

**Statement of  
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Regarding  
"Patient Safety: Instilling Hospitals with a Culture of Continuous  
Improvement"  
Before the  
United States Senate  
Permanent Subcommittee on Investigations  
Committee on Governmental Affairs**

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Mr. Chairman and Members of the Subcommittee, I am pleased to be here today to discuss the vitally important topic of patient safety and the critical factors for success needed if our hospitals are to succeed in this effort. In particular, I will discuss some of the critical elements for success that the VA has identified as we have implemented an aggressive, system-based, patient safety program throughout our healthcare system.

Inadequate patient safety is a critical worldwide problem in healthcare. In the U.S., estimates of the lives lost due to factors related to patient safety exceed that of the lives lost due to motor vehicle accidents, breast cancer, or AIDS (IOM, To Err is Human). In order to reduce medical errors, programs must first identify the underlying causative factors so that they can be understood, and then implement effective preventive strategies. Unfortunately, most healthcare systems and regulators have not modified their tactics to focus on prevention. The systemic problems that are associated with medical errors and close calls persist; namely the misguided belief that accountability systems and punishment are the primary and most effective means to achieve improvement in patient safety. While accountability systems play an important role in health care organizations, they cannot do all things. Albert Einstein once observed, "Insanity: doing the same thing over and over again and expecting different results." This is where we seem to currently find many individuals and organizations in their quest for patient safety improvement. Put another way - the health care system punishes providers without giving them the tools to improve patient safety.

An over-reliance on punitive accountability systems is a major stumbling block to improvement because it does not encourage identification of potential problems and provides disincentives for reporting. This state of events is not peculiar to

healthcare and has been encountered by other industries. Aviation recognized that further improvement in safety could not be achieved by putting in place yet another accountability system. Instead they introduced a system whose purpose was learning, whose goal was prevention not punishment, and most importantly was viewed as both beneficial and non-punitive by the end-users or those from whom reports are sought. Today in medicine there is no dearth of accountability systems but there is a scarcity of systems that are viewed as non-punitive reporting systems.

To address these needs, the VA developed and continues to implement an innovative systems approach to prevent harm to patients within VA's 163 medical centers. VA recognized that individual human behavior is seldom the basic reason for medical adverse events - adverse events are usually due to the complex interaction of known and unforeseen vulnerabilities in health care delivery. Innovations were necessary, since no one had ever instituted a comprehensive systems-oriented safety program for large medical organizations. VA combined lessons from industrial settings such as aviation and nuclear power with the theory and body of knowledge from human factors and safety engineering to fashion systems that would better contribute to prevention of unintended harm to patients. (Human factors engineering was cited by the 1999 IOM report as the discipline most often overlooked by health care when designing safety systems.)

VA implemented nationwide internal and external reporting systems that supplement the many accountability systems we already had. The new systems' sole purpose was for organizational learning and improvement. Said another way, the objective for reporting is to identify vulnerabilities that can then be mitigated, not to serve as a counting exercise as counting in itself is of very little value. They were constructed to encourage maximal reporting of potential and actually occurring problems by non-punitive methods that would then be converted into corrective actions. This was essential because, without the ability to identify system vulnerabilities and to analyze their root causes for common systematic problems, our ability to achieve meaningful and sustainable patient safety improvement is limited. 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, analyze, and most importantly correct 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.

One method VA employed to better understand how to make these systems optimally function was to first conduct surveys and focus groups of both VA and external healthcare workers to better understand their concerns and the characteristics that would help make our program effective. The use of punitive actions was a point of concern. Specifically, health care providers' view of punitive actions extended beyond typical administrative punishment to include factors such as shame, embarrassment, and negative impact on professional reputation. Protection from these factors was essential if we were to receive any reports from which we could then learn and proceed to undertake improvement and prevention efforts. This information convincingly demonstrated that confidentiality is pivotal to assuring the non-punitive intent and potential of your learning system to the personnel from whom you wish to receive reports and who you wish to subsequently implement corrective actions.

The importance of confidentiality has been shown in many safety systems ranging from military aviation safety programs to the NASA - Aviation Safety Reporting System (ASRS). The success of the ASRS program has been cited in numerous venues including the IOM Report 'To Err Is Human.' For more than 25 years, the ASRS has handled over 500,000 reports without compromising the confidentiality of its reporters. Maintaining this level of trust has been essential to allowing the ASRS to identify problems and systems vulnerabilities that were subsequently dealt with, which otherwise might have resulted in catastrophic events. There are also examples of other aviation safety systems patterned after the ASRS, such as the one in New Zealand, that were initially successful until they divulged the identity of a user resulting in the cessation of reporting and effectively the end of their system. In fact, after the passage of several years they tried to re-establish their system but failed to do so due to their inability to ensure that confidentiality would be maintained. This experience demonstrates that once trust is violated it can be extremely difficult or impossible to restore. Ultimately, public safety suffers because problems cannot be identified early and corrected.

Confidentiality is the common element that enables a safety system to be effective. It is important to recognize that making patient safety information confidential does not deprive any of the pre-existing internal or external accountability systems of information that they require. The two systems are mutually independent; that is, data reported and developed in the course of a patient safety activity is in addition to, separate, and apart from events identified to oversight reports. Voluntary reports on close calls and other problems would not otherwise exist were it not for a confidential system. Currently, the statutory protection for this type of information varies from state to state and does not permit the confidential and privileged sharing of information across state borders. If individual institutions do not have this confidentiality protection, their ability to

effectively run a patient safety program will be substantially hampered. Furthermore, confidentiality for patient safety information, if uniformly available, will facilitate the sharing of information between institutions in a particular locale as well as on a national basis. Without it, the fear of shame, embarrassment, as well as the fear of other punitive measures stands in the way of dissemination of information that will improve the quality and safety of health care and benefit patients everywhere.

Experience in the VA system has shown that reporting of events and especially close calls increased dramatically after clear definitions were enacted as to what constituted a confidential patient safety issue. This has resulted in the identification and mitigation of system vulnerabilities not just within the VA system but globally. Without confidentiality the same results could not have been achieved. Reports and information concerning systems vulnerabilities can be thought of as the fuel for the patient safety improvement “machine”. If the hospital/healthcare environment is not appropriately constructed with regard to creating a non-punitive approach towards reporting and systems improvement, little will change. This ‘environmental’ change must occur not only at a national but at a local, frontline, level as well. In the final analysis, the actions that ultimately improve patient safety and prevent harm to the patient occur at the level of the patient. If the systems that are implemented, the non-punitive approaches employed, and corrective actions taken aren’t translated to solving problems at the frontline where patient care actually occurs, all will be for naught.

Organizational leadership that is meaningfully and visibly involved is another component that is absolutely essential if the patient safety improvement effort is to be successful and sustainable. This requires more than merely issuing directives and emails. In the VA this type of leadership is exemplified by our medical center directors who personally meet with every root cause analysis team to understand the vulnerabilities that were studied as well as discuss the suggested systems improvements that will be required to prevent future problems. Leadership means becoming personally involved, it cannot be delegated to others, and the drumbeat must be relentless. CEO’s and healthcare systems boards must have patient safety be part of the way they evaluate their performance. Patient safety is the foundation upon which quality patient care is built. A health care provider can’t begin to say that it delivers high quality patient care if it isn’t first safe. Without this commitment at the top little can or will change. Leadership by itself while essential is not sufficient in and of itself. There must also be a safety infrastructure that enables the course leadership sets to be converted to action. The VA National Center for Patient Safety designed its patient safety system with a number of tools that overtly require or subtly encourage employees at all levels to identify problems, analyze them from a systems-based perspective, institute human factors oriented systems-based solutions, and track these interventions to assure their effectiveness, all with an eye to preventing harm to the patient which should be the real overall goal of any patient safety program. For example, 31 VA medical centers working in a

collaborative project reduced their major injuries due to falls by more than 60 percent. This is important because major injuries after falls can lead to premature deaths and increased health care spending. For example, more than 20 percent of nursing home patients experiencing a hip fracture due to a fall will die within a year, and hip fractures cost Medicare almost \$3 Billion per year. Other VA patient safety impacts include pacemakers and defibrillators in worldwide use whose designs were changed to make them less prone to failure in use as a direct result of the VA patient safety improvement system, and technology applications such as barcodes used for medication administration to virtually eliminate the misadministration of medication to VA patients.

Interest in improving patient safety is at an all time high. Very early, VA identified improved patient safety as a high priority. Our systems now serve as benchmarks and are being used and emulated by others both nationally and internationally. In the last two years alone, the VA has trained individuals from over 30 domestic health care systems or providers such as Vanderbilt, the University of Michigan, and Dartmouth. Internationally we have trained representatives from 9 countries including Denmark and Australia, which have subsequently implemented national programs based on ours. It is important to remember that patient safety is not a destination but rather a never-ending journey and commitment to self-examination that relentlessly and skeptically challenges the way we do things in the quest to prevent our patients ever being harmed while they are under our care. Uniform, unambiguous, and assured confidentiality of patient safety information is essential underpinning for these efforts to flourish and succeed. We must approach patient safety in a way that permits and encourages all healthcare providers to aggressively pursue patient safety initiatives and emphasizes and celebrates prevention, not punishment.

Thank you for the opportunity to appear before the committee. I will be pleased to respond to your questions.

"The significant problems we face cannot be solved at the same level of thinking we were at when we created them."

Albert Einstein