

**STATE COMMISSION ON PATIENT SAFETY  
REQUEST FOR TESTIMONY  
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**EXECUTIVE SUMMARY**

According to a recent poll conducted by several national agencies/entities, patient's fear of medical errors has increased. This report was released in November 2004 and shows a decline in the overall confidence level of Americans regarding the healthcare system. Reporting of medical errors to a public agency for release in some type of Consumer Report was a priority according to 92% of adults surveyed. This interest in reporting may be due to the 2000 Institute of Medicine report stating medical errors kill more people per year than breast cancer, AIDS, or motor vehicle accidents. The numbers of medical errors can and has been disputed but the real issue is what we do with the information and how we obtain it to prevent future patient harm. Ultimately, medical error information must be collected, analyzed and used to learn and to prevent future patient harm.

Currently, the tracking and trending of such medical error information is used only by the collecting (host) organization. This data is considered internal peer/professional review information in most Michigan healthcare facilities, as it should. The lack of legislative involvement in extending peer/professional review protections on a much broader basis limits the ability for the lessons learned from medical errors to be shared within the overall healthcare community. Some major factors that limit broad scale learning from medical errors include the fear of reporting them due to potential litigation or punitive action, the absence of formal risk identification processes, and the lack of an effective data system to aid in tracking and trending of the information.

The most important consideration inherent in identifying errors and learning from them is to prevent future harm. To that end, we need to develop a process that would not only encourage reporting of medical errors but would enhance the reporters comfort in reporting. A process that creates further fear of retribution is useless. An environment that encourages reporting of medical errors, whether facility specific, state wide or national basis should be created in the spirit of a "just culture". (A just culture is a shared understanding of how the acceptability of individual behavior is to be determined and how accountability/culpability is evaluated. Ultimately a just culture is shared accountability.)

A voluntary system of reporting errors to a central repository that provides anonymity and peer/professional review protection for the reporter may permit broad sharing and learning to prevent repeat errors. Likewise, such a system would contribute to overall patient safety. The primary purpose of collecting error data and sharing the lessons learned is to use the information as an opportunity to enhance patient safety by improving healthcare systems. Initially, the most important step would be for the State of Michigan to promulgate regulatory protection for reporting medical errors for the purpose of improving patient safety on a statewide basis. Next, a plan should be developed for designing a state wide reporting system. This reporting system would involve healthcare providers, facilities and consumers.

**Subject:** Identifying and learning from errors

**Background:**

On November 27<sup>th</sup>, 2004, *News Target Network* reported that patients are increasingly fearful of medical errors. A new poll conducted by Kaiser Family Foundation, the Harvard School of Public Health and the federal Agency for Healthcare Research and Quality showed that Americans are concerned about medical errors and that there is a dispute over public reporting of errors. The article reports that five years after the Institute of Medicine (IOM) issued the landmark report on widespread preventable deaths in U.S. hospitals; the new poll shows that confidence in the healthcare system has declined and pressure to reform it has grown. More than half of the 2,000 adults surveyed said they are dissatisfied with the quality of healthcare, up from 44 in 2000. At the same time, 92 percent of respondents said reporting of medical errors should be mandatory and that medical errors should be reported by a public agency in some kind of consumer report.

According to the 1998 Institute of Medicine report between 44,000-98,000 Americans die from medical errors annually (Institute of Medicine, 2000; Thomas et al., 2000; Thomas et al., 1999) and medical errors kill more people per year than breast cancer, AIDS, or motor vehicle accidents (Institute of Medicine, 2000; Centers for Disease Control and Prevention; National Center for Health Statistics: Preliminary Data for 1998, 1999). The numbers of medical errors have been disputed as either being too high or too low. However, the numbers are not the issue. The issue is what we do with this information and how we obtain it to prevent future patient harm. Medical error information must be used to educate and to prevent recurrence of the same or similar errors in the future. How we get medical error information on a broad scale and in a timely manner is, and has been, a challenge. This is a challenge that the leaders in the State of Michigan should embrace and resolve as part of a statewide patient safety endeavor.

**Current Situation:** Many healthcare organizations identify risk issues on an internal basis. They track and trend their internal reports of medical errors, risk issues and near misses. One of the primary purposes for identifying and trending this information is to

learn from these opportunities, to improve the quality of care for the patients they serve and to enhance patient safety by improving systems. The learning from these lessons is limited however, to just the organization that is collecting the information. Generally, the lessons learned are not shared outside the confines of the organization where the error occurred. This sharing omission not only reduces broad scale learning, but also limits the prevention of future potential patient harm. There are many organizations and providers that have relayed their desire to share and to receive information about the lessons learned from medical errors. In spite of the willingness to share, the process of sharing must be orchestrated in a manner that would diminish or, at best, eliminate the fear that already exists in regards to reporting of medical errors. Fear of litigation and retribution are but a few factors that prevent broad scale learning from the lessons of medical errors.

Another limiting factor is that there are many healthcare organizations as well as clinics, practices and outpatient settings that do not have a formal risk identification process and/or a data system to support tracking and trending for the purpose of enhancing systems.

Other factors in our current situation that contribute to the lack of sharing and learning from medical errors include:

- Lack of common database for sharing and tracking
- Lack of common definitions and nomenclature for trending/tracking
- Lack of comparative analysis/benchmarking tools and methods to retrieve the information and to produce reports
- Lack of processes to obtain risk issues from front line staff
- Lack of a “just culture”(shared accountability) to create an environment where error reporting is encouraged and perceived as “safe”
- Lack of understanding of the principles of the risk management process, of human factors principles and proactive risk assessments
- Lack of a central repository for users/providers to report errors/near misses without the fear of retribution
- Lack of a central repository to analyze medical errors and identify the methods for future prevention activities
- Lack of legislative protection for the purpose of confidential sharing of error outcomes and contributing factors

**Proposed action:**

There is great opportunity for learning and changing practice to improve patient safety through the lessons and knowledge gleaned from errors and near misses. The State of Michigan should develop a reporting system to collect and use medical errors and near misses data for the purpose of cultivating and sharing contributing factors to prevent and reduce future patient harm. This repository of data would become central to decision making for future patient safety initiatives. The data would identify areas where system changes need to occur and where human behavior may need modification. The State of Michigan should contract with a vendor who can respond to the limitations

listed above as to factors why organizations do not share errors today and that can demonstrate the following capabilities:

- An established and proven tracking system (software program for patient safety events/incidents) to recognize risk issues and to track and trend the data
- Analytical capability to turn the data into meaningful information to share the lessons for improvement
- Quarterly reporting to all users regarding trends and areas of opportunity for system, human and process improvement
- Real time reporting by the repository to all users of urgent issues that need to be shared (concurrently) to prevent harm
- Clinically qualified repository staff interpreting data and reporting information
- Mechanisms to involve consumers/patients in the reporting and learning process
- Information technology systems to support a statewide initiative
- Industry leaders with the ability to educate healthcare facilities and staff on the utility and value of error reporting, methods to implement a just culture and the design and use of accountability models for action determinations

### **Patient Safety Legislation:**

The first step is for the State of Michigan to establish regulatory protection for reporting of medical errors for the purpose of improving patient safety on a statewide basis. This legislation should embrace all types of reporting, regardless of the cause or outcome. The fear of litigation is a limiting factor in the ability to aggregate and identify issues that have or could cause patient harm. If we (patient safety leaders) can timely identify errors and near misses we can prevent their recurrence through proactive patient safety approaches.

### **Consumer Involvement:**

Consumers (patients) need to be involved in this reporting process ---they need a mechanism to report errors and near misses that reach/impact them, and they need methods to learn from the lessons as they are central to preventing harm and errors.

### **Information Technology:**

The technology that would be required for this type of voluntary reporting system is a web based data reporting system as well as an anonymous phone reporting process. The technology or process that is utilized needs to meet the various mechanisms of the users and their various technological capabilities.

### **Funding requirements:**

The initial funding should support the development of a white paper that outlines the necessary aspects and issues that must be considered to create a statewide mechanism for identifying medical errors and using this information for the purpose of

improving patient safety. The following areas include some of the aspects to be considered:

- Specifications of IT systems and software use guidelines
- Vendor/partner with recognized expertise in risk management processes and patient safety principles
- Organizational culture assessment tools and methodologies to ascertain perceptions of a just culture and shared accountability
- Education and support initiatives to ensure effective risk identification and reporting
- Assessment of user (patients/consumers, facilities, providers, staff etc.) needs and capabilities in regards to reporting and information application