

What is the Minnesota Adverse Health Events Reporting System? When did the reporting system begin and why was it necessary? Who benefits from the information gathered through these reports? How is this system being used to increase the safety of patients in Minnesota health care facilities?

As the world moved into the 21st Century, with amazing technology and unlimited information available to almost everyone, it may seem surprising the difficulty a prospective patient would experience should he want to research which hospitals had the best records for patient safety. Hospitals and other health care facilities, licensed by state health departments, had certain regulations for reporting errors, but few made that information openly available. Even in the year 2000, there were no standardized requirements for health care organizations to report errors and make the reports available to the public. Several case studies about patient safety had been done in a sampling of hospitals across the country by reviewing medical records of discharged patients. This information gave a general idea about the frequency of medical errors and could be extrapolated to predict the frequency of medical mistakes country-wide, but it still gave no specific information for consumers and health care organizations.

In the year 2000, the Institute of Medicine published an unprecedented report on medical errors, called *To Err is Human*. The Institute of Medicine's report cited studies which said that at least 44,000 and as many as 98,000 Americans died each year as a result of medical errors. Nationally, estimated costs resulting from preventable medical errors range from \$17 billion to \$29 billion.¹ These extreme statistics and the subsequent recommendations in the report initiated a significant change. Prior to this publication, secrecy and self-protection, exacerbated by the liability system and threat of malpractice lawsuits, seemed to be the rule. This made it difficult for the general public to find any information about the history of medical errors in specific hospitals, difficult for hospitals to share this type of information with other hospitals, and difficult for hospitals to learn from the mistakes of others and make improvements to the system. But in response to *To Err is Human*, patient safety efforts have become a priority, not just within individual hospitals, but with hospitals and state agencies working together to report and share this important information.

The report, *To Err is Human*, made several recommendations to address the issues of patient safety in our health systems. The first was to give this issue a national focus and national leadership by asking Congress to create a Center for Patient Safety. The second recommendation focused on identifying and learning from errors by implementing reporting systems. The third was to raise standards and expectations to improve safety. And finally, the Institute of Medicine recommended implementing safety systems and safe practices inside health care organizations where patient care happens. (Kohn et al. p. 6)

In response to the Institute of Medicine's report and recommendations, Minnesota was one of the first states in the nation to develop a public reporting system for adverse health events, focused on sharing of information, analyzing causes, and prevention of such events. In 2003 Minnesota passed The Adverse Health Care Events Reporting Law.² This law required mandatory reporting for all hospitals if any of 27 "adverse events" happened in their facilities, and that this information would be made public in a yearly report. Minnesota was the first state to legislate this type of public reporting, which included requiring hospitals to develop plans for prevention and improvement as part of the

annual report.

The mandatory reporting of adverse events in Minnesota began in July of 2003. For the past five years from 2005 through 2009, an annual public report entitled "Adverse Health Events in Minnesota" has been published by the Minnesota Department of Health. Each report, except the first, covers the one-year time period from October 7 through October 6 of the next year. The first report, published in 2005, included data from July 1, 2003 through October 6, 2004. At the end of these first five years of reporting a summary report was published in January of 2009 by the Minnesota Department of Health called, "Adverse Health Care Events Reporting System: What Have We Learned? 5-Year Review".³

In Minnesota, the list of reportable events, based on definitions from the National Quality Forum, are medical events that should never happen, also called "never events". There are a total of twenty-seven types of events organized in six different categories: surgical, products or devices, patient protection, care management, environmental, or criminal events. Examples of reportable events include surgery on the wrong patient or body part, objects retained in a patient's body after surgery, death associated with a fall, and death or serious disability from a medication error.⁴

The actual statewide counts of reportable events are included in each year's reports, grouped by category and organized into tables. The details surrounding the severity of the incidents list whether the event resulted in death, disability, or neither. Information about the number of facilities reporting and events per total patient days among those facilities is also outlined. Following the statewide counts, the reports are then broken down by facility. The total number of beds in the facility is listed, which is a measure of the size of the hospital. Also, included are total patient days, which measures how busy the facility was. For the facilities that had surgical events to report, the report gives that number of surgeries performed within that facility. If a facility in the state had no events to report that facility is not listed at all.

The reports themselves have evolved somewhat over the five years the reporting system has been in place. The first three "Adverse Health Events In Minnesota" public reports covered 27 events. In October 2007, a 28th event, artificial insemination with the wrong donor sperm or egg was added, and the definitions regarding reportable falls and pressure ulcers were changed. These changes resulted in a significant increase in reported events in the 2009 Public Report, which covered the time period from October 2007 through October 2008.

Quoting from *To Err is Human*, "the goal of reporting systems is to analyze the information they gather and identify ways to prevent future errors from occurring" (Kohn et al. p.8). From the beginning one of the goals of Minnesota's Adverse Health Care Events Reporting Law was to create a system that encouraged sharing of information between facilities as a way to increase learning. Basically, the idea was that by learning from the experience of others, health care organizations could help prevent similar events from happening in their own facilities.

The yearly reports provide information on what is called "Root-cause analysis". When an adverse health event occurs and a report is made, a team from the Minnesota Department of Health examines the factors that led to the event. The team seeks to determine the root-cause and contributing factors leading to the event such as difficulty with rules and procedures or communication

breakdowns.⁵ The yearly report includes overall findings that come from the root-cause analysis and a summary of contributing factors submitted by the hospitals and surgical centers for the top reporting categories. The specific information that emerges from these root-cause analysis can then be used as a learning tool.

From the start, Minnesota's Adverse Health Care Events Reporting system, has been a cooperative effort by several groups that have a vested interest in health care and share the goal of improving patient safety. Based on the information gleaned from the root-cause analysis, facilities and other groups have developed several initiatives to improve patient safety. The Minnesota Hospital Association (MHA) is a trade association representing Minnesota's hospitals and health systems. With educational programming, communication efforts, resources and expertise, MHA develops strategies to advance patient safety in Minnesota. The association also works with the Minnesota Medical Association and the Minnesota Department of Health as co-founders of the Minnesota Alliance for Patient Safety. In response to the data reported through the adverse health events yearly reports, the MHA has launched four major safety campaigns since 2007 aimed at reducing the top reported adverse health events. The SAFE from FALLS, SAFE SKIN, SAFE COUNT, and SAFE SITE campaigns grew out of the information that became available because of the reporting system.⁶

Minnesota hospitals that are participating in the MHA safety programs agree to implement a number of "best practices" to prevent adverse events. Best practices are solutions that can be applied across facilities. (2008 report p. 65) Best practices can be defined as the most efficient and effective way of accomplishing a task. They are based on procedures that are repeatable and that have proven themselves to be effective and efficient over time for large numbers of people.

Along with sharing information as a way to increase learning, the yearly reports are encouraging health care facilities to develop a systems approach to patient safety. What exactly is a "system's approach"? Basically, this approach involves examining all the components involved in health care systems and their interactions with each other. The systems approach is based on the thinking that the parts of a system can best be understood in the context of relationships with each other and with other systems, rather than in isolation. The only way to fully understand why a problem occurs and persists is to understand the particular event in relation to the whole system.

In the past, when an adverse health event occurred, the focus would be only on the individuals involved. "The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer" (Kohn et al. p.49). Health care organizations must move beyond only attaching blame to individuals and, instead, develop a systems approach to understand the causes of adverse health events, and to implement systems changes to prevent such events.

According to *To Err Is Human*, "the most important barrier to improving patient safety is lack of awareness of the extent to which errors occur daily in all health care settings and organizations. This lack of awareness exists because the vast majority of errors are not reported" (Kohn et al. p.157). The Minnesota Adverse Events Reporting System has resulted in many positive outcomes. Now it is

possible for a prospective patient to find safety information about specific hospitals in Minnesota. Now Minnesota hospitals are learning from the patterns of data that are emerging through the reporting system. Now facilities are implementing the systems approach to patient safety and using best practices, both of which have been developed and fine-tuned because of the information that is now available through the reporting system. Undoubtedly there is more to be learned and more tuning of the reporting system to be done, but the foundational vision of improving patient safety in Minnesota has certainly begun.

Statistical analysis can be used to mine the most information from the data set. To start with, reportable event data must be consistent and accurate. While never 100%, data sets must be audited for errors and root-cause, in an ever improving reporting data set. Corrective action can then be set in place to improve future data quality. Overall service statistics regarding the location are needed to quantify the event rate. Counts of surgeries, patient-days, and similar service totals are needed to scale the event rate to make them comparable year-to-year and between locations or states. Comparable event rates can then be statistically compared between locations according to a predetermined statistical confidence. Simple control charting can be used to detect improvement trends or unusual event patterns. Duane charting can be used to track improvement efforts and compare these efforts between location, state, and other industries.

Having a solid statistical baseline can be used to measure the effectiveness of any improvement efforts. Before and after snap-shots make the best stories and show the real effect of an improvement effort. Data set quality measures and analysis seems to be the largest missing link and logical next steps of focus for the Minnesota Adverse Health Care Events Reporting System.

Analysis and training is available from sf(x) Engineering Analytical Services, on the web at <http://www.sfxeng.com/> or by phone 218.469.4041, contacting Stephen Fisher

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Key Words: patient safety, medical errors, adverse health events, medical mistakes, Minnesota health care, reporting systems, wrong site surgery, never events, Minnesota hospitals, safety, Duane plot, statistical analysis, reliability

Appendix A - Event Categories

In the Surgical category, adverse events include surgery on the wrong body part or on the wrong patient, the wrong procedure being performed, or retention of a foreign object following surgery. Death during or directly following surgery is also a reportable event in the surgical category.

The next category concerns Products or Devices. Under this category three adverse events are reportable: contaminated drugs, devices, or biologics; misuse or malfunction of a device; and an intra vascular air embolism.

The third category concerns Patient Protection Events such as discharging the infant to the wrong mother, the disappearance of a patient, and patient suicide or attempted suicide.

Category four contains events related to Care Management. Events that caused death or disability due to medication error, hemolytic reaction, hypoglycemia, spinal manipulation, or during a low-risk pregnancy labor or delivery, or by failing to treat hyperbilirubinemia. Also included in the patient care category are stage 3 or 4 pressure ulcers that are acquired after admission.

The Environmental category concerns adverse events such as electric shocks, contaminated patient gas lines, burns, falls, and the use of restraints that result in the death or disability of the patient.

The final category contains Criminal Events such as if someone impersonating a physician or nurse orders care, or a patient is abducted or sexually assaulted, or a death or injury comes to a patient or staff person because of physical assault.