**Statement of**
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**On VA Patient Safety Programs**
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**Subcommittee on Oversight and Investigations**
**Committee on Veterans Affairs**
**U.S. House of Representatives**
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Mr. Chairman and Members of the Committee, I am pleased to be here today to discuss the vitally important topic of patient safety and some particular initiatives that are currently underway.

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, 1999). 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 – traditionally the healthcare system has punished providers without giving them the tools to improve patient safety.

In many healthcare systems, an over-reliance on punitive accountability systems remains a major stumbling block to improvement because it does not encourage identification of potential problems and provides disincentives for reporting improvement. 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 beneficial 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 156 medical centers. VA recognized that individual human behavior is seldom the sole 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 To Err is Human report as the discipline most often overlooked by health care when designing safety systems.) VA's accomplishments in patient safety improvement have been widely recognized, starting with winning the "Innovations in American Government Award" in 2001.

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 that would lead to improved patient safety for our veterans. 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 designed reporting systems that would identify adverse events that might be preventable now or in the future.

In addition, we implemented 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 before harm occurs. 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 that are paid by patients. Close calls enable us to learn and

institute preventive actions without first having to pay the costly tuition born of human tragedy. In addition, proactive patient safety 'walkarounds' are another method that facilities use to uncover system vulnerabilities so that corrective actions can be taken without first having to encounter an undesirable outcome.

Once system vulnerabilities are identified there is a need to have the tools and methods available by which meaningful corrective actions can be formulated and implemented. The VA developed, tested, and implemented a number of approaches that not only allowed systematic prioritization of vulnerabilities but also enabled the identification of the underlying root causes and contributing factors, as well as appropriate systems level solutions. These tools are designed for application by personnel at the local facility level since analysis and solutions that are generated at the front line generally have the most individual relevance and the biggest impact on the development of a culture of safety at the specific institution in question. These tools, which include the Safety Assessment Code, Root Cause Analysis (RCA) process, Triage Cards, and Healthcare Failure Mode and Effect Analysis, are used throughout the VA system and are being employed in health care systems throughout the U.S. and the world.

When the causes of an event are determined to have potentially wide-ranging and substantial impacts on patient safety, VA's National Center for Patient Safety (NCPS) develops and issues a Patient Safety Alert in concert with the Office of the Deputy Under Secretary for Operations and Management. Our alert process employs a formal, standardized, scoring and tracking system that considers such factors as detectability, severity, and probability of occurrence to determine whether a Patient Safety Alert is warranted. Alerts are written to be concise and effective. Each includes a problem statement, one or more required actions, and specifies whether feedback is required and to whom. A completion date and time is provided for all actions, and a point of contact for additional information is always included. The development and deployment of an alert is a resource-intensive process as it requires in-depth understanding of the problem, and a similar understanding of the standard process(es) that are impacted by the problem. Once a solution is potentially identified, numerous steps are taken to verify that the proposed solution will improve the overall state of safety for the patient. These steps include, but are not limited to, communication with front line VA staff, manufacturers, designers, regulators, and any other entity whose input we believe might materially improve the final alert.

Prior to issuance, extensive review and often field testing is required to identify implementation problems that could diminish the effectiveness of the alert. We routinely post Patient Safety Alerts on our internet site www.patientsafety.gov so that patients outside the VA can benefit from the identification and mitigation of vulnerabilities we have discovered and acted on. These alerts have been judged to have high utility both inside and outside the VA as demonstrated by the numerous entities inside and outside the U.S. who have applied the knowledge contained in our alerts in their own health care systems.

Many other patient safety initiatives have been undertaken by the VA. A few recent examples are as follows:

- Patient Safety Curriculum – Rather than just retrain health care workers as to appropriate patient safety practices, VA formulated and disseminated a patient safety curriculum that is in use in over 40 medical schools and 60 VA Medical Centers (VAMCs). Curriculum workshops and tools have also been shared with the Department of Defense and the Indian Health Service. This is an ongoing effort that continues to expand to additional sites where U.S. healthcare workers are educated or trained.
- Falls Injury Reduction – Falls are the number one cause of injury-related death for those over 65 years of age. Our Falls Collaborative documented that 31 facilities reported a 62% drop in major injuries from falls. This equated to a projected cost savings of $25,000 per facility per month. We have continued our efforts through a current Falls Project involving 65 facilities. In total, participating facilities reported a 44% decrease in the major injury rate for acute care settings and a 67% decrease in behavioral health settings. This freedom from injury translates into greater independence for our patients. We have shared our methods and results through a Falls Toolkit, available electronically in its entirety on our website and accessed by over 400 non-VA visitors every month.
- Medical Team Training – Communication failure has been identified as one of the primary contributing factors in nearly 80% of more than 7,000 Root Cause Analysis events reported to VA. Implementing Medical Team Training has improved surgical infection prevention, deep vein thrombosis prophylaxis, and intraoperative communication and teamwork.
- Ensuring Correct Surgery – The work underlying this Directive identified the factors that could contribute to incorrect surgery, such as wrong patient, wrong side, wrong site, wrong procedure, and wrong implant. This more expansive systems based approach was revolutionary to the healthcare field, showing that fewer than 50% of adverse events were simple left/right (wrong side) mistakes and indicating that focusing solely on the side would not solve this problem. The approaches and techniques outlined in the Directive set the foundation for what was adopted on a national basis and have been employed internationally as well.
- Hand Hygiene – Improper hand hygiene has been implicated in a large percentage of hospital acquired infections that can have severe or catastrophic effects on the patient. Nationally the compliance of health care workers with appropriate hand hygiene practices is typically reported at less than 40 percent. The VA aggressively attacked this problem and was able to identify and implement a number of interventions that raised the observed compliance rate with the Center for Disease Control (CDC) guidelines to 80 percent, and greatly increased the use of antimicrobial soaps and alcohol-based hand sanitizers.

Two recent incidents occurring at facilities in different areas of the country reinforced the successful implementation of these NCPS processes. The national uniformity of the processes and the inculcation of staff demonstrated VA's strong patient safety culture and that VA responds proactively to identified patient safety vulnerabilities. These incidents have been discussed in depth with the House Veterans Affairs Committee members and staff so that you would be informed if your constituents contacted your offices.

The first one of particular interest to this Subcommittee involved the use of non-sterile Stryker Custom Cranial Implants. This was reported by the Tampa VAMC to the National Center for Patient Safety (NCPS) on 3/2/06. NCPS staff called and spoke with the Manager of Regulatory Affairs and Quality Assurance at Stryker that same day. NCPS called the VAMC the same day and reported the outcome of the conversation with Stryker and in particular that this was not a widespread problem at VAMCs. The Tampa VAMC submitted a voluntary report to FDA's MEDWATCH program on 3/6/06 and received an e-mail confirming receipt on 3/8/06. A RCA was conducted by the facility. The VA Program Director for Supply, Processing, and Distribution (SPD) sent an e-mail to VAMCs to determine other facilities that use the Stryker implant and how they were sterilizing it. It was determined that only one other VA facility used the implant in question and that it had been properly sterilized.

NCPS met with the Manager of Regulatory Affairs and Quality Assurance at Stryker and discussed the suboptimal human factors design issues of the packaging of the implant that increased the probability that sterilization would not always be accomplished. NCPS informed the Stryker representative that the use of packaging that is typically used for sterile materials and which lacked prominent labeling as to its non-sterile status was hazardous, and strongly suggested that it should be corrected. Investigation of the event revealed that one veteran had a non-sterile cranial implant implanted and that the surgical field may have been contaminated by a non-sterile implant for one other veteran. To date, neither veteran has experienced any complications directly related to the events. Both veterans will be monitored to ensure that there are no delayed infections. The facility has implemented the corrective actions specified in their RCA. VA Office of Patient Care Services, which includes VA's Infectious Diseases and SPD programs, has formulated a national Directive so that appropriate measures to assure the sterility of implantable devices are instituted across the VA.

VA recognizes that device labeling can be sub-optimal and we also realize our role in ensuring that equipment is safe for use. VA's Supply, Processing and Distribution Operations has taken aggressive action to evaluate the department's overall performance and effectiveness. In addition, an ongoing education is occurring throughout the VA that will equip staff to properly assess equipment readiness.

The other event that attracted interest concerns the appropriate processing of B-K Medical Urology Ultrasound Transducers and their accessories. These devices are used for ultrasonic viewing of the prostate, as well as for biopsy of the prostate under ultrasonic guidance. On 2/14/06 a memo was sent by e-mail to NCPS from the VAMC Director in Togus, Maine reporting a problem with the disinfection and cleaning of a B-K Urology Ultrasound Transducer that had been detected during patient safety rounds. The same day NCPS staff spoke with staff at Togus, received additional information, and informed the top VA officials for Public Health, Infectious Diseases, and SPD. The very next day B-K Medical provided NCPS with their General Transducer and Model 8808 Transducer User Guides, and there was a follow-up conference call.

The Director of SPD sent an e-mail to all SPD chiefs at VAMCs reminding them to refer to the appropriate VA Handbook regarding device processing, and the following morning he provided further instructions regarding B-K Medical Urology Ultrasound Transducers in particular. Upon thorough review of the B-K Medical User Guides, it became clear to NCPS and other VA staff that the instructions concerning the cleaning and processing of the B-K devices were extremely confusing and that this could contribute to the improper processing of these devices and their accessories.

B-K Medical requested that NCPS help with advice as to how to make the processing instructions clearer and a B-K Medical representative brought the transducer assemblies to NCPS for demonstration. To obtain additional information, the Director of SPD and a representative from the Office of the National Director for Infectious Diseases made a site visit to Togus VAMC. NCPS staff contacted CDC and FDA and both agencies responded with feedback on a draft of VA's Patient Safety Alert.

All aspects of the alert were also reviewed by B-K Medical and endorsed as correct for implementation and then tested at a variety of field settings to determine usability by VAMCs prior to its release. On 4/3/06, VA issued a Patient Safety Alert to VAMCs describing the procedures for appropriate processing of B-K Medical Urology Ultrasound Transducers (models 8808 and 8551). The final alert was shared with the CDC and FDA, and subsequently with our colleagues at the Department of Defense.

Thank you for the opportunity to present this information to the Committee. I will be happy to respond to any questions.