND QUALITY MANAGEMENT

HEARING

BEFORE THE

SUBCOMMITTEE OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

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PATIENT SAFETY AND QUALITY MANAGEMENT

THURSDAY, JULY 27, 2000

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 11:38 a.m., in room 334, Cannon House Office Building, Hon. Terry Everett (chairman of the subcommittee) presiding.

Present: Representative Everett.

Mr. EVERETT. The hearing will come to order.

First of all, I apologize for the delay in the beginning of the hearing. We had a series of votes on the floor, and the nature of the business on the House floor did not permit Members to leave.

I appreciate the patience and forbearance that everyone has shown this morning, and I also appreciate all the preparation by the witnesses for this hearing on patient safety and quality management in the Department of Veterans Affairs.

It is apparent that the Subcommittee will not be able to take oral testimony in a timely way today. I apologize for that, and this is the first time in 6 years as Subcommittee chairman that I have been forced to do this. But I am ordering that all written testimony submitted by our invited witnesses be placed in the record, that members may place statements in the record, and that members may have 5 days to submit questions for the record.

[The prepared statements of Hon. Corrine Brown and Hon. Lane Evans appear on pp. 3 and 4.]

Mr. EVERETT. I want to assure the witnesses that your work in preparing for this hearing will become part of the official record and that your efforts have been worthwhile.

[The prepared statements of Richard J. Griffin, Cynthia Bascetta, Linda J. Connell, and James P. Bagian appear on pp. 6 to 31.]

Mr. EVERETT. I apologize if anyone has been greatly inconvenienced. As I said, this is the first time in 6 years that this sort of thing has happened in one of my subcommittees that I have chaired. And I do apologize for it. But we have no alternative today, because of the nature of the business on the floor, but to at this point adjourn the meeting.

Thank you very much for coming.

[Whereupon, at 11:40 a.m., the subcommittee was adjourned.]

APPENDIX

Remarks of Honorable Corrine Brown
Ranking Democratic Member
Subcommittee on Oversight & Investigations
Committee on Veterans Affairs

Hearing on Patient Safety and Quality Management
in the Department of Veterans Affairs

July 27, 2000

I want to thank Chairman Everett and the Committee's Ranking Member, Lane Evans, for this opportunity to examine patient safety and quality management in the Department of Veterans Affairs. Reports this year of patient deaths and of lapses in the quality of health care delivery have raised concerns about how adequate VA's quality assurance and quality management programs are. How effectively do these efforts correct, reduce, or prevent potentially serious incidents?

On December 20, 1999, the VA's Office of the Medical Inspector (OMI) released the results of an internal VA report concerning the number of medical mistakes within the VA hospital system. OMI reported a total of 2,927 medical errors within VA's 172-hospital system from June of 1997 to December of 1998, 710 of which resulted in patient deaths. Release of the VA study followed a frightening review of medical mistakes in all our nation's hospitals, which the Institute of Medicine (IOM) prepared. IOM reported that as many as 98,000 Americans die each year as the result of errors that their doctors and healthcare workers make.

Overall, I believe the VA operates a safe health care network. Accidents and suicide happen. Malpractice and even deranged murderers appear everywhere. In a system as large as VA, these things occur more frequently. What concerns Congress ought not to be that they ever happen, but how VA learns about these threats to the safety of our veterans and what VA does to minimize the danger.

Mr. Chairman, you and I agreed to hold this hearing to ensure Congress knows the facts about how safe veterans undergoing care in the VA hospital system are. Last November 30, the Oversight and Investigations Subcommittee asked the General Accounting Office to conduct an investigation of the VA patient safety program. I look forward to hearing their report this morning. We will also hear from the Office of the Inspector General, which regularly inspects and evaluates specific VA facilities, often in response to complaints. We will also hear from the VA's Veterans Health Administration on the initiatives launched by its past and present directors, Dr. Kenneth Kizer and Dr. Thomas Garthwaite.

I look forward to hearing this testimony and I expect to ask some tough questions this morning.

Statement of the Honorable Lane Evans
Ranking Democratic Member
Committee on Veterans Affairs

Hearing on Patient Safety and Quality Management in the Department of Veterans Affairs

July 27, 2000

Thank you, Mr. Everett and Ms. Brown for holding this hearing today. The Office of the Medical Inspector (OMI) of the Department of Veterans Affairs (VA) has reported a total of 2,927 medical errors in a period of a year and a half, of which over 700 resulted in accidental patient deaths or suicides.

Nobody wants to hear that they or someone they care about has been the victim of a life-threatening mistake. No member of this committee will defend *any* number of avoidable patient deaths at VA.

VA is certainly not the only health care system that makes mistakes. The Institute of Medicine (IOM) says VA is simply reporting the types of problems other providers would be reporting if they were required to do so. A recent study looking at *all* health care estimated that as many as 20% of deaths are linked to mistakes in managing prescription drugs. Medical errors throughout the health care industry are more common than it wants to acknowledge.

The Department of Veterans Affairs is the first health care system to come forward publicly with its recorded mistakes, and it takes a lot of courage for VA to do so. VA understands that someone needs to set a standard for our health care system that encourages clinical staff to admit their mistakes so these errors can be corrected.

While there is much that can be done to reduce such deaths, no health care system can ever eliminate them entirely. But if VA doesn't know what mistakes are made, and if staff feel they must hide them, our veterans hospitals will never know how to correct the problems that may lead to these tragic errors. The aviation industry has appreciated fact for a long time, and uses a "no-fault" reporting system VA is now installing. It takes pains to identify the causes of problems and take corrective actions to avoid problems reoccurring.

Most important, if the new systems work correctly, we will learn which mistakes are individual error and which ones are systemic. For example, VA has seen a significant number of problems with concentrated potassium chloride being given incorrectly in patient care units. While each such case was somebody's mistake, VA concluded there was no good reason to have concentrated potassium chloride available in patient care units. Having it there was a *systemic* mistake discovered through statistics. This is a significant discovery that allowed VA to take action.

Though VA has launched its own study of these risks, a study of private and other non-VA health care has not yet been undertaken. What are the issues that will be critical as VA explores patient safety? These include:

- Which problems have simple solutions?
- Which problems does VA identify as the most serious?
- How does VA assign task groups to find solutions to these problems?
- How quickly and effectively does VA apply solutions?
- Do the numbers for these problems actually decrease once they are addressed?

Today's witnesses will tell us what VA has learned to date, and what progress it has made in installing systems that may lead to identifying and minimizing medical misadventures. It is an important hearing, and there will be more in the future.

PATIENT SAFETY IN THE DEPARTMENT OF VETERANS AFFAIRS

TESTIMONY OF

RICHARD J. GRIFFIN, INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS

JULY 27, 2000

Mr. Chairman and Members of the Subcommittee, I am here today to discuss my office's efforts in overseeing and reporting on the issue of patient safety within the Department of Veterans' Affairs (VA). The vast majority of Department of Veterans Affairs employees who are engaged in patient care activities are well-trained, dedicated, and compassionate individuals who are devoted to providing high-quality, safe patient care to eligible veterans. We have noted that the Veterans Health Administration (VHA) is aggressively supporting these employees' efforts by establishing a National Center for Patient Safety (NCPS). In October 1999, the NCPS staff began providing nationwide training for VHA quality managers and senior clinicians on how to critically evaluate and identify the root-causes of serious patient incidents that occur in the course of medical treatment. The root-cause analysis process will ultimately evaluate aggregate patient incident data on events that occur frequently, such as medication errors, patient falls, and suicidal-related events. Once clinicians are able to identify the root-causes of an adverse event, they will be better prepared to formulate measures to reduce the possibility that similar incidents will recur. The initial training will be completed in August of this year, and I understand that the NCPS plans to present similar training once each quarter to ensure that all VHA employees who engage in quality management activities are trained. We salute the VHA employees who strive to provide safe patient care, and we commend the NCPS' efforts to provide training that should ultimately result in a reduction in the number of adverse patient events.

In spite of VHA employees' efforts to provide safe patient care, recent Office of Inspector General (OIG) investigations and inspections have uncovered instances in which some health care providers have ignored or circumvented established policies and procedures that have led to direct or potential patient harm. Even more alarmingly, some employees have engaged in criminal behaviors that have seriously harmed some patients, and may have caused other patients' deaths. The OIG has raised these issues and concerns with the Secretary of Veterans Affairs and with the Acting Under Secretary for Health in several reports and in a report of the deliberations of an OIG Medical Evidence Working Group.

Perhaps the most disconcerting part of our findings and Working Group deliberations is that many of the serious events that occur involve severely debilitated or otherwise compromised patients. It is the caregivers' responsibility to take extra precautions to protect these patients, because when controls are absent or break down, vulnerable patients can be harmed.

Eloping or Wandering Patients

The OIG's Office of Healthcare Inspections (OHI) is currently completing a report that discusses its findings and conclusions regarding the manner in which VA Medical Center employees assess debilitated and mentally infirmed patients' levels of risk for eloping or wandering away from the treatment environment. The report also discusses the effectiveness of VHA's methods to protect high-risk patients, and the effectiveness of patient search procedures. The missing patient data that the report discusses comprises all recorded missing patient episodes that occurred during fiscal years (FY) 1998 and 1999. We initiated this nationwide evaluation because we became aware of a series of tragic events in which patients wandered away from their treatment locales and were later found dead by VA employees or local citizens. Inspectors validated the data, and conducted focused reviews at 11 randomly selected VA Medical Centers during FY 2000. Our work shows that VHA managers are taking the issues of patient elopement and subsequent patient searches seriously, and that several medical center executives have initiated innovative procedures to more strongly protect these patients' safety, and to reduce the frequency of patient elopements. Nevertheless, my OHI inspectors will make recommendations that are aimed at strengthening protection of these patients nationwide in the forthcoming report.

My staff pointed out in a 1999 report[1], that VHA employees did not always report serious patient incidents when they occurred, nor did they initiate formal investigative actions. In two separate cases that my inspectors reviewed, severely debilitated patients, whom employees had secured to their beds with the use of soft vest restraint devices, had slipped from their beds. Both patients had apparently been strangled by the soft restraints that had been intended to keep them safe. In another instance, a similarly debilitated patient partially fell out of his bed, and became wedged between the mattress and the siderails, resulting in his apparent suffocation. In two of these three cases, employees who were directly involved in the patients' care failed to report the incidents to medical center managers, and the events did not become known until other employees reported the incidents to the local media. In the third case, employees reported the incidents, but did not accurately or completely report all of the circumstances surrounding the incident to the investigative panel. The effect of these failures to provide full and open disclosure of patient care incidents severely impedes managers' ability to fully examine the incidents in order to determine their true causes, and to address and correct those causative factors in order to prevent similar incidents from recurring.

[1] ***Oversight Evaluation of the Veterans Health Administration's Implementation of its Patient Safety Improvement Policy in Two Sentinel Events*** (Report No: 9HI-A28-051 – March 2, 1999)

There are several theories as to why employees don't report serious patient care events when they occur. One of these theories is that employees fear the potentially career-threatening disciplinary actions that managers may impose on individuals who have been implicated in such events. Another theory suggests that caregivers are themselves so devastated or embarrassed by the consequences of a possibly careless act, that they may attempt to hide the fact that the incident occurred, or obscure the surrounding circumstances in order to shift the blame from themselves. Whatever the reason for employees not fully and openly disclosing such events, VHA managers, need to continue to emphasize this very important issue, and encourage employees to report each incident that occurs.

Caregiver Criminal Actions

A series of untoward patient care events that involved alleged criminal actions on the part of certain caregivers led the OIG to develop suggested procedures for VHA managers and clinicians to follow to immediately secure evidence and preserve potential crime scenes when patients die suddenly or unexpectedly. To this end, in the summer of 1999, the IG convened a panel of OIG and external experts to review the related problems and to develop suggested guidelines that VHA managers could follow to strengthen law enforcement officers' ability to properly and effectively investigate possible criminal patient care activities, and to pursue prosecutions when such action is indicated. In our report dated November 22, 1999, we advised that VHA needed to focus on its procedures for reporting incidents of sudden, unexpected deaths, and on preserving evidence that is indispensable to determining what actually happened to the patients in these incidents. We also advised that VA personnel do not always consider as potential crime scenes the areas in which sudden, unexpected deaths or other serious patient incidents occurred. The lack of appreciation of this factor's significance has impeded VA's ability to answer the basic question of "what happened?"

VHA managers and General Counsel also need to clarify the standards as to when sudden, unexpected deaths must be reported to law enforcement authorities, and to update and clarify law enforcement jurisdictional issues so that managers and employees will know without delay what agency to contact while the potential evidence is fresh. Finally, we informed the Secretary and Acting Under Secretary for Health that VA needs to review its regulations and policy as to whether the VA can compel an autopsy and associated scientific/medical tests in the event of a possible homicide, suicide, unexpectedly fatal illness, or unexplained deaths. VA's autopsy regulation [2] is silent on the issue of obtaining an autopsy when the family refuses consent. Under the current regulation, there is no guarantee that clinicians can perform forensic autopsies when patients die suddenly and/or unexpectedly, because the facility Director's

[2] 38 C.F.R. § 17.170

discretion to order an autopsy is limited to only those rare occasions of abandoned bodies or in which families fail to respond after a patient's death. We provided the Secretary with three other Federal statutes that might serve as models for changing this VA regulation. We also provided the Secretary and the Acting Under Secretary for Health with recommendations to aid employees in doing a better job of identifying, reporting, and preserving evidence in all cases of sudden, unexpected patient deaths in VA facilities. The Acting Under Secretary informed us that VHA has created a work group to address these issues.

Combined Assessment Program Review Monitoring

In October 1999, my office initiated cyclic reviews of VA medical facility operations entitled Combined Assessment Program (CAP) reviews. In the course of conducting these CAP reviews, OIG healthcare inspectors and auditors systematically evaluate the effectiveness and comprehensiveness of the facility's quality management activities and patient safety assessment procedures. In addition, healthcare inspectors examine a range of health care activities that test controls that managers have established to ensure that all patients are receiving safe and appropriate patient care. Several CAP reviews have identified staffing shortages or staff distribution irregularities that have the potential to threaten the delivery of safe and adequate patient care, and in each of these cases, managers have ensured us that they would address and correct these problems. Inspectors and auditors have also identified issues in which local clinicians had stopped making required evaluative visits to contract community nursing homes and State Veterans Homes. Instead, they were simply reviewing other agency reports as a basis for ensuring that veterans who the facility had placed on contract care were receiving safe and appropriate care. We advised local managers of the VA requirement to conduct these inspections, and in each case, they indicated that they would do so. During future CAP reviews, we plan to examine the medical centers' and affiliated Universities' procedures for conducting pre-employment evaluations and certifying prospective employees. We also plan to test the NCPS' success as part of the CAP reviews, by evaluating employees' performance and actions taken on root-cause analyses, and their success in evaluating aggregate patient incident data on frequently occurring events.

Mr. Chairman, this completes my statement. I will be pleased to answer any questions that you or the Members of the Subcommittee may have on this subject matter.

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Thursday, July 27, 2000

VA PATIENT SAFETY

Initiatives Promising but Continued Progress Requires Culture Change

Statement of Cynthia A. Bascetta, Associate Director
Veterans' Affairs and Military Health Care Issues
Health, Education, and Human Services Division

GAO/T-HEHS-00-167

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 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

[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).

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 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,

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

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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 Stages 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 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.

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[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.

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 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

[7]As of July 7, 2000.

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 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.

[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.

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 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

[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.

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 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

[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).

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.

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

(406190)

[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).

Statement of
Linda J. Connell
Director
NASA Aviation Safety Reporting System

Before the
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
House of Representatives

July 27, 2000

Mr. Chairman and Members of the Subcommittee,

I am pleased to respond to your request for information on the Aviation Safety Reporting System (ASRS). The ASRS is a model for voluntary, confidential, non-punitive safety reporting that has been contributing to aviation safety since 1976. I would like to discuss some aspects of its applicability to the current efforts surrounding the improvement of healthcare within the Department of Veterans' Affairs (VA), Veterans Health Administration (VHA) and the recent Interagency Agreement between the VA and NASA in May of this year.

After the creation of the VHA Expert Advisory Panel on Patient Safety in 1998, NASA was asked to join this prestigious panel and present information on the ASRS. I was very pleased to participate and share the many proactive safety activities that the ASRS is able to perform for aviation. The ASRS is a highly successful and trusted program that has served the needs of the aviation community for 24 years. It is available to all participants in the National Aviation System who wish to report safety incidents and situations. The ASRS was established in 1976 under an agreement between the Federal Aviation Administration (FAA) and NASA. This cooperative safety program invites pilots, air traffic controllers, flight attendants, maintenance personnel, and others to voluntarily report to NASA any actual or potential hazard to safe aviation operations. The FAA's Office of System Safety provides most of the ASRS program's funding. NASA Ames Research Center administers the program, assures confidentiality, receives all reports submitted to the program, and sets policies in conjunction with the FAA and a fifteen member industry Advisory Committee.

The ASRS collects and responds to these voluntarily submitted incident reports, using this information to lessen the likelihood of aviation accidents. ASRS data are used to identify aviation system deficiencies for correction by appropriate authorities, support aviation system policy, contribute to planning and improvements, and strengthen the foundation of aviation human factors safety research.

ASRS reporters are protected when they report to this system. NASA and the FAA offer those who use the ASRS program two important reporting guarantees: confidentiality and limited immunity. These guarantees, as expressed in Federal Aviation Regulation 14 CFR 91.25 and FAA Advisory Circular 00-46D, are offered because this type of safety information is unique, and its value can only be obtained as a result of the confidence and trust placed in the program by the reporters. A NASA preaddressed and postage-free form, NASA ARC 277A-D, is used by the aviation reporters to submit information. The reports sent to the ASRS are held in strict confidence. More than 470,000 reports have been submitted since the program's beginning, without a single reporter's identity being revealed. The ASRS removes all personal names and other potentially identifying information before entering reports into its database. Currently, the ASRS program is receiving approximately 36,000 reports annually.

Reporters to ASRS are also guaranteed limited immunity by the FAA. This means that the FAA will not use, nor will NASA provide, information that has been filed with the ASRS in an enforcement action. Fines and penalties for unintentional violations of

Federal Aviation Regulations will be waived, as long as violations are reported within 10 days. However, accidents and criminal activities are not protected from enforcement actions, and should not be submitted to the ASRS. In addition to the immunity provisions associated with the ASRS program, reporters often mention other equally important motivations for using the program. The reporters feel increased satisfaction in knowing that they are helping to improve the aviation system by giving safety information to the ASRS, significantly increasing understanding of the factors contributing to safety incidents.

I would like to emphasize that the ASRS is a unique safety information system. No other such national reporting system, voluntary or mandatory, delivers the complete standard of confidentiality and anonymity provided by the ASRS program. An indication of the importance of confidentiality is provided by the fact that over 70% of the reports in the ASRS database contain statements revealing human error information. It is not unusual for reporters to discuss their own operational mistakes—mistakes they would never even mention to others (e.g., other Government Agencies or organizations), let alone explain the reasons why the incidents occurred. Confidential incident reporting provides an insight into events from the human perspective that can rarely be obtained through other methods.

The successful longevity of the ASRS and its continuing trust and strength arise from several factors. First and foremost is the promise of confidentiality, which is further reinforced by the 24-year history of proven ability to protect the identity of a reporter. The next important factor is the program's independence, both actual and perceived. NASA's involvement, as the "honest broker" between the regulator and the reporter, has been a significant reason that the ASRS has been trusted and that the reports received are honest appraisals of the performance of the reporter and others in the aviation system. NASA is a research organization with no regulatory authority and, therefore, is perceived as a safe place to report sensitive, possibly self-incriminating, information. NASA's distinct position, as an independent Government Agency with a strong influence on aviation safety policy and practice, has been invaluable in instilling trust in the ASRS.

Another important factor is the creation of the ASRS Advisory Committee. This body has assisted the ASRS by providing substantial advocacy, guidance concerning ASRS policy, assurance to reporter communities of bona fide confidentiality, and support for improvements in safety as a result of incident reports. This Advisory Committee has been very crucial from the initial steps of the creation of the ASRS and throughout its history. The Advisory Committee attempts to represent all potential reporter communities, as well as other industry organizations and government. Currently, this group exists under the NASA Aero-Space Technology Advisory Committee as the ASRS Advisory Subcommittee.

The Advisory Committee has substantially assisted the ASRS in providing another crucial factor important for its success. The importance of feedback to the reporter communities must not be underestimated. The ability of the ASRS program to convert the aviation community's report input into constructive output is evidenced by the many products produced by the ASRS (see Attachments A & B and http://asrs.arc.nasa.gov). The ASRS has released 2,500 alert messages concerning potential hazards and important occurrences. Approximately 42% of the alert addressee responses indicate that a follow-up action was taken as a result of the safety alert message. A monthly newsletter, CALLBACK, is distributed to over 88,000 recipients and captures and presents safety information from the incidents received by ASRS. The participation of ASRS at significant safety organizational meetings, conventions, and workshops continues to reinforce the participation by these communities. The reporters can see evidence that information provided is utilized for constructive changes to improve safety.

As we begin to apply the aviation model to the VHA and its current quality improvements efforts, it is noteworthy that the ASRS model has already been widely accepted by other aviation systems around the world. There are currently seven countries that have begun operating voluntary, confidential incident reporting systems. In addition to the United States, participating nations include the United Kingdom, Australia, Canada, Russia, Taiwan, and Korea. These countries have preserved the concepts of

voluntary and confidential reporting as key characteristics necessary to assure the filing of reports. Although most countries have provisions for "use immunity" (i.e., prohibition from use in enforcement action), none have "transactional immunity" (i.e., waiver of disciplinary action). All countries are, however, very aware of the necessity of confidentiality for the continuing viability of their systems. The vital role of confidentiality was graphically demonstrated when one nation's system collapsed, due to a dramatic decrease in reporting after a reporter's identity was revealed.

In assuring protection of a reporter's identity, methods for de-identification of reports are crucial. The ASRS employs aviation experts as its report analysts. These people are, in fact, retired aviation professionals, including pilots, air traffic controllers, flight attendants, and mechanics—all of whom have had lengthy careers in aviation. Analysts examine each report and maximize the pertinent safety information available within the report. The ASRS system (as opposed to one which has anonymous reporting) has the capability of contacting incident reporters and obtaining additional information, as well as discussing safety events with reporters. When these interactions occur, it is a matter of event reporters talking with individuals having comparable professional training and experience—pilots talking to pilots, controllers talking to controllers, etc. This collegiality produces an increase in the validity of the data. Analysts are able to find out the "why" of the event, not just a terse description. Consequently, the narrative section of the report record is quite complete in its description of the event, as well as the inclusion of key words and coding to facilitate subsequent retrieval from the electronic database.

In addition to providing expertise and quality assurance, ASRS analysts are able to reliably remove information that might identify a reporter. The ASRS places its highest priority on this protection. The goal is to remove enough information to protect the reporter while at the same time preserving the safety message, in the actual words of the person reporting. This process of de-identification also relates to other topics of interest, such as the public release of information and legal discovery. The ASRS database includes only the information that has been determined to be most important. Due to limited resources, the ASRS performs a type of triage to determine which reports will be fully analyzed for inclusion in the database. Once these data are placed in the database, it is accessible to the public through the ASRS Search Request process, an internet site managed by the FAA (http://nasdac.faa.gov/safety_data), or through a private CD-ROM product available on the market. The ASRS has accomplished over 5,800 database searches for government agencies, students, research organizations, international organizations, aircraft manufacturers, etc. The FAA is the top requester of the ASRS information. Often, we are asked for information through the Freedom of Information Act (FOIA), but recourse to this statute is not needed, since NASA's ASRS database is already openly available.

As for legal issues, incidents reported to ASRS rarely involve negligence and liability, often inherent in more serious events, such as accidents. After being rapidly de-identified, a narrative may be augmented in various ways. For example, analysts may add additional clarifying language. Also, a report from one reporter (e.g., a Captain) will be paired with other reports (e.g., a First Officer) describing the same event. Through such procedures, the content of the original report may to a certain extent be altered. Accordingly, ASRS has been informed that such alteration renders a report "hearsay evidence," due to its lack of an identifiable source, and therefore of less interest in legal proceedings. In some cases, for example, database reports have actually been used to defend a pilot. Instead of using information against an individual, data may be used to illustrate a potential system flaw that may also have victimized a number of other persons. Therefore, when event reporters do choose to share their experience with the ASRS, they are not faced with the added threat of complicating their own, or their employers', legal position. The de-identification process has been quite effective in driving out fear of incident reporting.

It is important to note that the ASRS is not an investigative system. The information contained in reports is evaluated carefully by experts, but the confidentiality requirements of the system make it impossible to obtain third party verification. The information relating to the existence and character of a phenomenon is relayed to the appropriate organizations in a manner that permits and encourages them to investigate the safety

issue further and seek a solution. Alternatively, they may implement interim procedures to accommodate the phenomenon until a solution can be identified and instituted.

We firmly believe that the ASRS incident database is the most authoritative source of human performance information that exists in aviation today. This program is a paradigm that can be utilized in many other disciplines.

The current NASA/ASRS effort to establish a new external reporting system with the VHA, entitled the Patient Safety Reporting System (PSRS), will be a challenge as well as an opportunity. The ASRS model will serve as a starting point for the proposed voluntary reporting system. However, the significant operational and structural differences between the health care environment and the field of aviation may present challenges for the PSRS system. It may well be necessary to develop VHA approaches that differ from those employed by the ASRS, but the salient characteristics of the ASRS will be captured so as to provide the maximal relevant information. The three-year agreement between the VA and NASA will explore how such differences impact the implementation of confidential and de-identified patient safety-related reporting within the VA health care system. This approach is intended to provide the most efficient path to discovering the benefits of voluntary, confidential reporting in health care settings. The VA and NASA are uniquely positioned to embrace this challenge. The opportunity for both NASA and the VA is to gain new insights into the nature of human performance in the complex and dynamic environment of medicine, exploring the best means of optimizing safety in patient care. Potential benefits have not only an immediate application to VA/VHA care of veterans but also long-term relevance to health care in general.

Thank you for providing me with this opportunity to present information on the Aviation Safety Reporting System, outlining our accomplishments in the effort to bring about improvements in aviation safety. NASA will be pleased to provide any further information that you may request.

Mr. Chairman, Members of the Subcommittee, this concludes my testimony. I will be happy to respond to your questions.

AVIATION SAFETY REPORTING SYSTEM

SIGNIFICANT PROGRAM SAFETY PRODUCTS

JANUARY 10, 2000

The following is a listing of the variety of safety products that were accomplished by the NASA ASRS staff:

General Accomplishments

- Since the implementation of the Aviation Safety Reporting System (ASRS) in 1976, over 474,000 reports have been submitted by pilots, mechanics, air traffic controllers, cabin attendants, and other aviation personnel.
- The ASRS is the largest repository of aviation human factors incidents in the world.
- The ASRS has an unblemished record of *never* breaching reporter confidentiality.
- The ASRS has accomplished over 5,800 database searches for government agencies, students, research organizations, international organizations, aircraft manufacturers, etc.
- Since 1976, the ASRS has issued over 2,500 safety alert messages in the form of Alert Bulletins & For Your Information Notices. Approximately, 42% of the addressee responses indicated that a follow-up action was taken as a result of the safety alert message.

Operational Impacts

- Identified and alerted the FAA Office of Aviation Safety & the NTSB to the wake vortices caused by B757 aircraft. Consequently, the FAA issued a directive requiring increased separation behind B757 aircraft and the issuance of wake turbulence advisories.
- Identified and alerted the FAA Office of Aviation Safety & the Air Transport Association to the affects of passenger electronic devices on air carrier communication & navigation systems.
- Issued an ASRS Alert Bulletin to the aircraft manufacturer that concerned an L-1011 electrical fire. The manufacturer subsequently issued a Flight Operations Advisory Bulletin to all L-1011 operators.
- Issued an ASRS Alert Bulletin to the air traffic managers at Los Angeles Control Tower and the Southern California TRACON concerning close-in instrument approach changes. The FAA collaborated with various manufacturers to implement a flight management system (FMS) program modification that would promptly display transitions to newly assigned runways.
- Issued an ASRS For Your Information Notice concerning the airport lighting and general conditions of the Pickens County Airport, Jasper, GA. The local FAA Flight Standards office conducted an on-site inspection of the airport and issued a warning notice to the Pickens County Commissioner to take corrective actions within 30 days of the notice.
- Issued an ASRS For Your Information Notice to the Airport Manager of Mitchell International Airport, Milwaukee, WI concerning an unsafe runway incursion incident. The airport authorities subsequently completed a project to install flashing warning lights at key runway intersections.
- Issued an ASRS Alert Bulletin to FAA Headquarters concerning a smoldering passenger's bag in a DC-10 aircraft that was caused by animal-shaped butane cigarette lighters. The FAA subsequently issued a notice to airport security personnel on the toy-shaped lighters.

NTSB Accident Support

- A database search of Jetstream-31 aircraft failure incidents was forwarded to the NTSB in conjunction with the Jetstream-31 accident at Raleigh-Durham, NC.
- A database search of EMB-120 aircraft engine incidents was forwarded to the NTSB in conjunction with the EMB-120 accident near Carrollton, GA.
- A database search of Colombian airspace incidents were forwarded to the NTSB in conjunction with the B757 accident near Cali, Colombia.
- Accomplished a database search request for the NTSB in support of the investigation of the MD-11 accident near Halifax, Nova Scotia.

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NASA/ASRS RESEARCH IMPACT: A PARTIAL LISTING

NASA/ASRS Research Product or Data	Year	Regulatory / Operational Effects	Cited In
Human Factors Associated with Runway Incursions, C.E. Billings, NASA TM 78540 (ASRS QR#8). An analysis of ASRS incident data.	1978	Used as resource in NTSB and FAA studies of runway transgressions; 1991 FAA study resulted in new procedures and improved runway/taxi marking systems	• *Runway Incursions at Controlled Airports in the United States,* NTSB special Investigation Report, (NTSB.SIR-86/01). • *Runway Incursion Plan,* DOT/FAA Associate Administrator for System Engineering and Development, ARD-100, January 1991. • *Pilot Surface Incident Safety Study,* David R. Kelley and J. Glenn Steinbacher, MITRE, report prepared for DOT/FAA Office of Integrated Safety Analysis under the direction of the Associate Administrator for Aviation Safety (March 1993).
Knowledge of the limitations of the ATC system in conflict avoidance capabilities, William P. Monan, NASA TM 81197.	1978		• *Altitude Deviation Study: A Descriptive Analysis of Pilot and Controller Incidents ,* MiTech, Inc. and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992
Distraction–A Human Factor in Air Carrier Hazard Events (ASRS QR#9)	1979	Provided data and motivation for FARs Part 121.542 and Part 135.100, "Flight Crewmember Duties" ("The Sterile Cockpit Rule")	• Federal Register, *Notice of Proposed Rulemaking,* Vol. 45, No. 169, August 28, 1980, p. 57684. • Federal Register, *Final Rule,* Vol. 46, No. 12, January 19, 1981, p. 5500. • *Flight Safety Digest,* "Accident and Incident Reports Show Importance of Sterile Cockpit Compliance," Vol. 13, No. 7, July 1994, 1-8.

NASA/ASRS Research Product or Data	Year	Regulatory / Operational Effects	Cited In
Probability Distributions of Altitude Deviations, R. Thomas and L. Rosenthal, NASA CR 166339.	1982	First in-depth study of the characteristics of altitude deviations in the ASRS database, including geometry and distribution of altitude deviations.	• *Altitude Deviation Study: A Descriptive Analysis of Pilot and Controller Incidents*, MiTech, Inc. and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992.
Non-Airborne Conflicts: The Causes and Effects of Runway Transgressions, Richard J. Tarrel, NASA CR 177372. An analysis of ASRS incident data.	1985	Used as resource in NTSB and FAA studies of runway transgressions; 1991 FAA study resulted in new procedures and improved runway/taxi marking systems	• *Runway Incursions at Controlled Airports in the United States*, NTSB special Investigation Report, (NTSB.SIR-86/01). • *Runway Incursion Plan*, DOT/FAA Associate Administrator for System Engineering and Development, ARD-100, January 1991. • *Pilot Surface Incident Safety Study*, David R. Kelley and J. Glenn Steinbacher, MITRE, report prepared for DOT/FAA Office of Integrated Safety Analysis under the direction of the Associate Administrator for Aviation Safety (March 1993).
Human Factors in Aviation Operations: The Hearback Problem, William P. Monan, NASA CR 177398	March 1986	Motivated 1986 change to FAA Air Traffic Control Handbook (Order 7110.65) requiring controllers to ensure that pilot readbacks are correct. Also Introduced the term "hearback" to the aviation community (subsequently widely adopted);	• *FSF Accident Prevention Bulletin*, Vol. 43, No. 10 (3), October 1986, "The 'Hearback' Problem" • *Flight Safety Foundation Accident Prevention*, "My Own Mouth Shall Condemn Me, "Vol. 47, No. 6, June 1990.
Cockpit or Cabin Crew Coordination, Kim M. Cardosi and M. Stephen Huntley, Jr., DOT/FAA/FS-88/1, Final Report. Utilized ASRS data.	February 1988	Motivated issuance of FAA Advisory Circular 120-48 (7/13/88), "Communication and Coordination Between Flight Crewmembers and Flight Attendants"	
VFR Flight Near TCAs: Practices, Perceptions & Problems, R. Tarrel, et al (ASRS)	November 1989	Study performed at request of FAA Office of Aviation Safety; believed to have influenced moderation of FAA enforcement posture toward General Aviation pilots	

NASA/ASRS Research Product or Data	Year	Regulatory / Operational Effects	Cited In
Human Factors of Flight-Deck Checklists: The Normal Checklist, Asaf Degani and Earl Wiener, NASA CR 177549. Findings based on ASRS data.	1990	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); more than 2,400 copies requested by operational community as the result of *CALLBACK* summary	• Incorporated in FAA Advisory Circular 120-64. • *NASA/ASRS CALLBACK*, No. 136-137 (Sept-Oct 1990). • *Aviation Daily*, November 5, 1990, p. 241. • *USAir Airwaves*, December 1990, 12-13. • *Journal of flight engineers (Varig)*, Vol. 17 (63), 1990. • *All Nippon Airlines Journal*, No. 149, 17-21, 1991. • *Journal of the United Nations Civil Aviation Organization*, Vol. 46 (6), 18-21, 1991. • *Delta Airlines Safety Newsletter*, Vol. 6 (1-2), 1991. • *Human Factors*, Vol. 35, No. 2, June 1993, 345-359.
"Eliminating Pilot-Caused Altitude Deviations: A Human Factors Approach," Robert L. Sumwalt, in *Proceedings of the Sixth International Symposium on Aviation Psychology*, The Ohio State University.	1991	Described genesis of USAir's Altitude Awareness Program and usefulness of ASRS data in this enterprise.	• "The Development of an Altitude Awareness Program: An Integrated Approach," Thomas M. Granada, Carlow Associates; Capt. Donald H. McClure, ALPA; Capt. James W. Fogarty, USAir, paper presented at the Human Factors Society Meeting, 1991. • *Altitude Deviation Study: A Descriptive Analysis of Pilot and Controller Incidents*, MiTech, Inc. and Carlow Associates, DOT/FAA Research and Development Service, Final Report, October 1992.
The Use and Design of Flightcrew Checklists and Manuals, John W. Turner and M. Stephen Huntley, Jr., U.S. DOT Research and Special Programs Administration, Final Report. Findings based on ASRS data.	April 1991	Study was supported by six Part 121 and nine Part 135 carriers, and an ALPA survey. Contained recommendations for formatting and content of checklists and manuals, and use by flight crews.	

NASA/ASRS Research Product or Data	Year	Regulatory / Operational Effects	Cited In
"One Zero Ways to Bust an Altitude," Donald George, *ASRS Directline*. Review of ASRS data on altitude deviations.	Fall 1991	Distribution to an estimated 50,000+ pilots in US. and foreign operations	• United Airlines excerpted portions of article and distributed to all of its 9,000 pilots in a *United Airlines Flight Safety Brief*. UAL also reproduced a graphic from the article and made it into a poster for company-wide distribution. • Article reprinted by TWA, USAir, New Zealand Air, GATCO, *Commercial Aviation Safety* (UK), and *Focus on Commercial Aviation*.
"Air Carrier Ground Deicing/Anti-Icing Problems," Robert L. Sumwalt, in *Proceedings of the Seventh International Symposium on Aviation Psychology*, The Ohio State University. Review of ASRS data on ground deicing operations. The author summarized the results of this research in personal correspondence to the FAA in April 1993, in response to Docket No. 26930 (interim NPRM).	April 1993	FAA Advisory Circular 120-60 (5/19/94) contained a provision recommended by the ASRS study and its author requiring an outside-the-aircraft check for icing contamination.	• "Aircraft Ground Deicing Problems: Recommendations from Analysis of ASRS Incident Data," SAE Ground Deicing Conference Transcription of Proceedings, June 15-17, 1993, Salt Lake City, Utah. • "Incident Reports Highlight Problems Involving Air Carrier Ground Deicing/Anti-icing," Robert L. Sumwalt, *FSF Airport Operations*, Vol. 19, No. 5, September/October 1993.
A Review and Discussion of Flight Management System Incidents Reported to the Aviation Safety Reporting System, Donald Eldredge, Susan Mangold, and Robert Dodd, U.S. DOT/FAA Research and Development Service. Analysis of ASRS FMA-related database reports	February 1992	Frequently requested by air carrier and aviation industry organizations	

On the Typography of Flight Deck Documentation, Asaf Degani, NASA CR 177605	December 1992	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); more than 800 copies requested by operational community as the result of *CALLBACK* summary	• Incorporated in FAA Advisory Circular 120-64. • *Human Performance Considerations in the Use and Design of Aircraft Checklists*. Federal Aviation Administration, Office of Safety Services-Safety Analysis Division, 1995. • *NASA/ASRS CALLBACK*, No. 168 (May 1993).
On the Design of Flight Deck Procedures, Asaf Degani and Earl Wiener, NASA CR 177642. Findings based on ASRS data.	June 1994	Published as a mandatory requirement for all FAA inspectors that certify checklists (1995); 200 copies requested from NASA as the result of *CALLBACK* summary	• Incorporated in FAA Advisory Circular 120-64. • *Human Performance Considerations in the Use and Design of Aircraft Checklists*. Federal Aviation Administration, Office of Safety Services-Safety Analysis Division, 1995. • *NASA/ASRS CALLBACK*, No. 184 (Sept 1994).

Statement of
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and
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Chief Quality and Performance Officer
Veterans Health Administration
Department of Veterans Affairs
Before the
House Veterans' Affairs Subcommittee on Oversight & Investigation

July 27, 2000

Mr. Chairman and Members of the Committee,

We are pleased to appear before you to discuss VA's ongoing activities and initiatives to ensure the provision of consistent, high quality and safe care to patients. The committee rightly recognizes the link between quality and safety and the fact that quality and safety are fundamental to the work of the VA health care system at all levels. It is important to note that achieving the best possible outcomes for our patients while minimizing safety risks are overarching goals for all elements of the VA system. The Office of Quality and Performance and the National Center for Patient Safety and all other VHA offices have leadership roles and share responsibility for achieving these goals.

For clarity, the fundamental principles, philosophy and basic elements of VA's quality and safety activities are presented separately. However, it is only when all elements work together that the full benefit of each is realized and a number of programs that exemplify this are also discussed.

PATIENT SAFETY

Starting in 1997, VA intensified its already extensive efforts in quality improvement by launching major overt initiatives on patient safety per se (see Attachment 1). By no means were these initiatives the first safety related efforts by VA. For example, prior to 1997 the development and implementation of clinical guidelines ensured uniform, safe provider performance across all facilities. VA recognized that programs to improve quality and safety in health care often share purposes and corrective actions. However, it believed that patient safety required a new and different approach and set out to create a new culture of safety in which VA employees detect and report unsafe situations and systems as part of their daily work. Studies have shown that this change of culture is a multi-year task. VA is committed to designing and implementing new systems and processes that diminish the chance of error and the elimination of unsafe situations. VA is using a systems approach that emphasizes **prevention -- not punishment** -- as the preferred method to accomplish this goal.

In December 1999, the Institute of Medicine (IOM) released a report "To Err is Human: Building a Safer Health System." The report's review of existing studies, which concluded that as many as 98,000 preventable deaths occur each year in United States' health care due to error, focused national attention on patient safety. The IOM recommended creating a new National Center for Patient Safety (not to be confused with the VA's own National Center for Patient Safety, which already existed) that would focus on research and policy related to errors in health care, improved error reporting systems, improved analysis/feedback methods, performance standards for health care organizations and individuals, and other specific governmental actions. Importantly, the IOM report cautioned that the focus must be on creating a culture of safety that will require improving systems, not assigning blame.

VA interpreted the IOM report as a validation of its commitment to improving patient safety in its health care system. All of the IOM recommendations applicable to VA have either been in place or were in the process of being implemented prior to the release of the report. While VA has had quality and safety related activities ongoing for many years, it was in 1997 that its formal patient safety program was launched. Leaders in the field of patient safety and medical error outside VA have participated in the design of the system and recognize VA as a pioneer in these efforts.

VA recognized that patient safety is not a VA-specific issue, therefore it asked other health care organizations to join in an effort to understand the issues and to act for patient safety. As a result, the **National Patient Safety Partnership (NPSP),** a public-private consortium of organizations with a shared interest and commitment to patient safety improvement was formed in 1997. The charter members, in addition to VA, included the American Medical Association (AMA), the American Hospital Association, the American Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Association of American Medical Colleges, the Institute for Healthcare Improvement (IHI), and the National Patient Safety Foundation at the AMA. Five additional organizations have subsequently joined the charter members in the Partnership: the Department of Defense (D0D) -Health Affairs, National Institute for Occupational Safety and Health, the Food and Drug Administration (FDA), Agency for Healthcare Quality and Research, and the Health Care Financing Administration. This group addresses high impact issues that are of importance to a broad cross section of the health care industry. An example of the Partnership's action and influence was the establishment of an FDA clearinghouse for information related to the effect of Y2K computer issues on medical devices. The NPSP also called public and industry attention to Preventable Adverse Drug Events and promulgated simple actions that patients, providers, purchasers and organizations could take to minimize their chance of an adverse drug event. VA is leading development of an NPSP anthology on issues in patient safety that will serve as a resource for industry, educators, and policy discussion. Also, VA is leading the way in the use of bar-code technology to prevent errors. The NPSP serves as a model of what a private-public collaboration can do to improve patient safety.

VA instituted a **Patient Safety Improvement Awards Program** in 1998 to focus interest on and reward innovations in identifying and fixing system weaknesses. Not only does this produce ideas for patient safety improvements that might otherwise go unnoticed, but it further reinforces the importance that VA places on patient safety activities and involves those at the 'front-line' in a very direct and tangible way.

In 1998, VA created the **National Center for Patient Safety (NCPS)** to lead and integrate the patient safety efforts for VA. This Center was created to lead VA's patient safety efforts and has a direct reporting relationship to the Under Secretary for Health. The NCPS employs human factors engineering and safety system approaches in its activities. The first task for the Center is to devise systems to capture, analyze and fix weaknesses in our systems that affect patient safety.

In 1998 VA formed the **Expert Advisory Panel for Patient Safety System Design** to obtain expert advice to enhance the design of VA's reporting systems. These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System (ASRS), as well as other experts from NASA and the academic community. They advised us that an ideal reporting system: a) must be non-punitive, voluntary, confidential and de-identified; b) must make extensive use of narratives; c) have interdisciplinary review teams; and d) most importantly, focus on identifying vulnerabilities rather than be a counting exercise. VA has used these principles to design the patient safety reporting systems we have in use or in development. Based on the expert advice and on lessons learned from our mandatory adverse event reporting pilot, the NCPS has developed and rolled out a comprehensive adverse event, close call analysis and corrective action program and computer assisted tool that includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes, but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as human factors decision support tools and computer aided report tools to determine the root cause of adverse events and close calls.

In 1999, VA established four **Patient Safety Centers of Inquiry**. These Centers conduct research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, California, which is affiliated with Stanford University, is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient. VA expects to create additional simulation facilities to train its physicians and other health care professionals. One simulator with appropriate staff could train approximately 600 anesthesiologists and residents per year. This means that virtually all VA anesthesiologists/anesthetists can be trained in a year on clinical situations that could not be simulated safely in actual patients. Another Center at White River Junction, Vermont, is partnering with the Institute for Healthcare Improvement (IHI) to

build learning collaboratives aimed at reducing medication errors, a major issue identified in the IOM report. IHI collaboratives will affect several hundred VHA personnel each year. Other IHI collaboratives have resulted in measurable improvements and similar results are anticipated with medication errors.

In November 1999, the new event and close call reporting system was first pilot tested in VA's VISN 8 (Florida, South Georgia and Puerto Rico). Extensive training and constant mentoring and feedback are provided to assure full understanding of the search for the root cause and redesign of the system. The quality managers, risk managers, and clinicians using the system believe that the new methods analysis of error will make a significant improvement in the care of veterans. Independently, VHA's Patient Safety Improvement Oversight Committee has stated that the reports and corrective actions that are the product of this new approach are superior in numerous ways to the ones from the previous system. By August of this year, all VA hospitals will have received this training and be using this system. To date, there have been nearly 600 participants at these national training sessions. While the vast majority of these participants have been VA employees, we have been pleased to accommodate requests for training about our system from participants in both the public and private sector. Participants have included guests from AHA, Baylor University, DoD, FDA, the Government Accounting Office, Kaiser Permanente, the University of Michigan, the University of Texas, and other private and public health care systems or affiliates. Response from participants has been overwhelmingly positive.

We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a health care provider -- we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask system weaknesses before a patient is injured thus enabling preventive actions to be taken. This emphasis on "close calls" has been employed by organizations outside of health care with great success. It has been said that experience is the best teacher, however it is also the most expensive. In the case of medically related experience that cost can be expressed in terms of tragic consequences. "Close calls" enable us to learn and institute preventive actions without first having to pay the costly tuition born of human tragedy.

To complement our internal system, an agreement to establish the Patient Safety Reporting System (PSRS), a complementary, de-identified voluntary reporting system, was finalized in May of this year with NASA. The PSRS is patterned after the highly successful Aviation Safety Reporting System that NASA operates on behalf of the FAA. It is external to VA and allows all physicians, nurses, pharmacists, laboratory personnel, and others to report unsafe occurrences without fear of administrative or other action being taken against them.

Another key VA strategy to reduce medical errors involves the development of a new curriculum on safety. VA is moving forward with plans to provide education and

training relevant to patient safety not only to those already in practice but also at the medical, nursing, and health professional school levels. This will be the first time an extensive safety curriculum will be developed and broadly implemented. VA is particularly well situated to lead the educational effort due to the extensive role it plays in the education of health care professionals in the United States. (VA is affiliated with 105 medical schools and up to one-half of all physicians in the country train in a VA facility during medical school or residency.) Additionally, we have instituted a performance goal to provide VA employees 20 hours of training on patient safety this year.

Based on lessons learned from the review of adverse events, actions are taken at both the local level and nationally. Examples of national level actions are as follows:

- Restricting access to concentrated potassium chloride on patient care units
- Requiring use of barcode technology for patient identification and blood transfusions in operating rooms
- Establishing new procedures for missing patient searches
- Enhancing violent behavior prevention efforts
- Establishing new procedures for verifying water temperature for patient baths/treatments
- Enhanced procedures to ensure safe injection of Radio-Labeled Blood Products
- Enhanced requirements for protective fencing around construction sites

We believe that patient safety can only be achieved by working towards a "culture of safety." Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the "hidden" opportunities behind the more obvious errors. Unfortunately, systems' thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame-and-train approach to error reduction. Such an approach by its very nature forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and fault finding approach to a system-based approach that seeks the root causes of errors to guide them in preventive actions. VA realized how pivotal culture is to improving safety and in 1998 conducted a culture survey of a sample of employees. Of interest, the shame of making an error appeared a more powerful inhibitor of reporting than was fear of punishment. The survey provided information that indicated that employees were intolerant of their own errors and were "ashamed" if others knew that an error had been made. People who have expressed strong feelings of shame are less likely to exchange learning experiences with others, thus thwarting the opportunity for the entire institution to learn from the experience. We plan to survey culture broadly in VA for several years to track the progress of our efforts.

QUALITY MANAGEMENT

Aviation safety has been used metaphorically to describe both opportunities and processes to improve patient safety. It is also an appropriate metaphor for describing the relationship between safety and quality. While much is learned from understanding adverse events and close calls, quality has to be "engineered in." Safe health systems, like safe aviation, must be designed and implemented to tolerate human imperfection and still achieve reliably good outcomes. Neither quality nor safety can be adequately described independently. While each may receive identifiable and specific support, the overall fabric is far more complex than the individual threads.

VA processes systematically seek to "engineer in" quality. Clinical practice guidelines, electronic medical records, computerized clinical reminders, bar code blood and medication administration all exemplify systems which are not only designed to reduce the risk for bad outcomes based on human factors, but designed to support achievement of the optimal outcomes possible for patients. All of these initiatives, except practice guidelines, originated outside of the quality and safety offices. VA Research also makes significant contributions to improving quality and safety of patient care (See Attachment 2). All of these efforts and many others represent organizational commitment to quality and safety.

The history of VA's commitment to "engineering in" quality is important. The 1995 publication *Vision for Change* (page 7), described a radical, yet rational, transformation of structure that would support a transformation of culture. The ensuing structural transformation made it possible to embark on a "quality and safety transformation" that is now being realized.

VA articulated its commitment to quality in the broadest sense, and expressly inclusive of safety, in 1996 with the publication of *Prescription for Change*. VA's commitment to quality is galvanized by the Performance Measurement Program operated through the Office of Quality and Performance. The Performance Measurement Program begins with the principle that quality outcomes can, and should, be specified. Through performance contracts, clinicians and managers are accountable for achieving realistic, but ambitious performance targets in defined time frames. A highly evolved measurement program provides ongoing assessment of performance and the data necessary for effective management. Improvement since inception of performance measurement in 1995 is impressive. In many areas where comparative quality data are available, VA meets or exceeds published levels of performance in health care.

VA expressed its commitment to preventive health through development of the Prevention Index. This index supports improvement in evidence-based health services such as immunization, cancer detection, and substance abuse screening. On a 100 point scale, the Prevention Index improved from 33 (1996) to 67 (1997) to 79 (1998) to 81 (1999), a 145% improvement since inception. A parallel 100 point Chronic Disease Index including indicators of care in heart disease, lung disease, diabetes, and hypertension has increased from 45 (1996) to 77 (1997) to 85 (1998) to 89 (1999), a

98% improvement since inception. VA's rates of immunization against pneumonia and influenza now exceed U.S. Public Health Service goals and published private sector performance.

What does this mean in terms of real outcomes for real patients? In the United States, only about 50% of the elderly and patients with chronic disease appropriately receive the recommended pneumonia vaccination. In contrast, in VA, by 1998, the improvement in pneumonia vaccination, from levels consistent with prevailing community rates in 1996, is estimated to have saved almost 4,000 lives in patients with chronic lung disease alone.

These achievements exemplify a critical aspect of the relationship between quality and safety. We may only think of adverse events as the result of an action, be it a preventable error or an unforeseeable and unpreventable consequence. However, adverse outcomes may also be the result of inaction.

VA has approached both under-utilization as well as mis-utilization of appropriate therapy through the development of Clinical Practice Guidelines. The expected outcomes of these guidelines are again supported by performance measures. The myocardial infarction or "heart attack" module of the heart disease guideline endorses the appropriate use of "beta-blocker" medication for eligible patients. While it has been well known for almost a decade that these beta-blockers can significantly reduce the risk of death and rehospitalization, a recent study by Krumholz *et al* revealed administration of this life-saving therapy to only 51% of 58,000 eligible non-governmental patients. The rate of provision of beta-blockers to patients treated for heart attack in VA hospitals is currently 96%. Improvements in beta-blocker administration from rates already above prevailing community rates in 1995 are estimated to have saved an additional 500 lives.

"Engineering in" quality reduces opportunities for breeches in safety and supports achieving the best possible outcomes. Examples of other formal mechanisms for quality management in VA, which have contributed to objective improvement in the intended health benefits as well as the safety of patients, include the National Surgical Quality Improvement Program, the Continuous Improvement in Cardiac Surgery Program, and the Quality Enhancement Research Initiatives. VA has also established its leadership in programs for development and implementation of Clinical Practice Guidelines in collaboration with the DoD, and in the area of reliable and efficient electronic physician credentialing through the VetPro initiative of the Federal Credentialing Program.

VA feels strongly that quality can be defined from many perspectives. Admittedly, in this context, technical quality is at issue. However, VA defines six "domains-of-value" which serve as focal points for systematic organizational improvement. Foremost among these is technical quality, and the relationship with safety is incontrovertible. The remaining five domains – access, satisfaction, maximizing functional status, cost-effectiveness, and building healthy communities – are also critical. While all are important to various stakeholders, satisfaction and functional

status, in particular, represent outcomes from the Veteran patient's perspective. As with technical quality, each of these domains is supported by performance measures which link the "vision" for improvement with markers of progress on the journey.

While VA has objectively achieved noteworthy performance successes over the past half decade, we share your concern and empathize with those patients whose care was not representative of the overall progress. We share your outrage when any patient comes to harm, and we recognize that our journey is incomplete. We seek your support in continuing to foster a quality transformation that is the result of the systemization of quality, and that fundamentally embraces the systemization of safety.

CONCLUSION

The National Center for Patient Safety and the Office of Quality and Performance work closely with all elements of VHA to support complementary activities in quality and safety. In the area of quality management, VA's commitment to linking organizational goals with performance measures has resulted not only in objective improvements in the quality of care, but even achieving some benchmark outcomes. VA has been twice awarded a grade of "A" in managing for results, and will use the performance measurement program and other quality management activities noted to continue to improve quality.

The 2000 Innovations in American Government Awards Program recently selected the National Center for Patient Safety and the Performance Measurement Program as two of 96 semifinalists from among more than 1,300 applicants for this year's awards. Innovations in American Government awards are recognized as one of the most prestigious public service awards in the country. Final selections will be conducted in October.

In the area of patient safety, with no successful models in large health care systems to guide us, VA turned to other high risk, high reliability industries to adopt and adapt principles. We have borrowed both methods and people from safety-conscious settings such as aviation and space travel and from underutilized disciplines like human factors engineering. We have also developed novel approaches and tools where none existed before. These efforts have already produced significant improvements in VA, and we believe will do the same in all health care settings.

We would prefer that all of health care had begun to address the issue of patient safety long ago. For too long, the emphasis has been on holding individuals accountable and hoping that well-intended and well-educated professionals wouldn't make human mistakes, rather than designing systems that don't fail if human errors occur. As the IOM aptly states in the title of its report: "To err is human." We are pleased to be on the leading edge as health care takes a systems approach to patient safety. We are anxious to discover new ways to make VA and all health care safer and improve quality. We appreciate your support of these efforts and intend to keep you fully informed of our progress.

(Attachment 1)

Highlights of Patient Safety Activities at VA: 1995-Present

1995 -- Vision for Change Initiated

- Then Under Secretary for Health Dr. Kenneth Kizer releases *Vision for Change* statement that unveils a radical, yet rational, transformation of structure that would support a transformation of culture.

1997 -- National Patient Safety Partnership (NPSP)

- VA launches public-private partnership of eight health care organizations (now 13) to address national patient safety concerns.
- NPSP takes public position regarding preventable adverse drug events in May 1999.

1997 -- National Patient Safety Registry

- Database designed to collect information on a nationwide basis that includes adverse patient events, their root causes, and information to guide systematic improvements to prevent future occurrences.

1997 -- Patient Safety Improvement Handbook

- Provides national framework for patient safety improvement efforts.

1997 -- Patient Safety Improvement Oversight Committee

- Multi-disciplinary headquarters committee charged with oversight of patient safety issues.

1998 -- Patient Safety Improvement Awards Program

- Mobilizes and recognizes innovations in patient safety from all levels of the organization.

1998 -- VHA Expert Advisory Panel on Patient Safety System Design

- Provided recommendations on elements for reporting systems leading to nationwide improvements.
- Comprehensive, non-punitive analytic approach for close calls and actual adverse events defined.

1998 -- VHA National Center for Patient Safety (NCPS)

- Created to lead and integrate the patient safety effort for the entire VA.
- Employs state-of-the-art human factors and safety system approaches.
- Develops and nurtures a culture of safety throughout the VA.

1998 -- Patient Safety Redesigns included in VHA Performance Measurement System

- Provided concrete targets and mechanisms to focus leadership efforts.

1999 -- Pilot of Comprehensive Adverse Event and Close Call Analysis Program

- Extensive hands-on training to truly understand a human factors and safety systems approach to close call and adverse event analysis.
- Computer assisted tool to aid implementation of comprehensive event analysis.
- Captures critical elements needed to ensure a thorough and effective job.
- Results in preventive actions that are superior to the status quo.

1999 -- National Implementation of Bar Code Medication Administration (BCMA)

- Multi-year development at one medical center resulted in cutting medication errors by two-thirds.
- National implementation is now in progress throughout entire VA medical system.

1999 -- Patient Safety Centers of Inquiry

- Research groups (4) charged to develop practical solutions to critical patient safety challenges.

2000 -- National Training Program and Roll-Out of Comprehensive Adverse Event and Close Call Analysis Program

- As of this date, VA has trained 18 of the 22 VA VISNs.

2000 -- Development of National Patient Safety Reporting System (PSRS)

- In May 2000 VA and NASA signed an agreement that has NASA operating the external and voluntary de-identified reporting system.
- National in scope; supplementary to mandatory reporting efforts.
- Modeled after NASA's successful, longstanding Aviation Safety Reporting System (ASRS).

(Attachment 2)

Patient Safety and Health Care Quality:
The Interface of Research and Practice

In addition to its administrative and clinical concerns with patient safety, VA embraces the important role of research in fostering a safer and more effective health care system. VA policy makers and managers recognize that delivering the highest quality care depends on collection of accurate data and continuous monitoring, analysis, and evaluation of outcomes. Improving quality and reducing errors requires cooperation among clinicians, managers, information technology specialists, and researchers at all levels of the organization. Unique among Federal health agencies, VA can take research discoveries and put them to work, nationally, to improve patient outcomes and system efficiencies.

VA has established several quality management research initiatives to enhance evidence-based practice in the VA health care system:

- National Surgical Quality Improvement Program (NSQIP) provides clinicians, managers, and policymakers continuous high quality information about the outcomes of major surgery performed in 123 VA hospitals nationwide. Significant gains in patient outcomes and systems efficiency have been documented since implementation of NSQIP in 1994. These achievements were enabled by research (The National VA Surgical Risk Study) that developed the methods for collection of valid and reliable patient data, for carrying out risk adjustments, and for monitoring, analyzing, and reporting results.

- Quality Enhancement Research Initiative (QUERI) is an even more ambitious program focused on improving care for diseases and conditions that are especially common among veterans such as heart disease, strokes, and diabetes. QUERI researchers compare the outcomes of different treatment strategies, develop instruments for assessing outcomes, and test methods to improve adherence to evidence-based practice guidelines and quality standards. QUERI creates a formal link between research and clinical care.

- Patient Safety Research is a natural component of VA's interdisciplinary health services research program. A specific call for research proposals on, "Patient Safety and the Prevention of Adverse Events," was announced in May 1998 and will remain open indefinitely. VA is building a research portfolio in patient safety that will identify avoidable risks, develop and test indicators of potential errors and injuries, determine the cost-effectiveness of alternative approaches to reduce or prevent medical errors, and evaluate the applicability to VA of safety concepts, measures and initiatives developed in the private health care sector or outside the health care arena. VA has already invested over $ 2 million in patient safety research projects in such areas as prevention of falls and adverse drug reactions since 1997.

VA also has policies and procedures in place to enhance patient safety during the conduct of research:

- VA is a signatory to the Federal Government-wide Common Rule for the Protection of Human Subjects of Research, and requires that all VA funded research be subject to the twin protections of scientific merit review and human studies review. VA has established the Office of Research Compliance and Assurances (ORCA) to enhance its human subjects protection program, and is the first public or private organization to require external accreditation of all Institutional Review Boards (IRBs) providing human studies review for VA facilities.

- VA carries out an extensive program of study monitoring oversight activities for all large-scale multi-center clinical trials funded by the agency under its Cooperative Studies Program (CSP). Before any trial can begin, two planning meetings involving the CSP Director, the responsible CSP Coordinating Center, and the CSP site management team are held, the proposal is approved by the Human Rights Committee at the responsible CSP Coordinating Center, and authorization is given by the Federally-chartered Cooperative Studies Executive Committee (CSEC) following scientific merit review. The trial must also be approved by the institutional review board (IRB) at each study site. While the study is in progress it is monitored by an independent Data Safety Monitoring Board, the Study Executive Committee, the site management team, and, at mid-term, by CSEC. If the study involves a new medication or device or a new use for a marketed product, it is also subject to oversight by the U.S. Food and Drug Administration.

Written Testimony

of the

American Nurses Association

to the

House Committee on Veterans' Affairs

Subcommittee on Oversight and Investigations

on

Patient Safety and Quality Management

July 27, 2000

AMERICAN NURSES ASSOCIATION
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The American Nurses Association (ANA) and the United American Nurses (UAN) appreciate this opportunity to present our comments and concerns about the status of patient safety and quality management initiatives at the Department of Veterans Affairs (VA). As frontline health care workers, nurses have substantial contributions to make in the effort to reduce health care errors. ANA is the only full-service professional organization representing the nation's 2.6 million registered nurses. The UAN is the labor arm of the ANA.

ANA has been active in patient safety endeavors throughout our history. Patients deserve care that minimizes the likelihood of errors and always puts their safety first. We believe that errors in nursing care are rarely due to carelessness or incompetence but rather that the environments in which nurses work are complex systems that are prone to error. We have testified before Congress several times this year in support of the Institute of Medicine's (IOM) 1999 report *(To Err is Human: Building a Safer Health System)* recommendations identifying the need for a radical culture change in health care organizations to that of a blame-free environment, with open communication that enables health care workers to identify, discuss and ultimately prevent health care errors. We have stated our opinion that despite IOM's recommendations advocating widespread efforts to reduce errors, ANA believes that the report lacks important information on the relationship between system errors and appropriate staffing. We firmly believe that health care organizations must approach problem-solving strategies through shared accountability and partnerships for quality improvement.

A shared accountability approach diminishes focus on individual blame and enhances long-range process improvements. The establishment of programs geared toward improved patient safety must include a balanced and appropriate representation of key players and this means substantive nursing representation. Nurses are pivotal to improving patient outcomes and excellent evaluators of the work environment for deficits and solutions for quality improvements.

ANA applauds the innovative steps taken by the Veteran's Health Administration (VHA) to recognize, analyze and correct a system prone to errors to ensure that quality health care services

are provided to our country's veterans. The efforts within the VHA are far ahead of the private sector. These steps make great inroads toward implementation of the recommendations of the IOM report as well as many of ANA's own recommendations including the introduction of the Bar Code Medication Administration system, a new internal mandatory reporting and root cause analysis system, and development of an external voluntary adverse event reporting system. However, as with the VA report, we are concerned that these efforts do not focus enough on nursing's main concern for patient safety, namely, inadequate, insufficient or inappropriate nurse staffing. We believe that a working partnership between frontline nurses and VA management and central administrators is the critical factor in the success of the programs already instituted and the successful identification of the true root causes of error.

The scope and degree of organizational change being made at the VA is ambitious. We recognize that these programs are developed centrally and implemented locally. Successful training of workers and roll-out of programs is site dependent and therefore rests on the strength of the leadership and the quality of the labor-management partnerships at the particular facility. Changes that affect working conditions covered by the nurses' local contract must be considered, discussed and possibly renegotiated, requiring sufficient lead time between program mandate from the central office and its implementation. Although the VA may recognize this as a delay in their implementation plan, ANA views the renegotiation of union labor agreements as integral to the success of the program, not an unnecessary delay. Some of our local units question the adequacy of that time and whether enough attention is being focused on labor issues and staffing. While in the long term, these programs are quite promising for reducing system error and improving the quality of patient care, in the short term, nurses at the bedside are often faced with the ethical dilemma of choosing between time spent on mastering a new system and the demands of attending to competing patient needs. Planning and implementation of new systems must include adequate, and if needed, supplemental, staffing during the learning curve. The implementation of the Bar Code Medication Administration system (BCMA) is bringing this and other concerns to the forefront for front line nurses at VA facilities. While pilot studies reveal dramatic reductions in medication error following BCMA implementation, ANA urges the VA to

be vigilant with surveillance with other adverse events, such as patient falls, which may reflect inadequate staffing during BCMA training and implementation. Presently, nurses in several VA units are using Assignment Dispute Objection (ADO) forms to shift accountability for unsafe staffing situations from the frontline nurse to management. ANA is encouraging more widespread use of these ADO forms in the VA to provided the needed documentation to identify potential problems which may be an indirect outcome of this program implementation.

There is no doubt that computerized medication systems are a step in the right direction. ANA supports the implementation of medication safety practices that are based on sound science and the evaluation of those practices. The BCMA system holds promise in eliminating tragic errors related to illegible medical orders, faulty labeling and reliance on large dose floor stock medications. The unique computer technology in place at the VA allows for this innovation to occur right now and will provide useful data for root cause analysis to further reduce medication errors. However, it is just this readily available computerized data that is of concern to nurses.

The experience of workers with new computer technology in the workplace today has unfortunately included the prospect of employers using this data for employee surveillance and disciplinary purposes. Nurses are justified in these assumptions if there is no clear VA policy that the overarching goal is a blame-free environment which enhances communication and reporting of near-misses and errors and that the information will not be used for disciplinary purposes.

Sweeping organizational changes are needed in the health care industry, including the VHA to reduce health care errors. The vital importance of the registered nurse at the bedside is a critical piece in any system-wide reduction of health care errors. Frontline nurses individually or as members of their collective bargaining unit must be included in all phases of program change, including design, pilot, implementation and evaluation. Adequate lead time and considerations must be given to the impact that program changes will have on working conditions and a commitment must be made by top level and local VA administrators and managers to include

labor representatives in these discussions. Systems must be designed to assure a blame free environment. The working partnerships that the VA has already established with other federal agencies, unions, management, VA facilities and departments are a good foundation for success and should continue to be used to develop programs and policies to reduce medical errors.

ANA thanks you for the opportunity to comment on this issue and looks forward to working with the Committee to improve patient safety and quality care in the VA health care system.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

CHAIRMAN EVERETT TO CYNTHIA BASCETTA, ASSOCIATE DIRECTOR, VETERANS' AFFAIRS AND MILITARY HEALTH CARE ISSUES, U.S. GENERAL ACCOUNTING OFFICE

1. Regarding VA's four Patient Safety Centers of Inquiry, how does their role and research focus relate to the work conducted by VA's Research and Development (R&D)? In what way does the work of the Centers address the principal adverse and sentinel events that were disclosed in VA's 1999 Office of the Medical Inspector's report?

   The Patient Safety Centers of Inquiry and VA's Office of Research and Development (R&D) are not directly linked organizationally. The four Centers of Inquiry neither report to nor are funded by the Office of Research and Development. Rather, the Directors of the four centers report to either the VISN or Medical Center manager where they are located. When the Centers of Inquiry were originally chosen, R&D staff assisted the Undersecretary for Health in developing the request for proposals and subsequently helped in rating and ranking the proposals that were submitted. The Centers were then chosen by the Under Secretary for Health and received $500,000 per year in funding from medical care funds. Some of the staff associated with the Centers for Inquiry also have active Health Services Research and Development (HSR&D) funded projects. In addition to these projects, HSR&D funds other patient safety research projects that are not directed by the Centers and is currently funding four projects that overlap with the work being done by the Centers. Two of these are focused on selected aspects of adverse drug reactions and the other two address fall prevention in the hospital and home environment. As the patient safety effort develops, we would expect VA to articulate clear linkages between these efforts to maximize efficiency of the research effort.

   The work at the Centers of Inquiry address some but not all of the known principal adverse and sentinel events at VA medical facilities. In December 1999, a report by VA's Medical Inspector disclosed that between June 1997 and December 1998, the top five categories of adverse events reported by VA facilities were: patient falls, suicide and attempted suicide, other unplanned occurrences, and patient abuse. Adverse events in these five categories account for 69 percent of reported events during the timeframe reviewed by the Medical Inspector. The Patient Safety Center of Inquiry at the Tampa VA medical center is studying fall prevention and injury reduction related to patient falls in the high-risk populations that have mobility problems. The Center in White River Junction is currently working to reduce medication errors (ranked seventh on the Medical Inspector's list) using a collaborative technique. Not targeted by the Centers are unplanned occurrences, patient abuse, and suicide and suicidal behavior.

   "Unplanned occurrences" is a general category for events that don't neatly fit into one of the other categories used by VA. In order to perform work in this area, the events would need to be further categorized. VA is no longer handling cases of alleged patient abuse under the patient safety program and has instead mandated that facilities take immediate administrative steps to investigate these incidents.

   Although none of the Centers are currently studying suicide prevention, VA has undertaken a variety of suicide prevention efforts since the 1970s, including most recently its March 1, 2000, Suicide Summit called Suicide: Recognizing Risks across Treatment Settings. (In VA, a summit is a series of educational and networking events designed to share best practices across the VA healthcare system.) This program was designed to encourage caregivers to screen veteran patients for risk of suicide; share resources regarding suicide awareness, prevention and treatment; and recommend proper treatment and referral. Suicide risk assessment pocket cards were also printed and distributed to clinicians so that they could be referred to in their daily activities. VA has also implemented depression screening in non-mental health care settings in order to identify veterans at risk for suicide and to get them help from a mental health professional. There are also 12 VA facilities with active projects related to improved prevention and management of suicidal behavior.

2. Given GAO's early assessment of VA's efforts to improve patient safety, what obstacles or other problems might VA have to overcome to assure continued progress?

As we testified, the key challenges VA faces are setting goals, planning, and communicating the priority of patient safety to its employees. Beyond that, VA's needs to overcome obstacles that impede moving from a "blame and shame" way of handling adverse events to a culture of safety that openly looks at how and why adverse events occur and how systems can be improved to prevent them in the future. To make a major change in patient safety, VA must convey the message to all its employees that patient safety is everyone's responsibility and then operationalize this belief by making it an integral part of every day work. Management officials–many of whom have been trained to look for who is responsible when an error occurs—need to shift their mindset to one that focuses instead on the systems design that allowed the adverse event to occur. They must also be able to create a nonpunitive work environment in which employees feel safe to report and investigate adverse events and, even more important, close calls (situations in which an adverse event could have but did not occur). Because any successful culture change takes years, patience and sustained commitment in the event of leadership changes should also be a top priority. And, once the culture change has taken root, VA leadership at all levels in the organization must remain committed to continuous improvement in trying to drive the medical error rate to zero.

It is also important to point out that, in the short run, if the culture change is successful, we should expect an increase in the number of adverse events that are reported, and we should view this increase as a positive result of VA's efforts. As reports increase and more errors come to light, managing the potential negative reaction from skeptics and highlighting that staff are able to learn from these errors will be critical to ensuring that the patient safety program stays on track.

3. Much has been said about VA's patient safety program and some people point to it as a model for the private sector to follow. Does GAO believe that it is a model program?

VA's patient safety program has not been fully implemented and it is too early to predict whether in the final analysis it will be a model for other healthcare organizations. While some of VA's patient safety initiatives are clearly exemplary, such as removing concentrated potassium chloride from wards and bar-coding medications, they preceded the broader patient safety program VA is now trying to put in place. In other words, more fundamental than such stand-alone initiatives is VA's effort to create a system-wide culture of safety. In this key endeavor, VA is not yet a model. While they lead the rest of the healthcare sector in adopting the right concepts and consulting with the right experts, they need to do much more to achieve their goals. Until VA demonstrates results attributable to the processes they are putting in place, others will be unable to emulate them and, in our view, calling VA a model would be premature.

4. VA's National Center for Patient Safety promises to have a pivotal role in the development of new systems that will be used to analyze and report on sentinel and adverse events. If the Center's new processes are successful, what will be the likely impact on the number of patient safety events that are reported?

In the short run, if the processes instituted by the National Center for Patient Safety (NCPS) are successful, there should be a dramatic rise in the number of reported adverse events at VA facilities. In fact, we should be suspicious that the system is not working well if the numbers are too low. The magnitude of this increase is unknown, but it could be steep. We believe this will reflect a willingness on the part of employees to report events that have been occurring all along, not a real increase in the number of adverse or sentinel events. Increased reporting will offer employees a chance to learn from events and especially from close calls as well as an opportunity to propose changes that can prevent such events from happening in the future. In the long run, more reports should lead to a drop in preventable adverse events as proposed solutions or action plans are disseminated system-wide to reduce or prevent occurrences.

5. In addition to more definitive goal setting and measurement, comprehensive planning, and communicating the importance of the program to all its employees, are there other actions VA can take to ensure the success of its patient safety program?

One of the most important steps VA is taking to improve patient safety depends on the cooperation and participation of VA employees to report adverse events. But a reporting system is not enough. In its training for employees on VA's new method for reporting and analyzing the root causes of patient safety problems, the NCPS emphasizes the importance of feedback to all employees who are participating in the process--from the individual who reports the adverse event or close call down to the team of employees who are selected to perform the root cause analysis or aggregate review. This integration, involvement, and follow through with all employees will enhance the success of VA's efforts by motivating employees beyond the basics of goal-setting and communicating patient safety as a top priority. In particular, the importance of feedback to teams and dissemination of findings throughout VA cannot be overemphasized. Managers must be willing not only to find time for their employees to participate in the root cause analysis process but must also support the implementation of recommendations made by the teams. We believe that only when these processes run smoothly and employees participate fully as part of their every day work will the benefits of the culture of safety be realized.

6. The VA OIG's Combined Assessment Program reviews (CAP Reports) often identify critical nursing staff shortages. Can you comment on how these shortages impact on patient safety?

The nursing shortage is a national problem that affects VA and private sector hospitals alike and is projected to worsen in the coming years. GAO has not conducted an evaluation of the adequacy of nursing staff ratios in VA and, therefore, we cannot comment directly on the potential impact that a nursing shortage may have on patient safety. However, in 1998, VA and Kaiser Permanente jointly sponsored a public/private sector focus group of healthcare professionals to identify perceived barriers to patient safety. These care providers, including the VA participants, identified inadequate staffing as the largest barrier to patient safety. Not surprisingly, they reported that inadequate staffing lead to fatigue and frustration in employees. Other high-risk industries, such as aviation, have established strict rules that prevent, for instance, flight crews from working without adequate rest periods. VA is currently doing research in this area to determine the applicability of this preventive measure in health care situations.

7. The VA points to its bar-coding system for medications as one of its great success stories. I understand the implementation of this system has encountered problems in operating rooms and in interfacing with VA's computerized patient record system. Would you please elaborate on these difficulties?

VA reports that it has implemented bar code medication administration (BCMA) in over 60 percent of its inpatient care areas. In order for BCMA to work, the physician order entry package – a part of the Computerized Patient Record System (CPRS) – must be functioning. One reason for the slippage in the BCMA schedule is that CPRS is not available uniformly in all facilities, although VA tells us that the software has been installed at all VA facilities. We are unaware of any specific interface problems between BCMA and CPRS, but VA has experienced hardware and training problems in some locations that have prevented full implementation of CPRS.

The ICU situation is more complex. In discussions with VA, they told us that the intensive care units (ICUs), in which about 70 percent of medications are administered intravenously, are further behind other inpatient care areas; specifically, only about 40 ICUs have implemented BCMA. (VA did not indicate that problems in operating rooms were occurring.) According to VA officials, the original BCMA computer package was intended primarily for administration of

oral medications and not for intravenous therapy. VA tells us that the Version 2 upgrade of the software is scheduled for 2001 and will resolve this problem.

8. What evidence have you seen of VA's senior management participation or commitment to the ambitious safety training programs being conducted throughout the VA system?

There has been little participation by VA senior management in its safety training programs. We asked the NCPS to provide a breakout of the job titles of those employees who attended one of the three-day patient safety improvement training sessions. On July 19, 2000, VA told us that, until then, no VISN or medical center directors had participated in the training sessions. Highest level managers who did attend included 41 Chiefs of Staff, 49 service chiefs, and 83 Associate Directors for Patient Care Services/Nurse Executives. According to VA, of the nearly 600 employees trained, the majority were facility risk managers or quality managers.

9. Has the VA identified the highest priority areas for medical errors and have they developed a standardized system for measurement of these reductions of errors?

VA can use its adverse event registry to categorize adverse events that occur most frequently and that would merit priority attention, such as falls, suicides, and medication errors. VA has not yet developed a standardized system for measuring a reduction in medical errors, and we are not aware of any VA plans to do so. However, before VA can target the patient safety problems that most need attention, it will have to put in place a well-functioning reporting system and establish an accurate baseline from which to measure change system-wide. Until VA's new system is fully in place and operating for some time, VA will use the root cause analysis process to provide a standardized tool for assessing the causes of errors and to compare analyses across all VA facilities.

10. The IOM report uses the Harvard Medical Practice Study in New York, which states that adverse events occurred in 2.9 percent of hospitalizations. Now this is a widely respected peer reviewed study. The VA reported 2927 adverse events in a 19 month period. The July 17, 2000 US News and World Report has cited the Johns Hopkins Hospital in Baltimore, MD as the highest rated hospital in America for several years running. Johns Hopkins had 69,603 inpatients in FY 1999. If you use IOM's 2.9 percent times 69,603, Johns Hopkins would have had just over 2,000 adverse events. This is just one hospital. How can the entire VA hospital system only report 2927 adverse events? Using the same formula one would predict 21,802 possible adverse events. Can GAO try to explain this phenomenal discrepancy?

First of all, if Johns Hopkins has a reporting system, it would be interesting to know the number of adverse events it contained. And second, this example underscores the growing consensus in the healthcare industry, including the VA system, that underreporting of adverse events is a serious problem. The percentage used by the IOM to determine how many adverse events would likely occur in a facility is based on just two studies, so the research base is limited. Other researchers have made compelling arguments in different directions – that the IOM report overstates and understates the extent of underreporting. There simply aren't adequate data to estimate the degree of underreporting with much precision. So, whether 22,000 adverse events is the "right" number or not is impossible to say. During fiscal year 2001, VA will be conducting a survey in order to establish a baseline measure of how employees feel about reporting adverse events. If employees report that they don't feel safe to report adverse events, we can presume that underreporting will continue to be a problem, but determining the magnitude will continue to be problematic.

CHAIRMAN EVERETT TO LINDA J. CONNELL, DIRECTOR, NASA AVIATION SAFETY REPORTING SYSTEM

Responses to written questions submitted by Chrm Everett resulting from the July 27, 2000, hearing.

QUESTION 1:

What do you think the obstacles will be in adapting this reporting system from the FAA to a healthcare setting?

ANSWER 1: The compelling features of the FAA/NASA reporting system - - making it invaluable to the aviation industry - - are directly transferable to the VA/NASA healthcare reporting system. These features are de-identified reporting, analysis of reports by an objective third-party subject matter expert, and identification and reduction of VA wide vulnerabilities.

The greatest challenges in implementation will be to exhaustively communicate with medical centers and employees about the methods, processes and desired outcomes of the VA/NASA healthcare reporting system, and consistently demonstrate that the system is trustworthy (i.e., that neither individuals submitting reports nor unique medical centers will ever be identified).

QUESTION 2:

How long will it take before we know this system is effective and how will NASA measure effectiveness?

ANSWER 2:

The introduction of the VA/NASA Patient Safety Reporting System (PSRS) will require a phase-in approach, followed by continued expansion across the VA. We anticipate that effectiveness of the PSRS will mirror the experience of the Aviation Safety Reporting System (ASRS), and that the volume of reports will grow steadily over several years, achieving substantial levels once the system is considered trustworthy and productive.

NASA will measure PSRS effectiveness primarily through analysis of report quality/quantity and successful identification of under-reported system vulnerabilities. When reports are received, which is proposed to begin around the beginning and middle of FY'01, the effectiveness can begin to be assessed. Although the ASRS has a long history in which to show effectiveness, there were valuable safety information provided to the program from the very initial reports.

QUESTION 3:

Is NASA's national safety reporting system responsible for developing educational programs in order to keep employees informed about safety issues?

ANSWER 3:

NASA's safety reporting system is not responsible for developing educational programs, nor is it NASA's intent to directly educate VA employees. NASA intends to work with the VA on the PSRS to determine what method of feedback is necessary to ensure success of the PSRS system. NASA has historically recognized the importance of completing the feedback loop to those who support the ASRS voluntary reporting system. Some aspects of the ASRS feedback

approach will be applied in the development of the PSRS. NASA and the VA will be determining which products, like a newsletter or data reviews, will be the best to provide information to the VA medical centers and employees about lessons learned and potential ways for reducing vulnerabilities. Once the mechanism for communication and feedback is identified, NASA will produce those materials.