

**Testimony for  
The Michigan Health and Safety Commission**

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Mr. Chairman and members of the Michigan Health and Safety Commission, we are pleased to provide our testimony on a vitally important topic. The safety of health care delivery is a critical problem faced by all receiving medical care in Michigan and throughout the U.S. The IOM report in 1999, *To Err is Human*, estimated that injury from health care is the 3<sup>rd</sup> to the 8<sup>th</sup> leading cause of death in this country, which is more than cancer, HIV and motor vehicular accidents. The Health Grades quality study released in March 2004 estimated 190,000 deaths due to health care per year during the 2000-2002 period. Such an estimate would translate to more American lives lost from patient safety incidents every 6 months than from the entire Vietnam War.

We will discuss some of the critical elements for success in our aggressive systems-based patient safety program established in the Veterans Health Administration since 1999. Our mission at the National Center for Patient Safety is to **prevent harm to patients**. The term “medical error” is not in our lexicon since to err is human, and all humans providing health care will commit errors. Our goal in the provision of health care is to prevent harm to patients by building fault tolerant delivery systems that absorb human error and thereby mitigate or eliminate its effect on patients. If a physician prescribes the wrong medication for a patient, a safe health care delivery system will prevent that medication from ever getting to the patient.

To reduce harm to patients, health care systems must have a means of identifying the causal contributing factors to understand why an adverse event occurred. When the “root causes” of an event become better understood, that enhanced understanding will inform the implementation of effective preventive strategies.

The underlying systemic factors associated with adverse events and close calls (both patient safety events) are rarely, if ever, determined by punitive accountability systems. Unfortunately, many believe that mandatory, public reporting would be the most effective method to achieve improvement in patient safety. Accountability systems are already in place at several levels in health care delivery, and very few adverse events are actually reported. Approximately half the states have mandatory reporting of sentinel events. However, the experience in these states is that most adverse events are not reported due to the fear of regulatory punishment, tort liability, or media exposure.

Reporting events does not improve patient safety unless it leads to action. Reporting “counts” should not be the purpose of a reporting system as the counts from self reporting are notoriously unreliable.

Aviation recognized that further improvement in aviation safety would not be achieved by instituting another accountability system. The Aviation Safety Reporting System (ASRS) was spawned in 1975 as an effort to provide incentives for reporting safety events in a voluntary, confidential, non-punitive reporting system. The purpose of ASRS was learning, and the goal was prevention not punishment. ASRS has received more than a half million reports because it is viewed by the end user as beneficial for a safer environment and it is non-punitive.

In health care today, there is no shortage of accountability systems, but there are very few learning systems based upon voluntary reporting of safety events. To address these needs, the VA developed an innovative systems approach of preventing harm to patients in 163 VA medical centers. We recognized that individual human behavior is seldom the basic reason for adverse events in health care. Adverse events are usually due to the complex interaction of known and unforeseen vulnerabilities in health care delivery.

In 1999, the VA implemented a nationwide internal and external reporting systems based on confidentiality protections for the purpose of learning about risks and hazards that threaten patient safety. **The confidentiality of reported information is critical to the success of a reporting system.** Without assurance that this information could not be used in a punitive way against the reporter, there would be not be a rational incentive to report patient safety information. Federal statute *38 USC 5705* prohibits the confidentiality breach of any information contained in a report for the purpose of quality improvement and patient safety in the VA. Disclosure of patient safety information is also prohibited for peer review or credentialing purposes.

We are not suggesting that an entirely blame-free approach to adverse events exists in the VA. It does not. We do not allow events defined as ‘intentionally unsafe acts’ to be protected as patient safety information. These events are managed through an administrative investigation, which allows full disclosure of information. In this respect, the patient safety program in VA facilities is viewed as fair by all stakeholders. Since the initial implementation of our program in 1999, the rate of reporting patient safety information increased 30-fold, which has sustained that level of reporting to the present day.

In order to place the importance of confidentiality of patient safety information in context, reporting activity in the VA can be compared to reporting to the Joint Commission of American Healthcare Organizations (JCAHO). JCAHO represents over 80% of American hospitals and has accepted reports of sentinel events since 1996. As of late 2004, approximately 3500 reports have been received by JCAHO. By comparison, VA medical facilities representing nearly 2% of American hospitals, have generated approximately 150,000 patient safety reports since 1999. The key difference is confidentiality protection of patient safety reports, which is not available for non-VA

health care institutions in this country. Some states, like Oregon, have successfully passed legislation protecting patient safety reports from all health care entities in that state.

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 are required. A clinical case involving a reviewable sentinel event should require a Root Cause Analysis (RCA) in any hospital system, which does not interfere with reporting to the state Department of Public Health if mandated in that state. The two activities would require separate reports, but they don't mix. The two systems, one about learning and the other accountability, are mutually independent.

Experience in the VA has shown that reporting adverse events and especially close calls increased dramatically after clear definitions were established for a confidential patient safety issue. Since the inception of our patient safety system in 1999, over 4500 RCAs and over 300 proactive risk analysis teams have identified and mitigated system vulnerabilities throughout the VA health system. Without confidentiality protections in federal statute, the same results could not have been achieved.

Organizational leadership that is meaningfully and visibly involved is another component that is absolutely essential to a successful and sustainable patient safety improvement effort. In the VA this type of leadership is exemplified by our medical center directors who meet personally with every root cause analysis team for a briefing on the system vulnerabilities that were identified as well as discussing the suggested system improvements to prevent future adverse events.

We also require that all medical center directors personally approve or disapprove all proposed corrective actions. In cases where they disapprove, directors must state on the record their rationale for disapproval. In addition, directors will ask the RCA team to consider alternative solutions to address the contributing factor in question. This approach communicates respect for the RCA team and a serious commitment to the RCA process. Leadership must become personally involved, and the drumbeat must be relentless.

The VA National Center for Patient Safety has designed a the patient safety program with a number of tools like Root Cause Analysis (reactive to adverse event or close call) and Health Care Failure Mode and Effect Analysis (proactive "what if analysis") to recruit staff at all levels in the following activities:

- identify safety problems
- analyze problems from a systems-based perspective
- invoke principles of human factors engineering in the proposed interventions
- track interventions and evaluate their effectiveness
- define effectiveness as preventing harm to patients rather than preventing human errors

An example of how the patient safety program in the VA operates can be illustrated with the problem of patient falls. Our rich RCA database informed our office of the magnitude of this problem in our patient population. Major injuries from falls can lead to premature deaths and increased health care spending. Also, more than 20% 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. A collaborative project involving 31 VA facilities studied the problems of patient harm due to falls. This group developed interventions to mitigate patient harm due to falls and demonstrated a 60% reduction of major injuries from falls by the use of hip protectors and other measures for patients identified in high risk categories. Other VA patient safety impacts include:

- pacemakers and defibrillators in worldwide use whose designs were changed to make them less prone to failure
- barcode medication administration
- computer order entry of medication prescriptions
- ensuring correct surgery initiative to assure that the right patients receive the right procedure at the right time in a safe and secure environment
- developing a patient safety curriculum for residents in training, medical and nursing students
- developing a training program to improve communication among health care professionals in high risk environments like the ICU and OR
- leadership training in patient safety for senior administrators in VA facilities

Based upon our experience in forging a high profile, successful patient safety program in the largest health system in the US, we recommend the following measures for the Michigan Health and Safety Commission to consider in an effort to enhance the safety of health care delivery in this state:

- 1) Recommend that the state legislature **pass legislation** that will establish a privilege of confidentiality for all reported patient safety information (eg. Oregon);
- 2) Encourage the **development of voluntary, confidential reporting** of adverse events and close calls within individual health systems;
- 3) Encourage Chief Executive Officers of Michigan health systems to **invest in patient safety organizational structure** by committing human and fiscal resources to operationalize a robust patient safety program in their respective institutions (eg. patient safety manager/officer, medical director of safety, patient safety line item budget)
- 4) Establish a **state voluntary reporting system** of de-identified reports from Michigan health care facilities that could be aggregated at the state level, and lessons learned would be shared with all Michigan health care institutions.

In conclusion, we would emphasize that patient safety does not improve by fiat or regulatory mandate. The goal of a patient safety program is to prevent harm to patients and not to prevent human error. To achieve that goal, there must be uniform, unambiguous, and assured confidentiality of patient safety information. Successful patient safety programs permit and encourage all healthcare providers to aggressively pursue patient safety initiatives that emphasize and celebrate prevention, not punishment.

It would be well to consider the wisdom of Albert Einstein when we contemplate efforts to improve the safety of health care: “The significant problems we face cannot be solved at the same level of thinking we were at when we created them.”

Respectfully submitted,

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