

JANUARY 2014

10

ADVERSE HEALTH EVENTS

10 Year  
Program  
Evaluation



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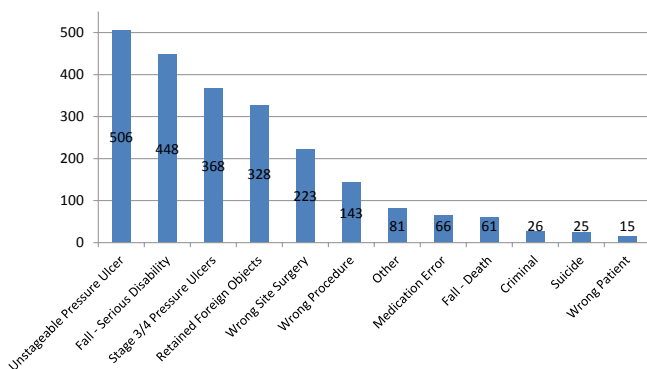
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# Executive Summary

In 2003, the Minnesota Legislature passed the Adverse Health Care Events (AHE) Law, requiring hospitals and, later, ambulatory surgical centers to report to the Minnesota Department of Health whenever one of 27 serious adverse health events occurred. The law was modified during the 2007 legislative session to add a 28th reportable event, and again in 2013 to add four new events and modify or delete others to make 29 reportable events and to expand or refine definitions of several other events. This revision to the law was not put into effect until Oct. 7, 2013, the start of the 11th year of AHE reporting, therefore those changes will not be cited in this report (Appendix A).

Since the inception of the AHE reporting law 10 years ago, the field/knowledge of patient safety, as well as the healthcare environment has changed significantly. At its core, the AHE system strives to balance learning and accountability. MDH and its partners believe that in order to encourage facilities to continue to share data and learnings throughout Minnesota, hospitals and surgical centers need to see the value in the system, which includes receiving support to identify root causes and identify action steps to proactively prevent future events from occurring. Since 2003, over 2,200 events have been reported through the adverse events system (Figure 1). However, while counting the frequency with which adverse health events occur and reporting the results publicly is part of the law, it is the focus on improving systems and learning that is of the utmost importance to sustainable improvements in patient safety.

**FIGURE 1:**  
Reportable Adverse Health Events, 2004 – 2013



For the 10-year evaluation, MDH convened a series of focus groups with patient safety managers, conducted a survey of staff from reporting hospitals and ambulatory surgery centers, and worked with the Minnesota Hospital Association (MHA) and Stratis Health to further analyze data from both an epidemiological and statistical perspective over the 10 years of the reporting system. Throughout the evaluation, areas of success were identified as well as areas for future improvement. Key findings from the 10 year evaluation include:

- The AHE law was a catalyst for patient safety throughout the state. It has helped to bring patient safety to the forefront, increased awareness, and led to focused patient safety improvement activities.
- As the system has evolved, facilities have been asked to submit much more robust data and root causes than at the inception of the system. This has led to more in-depth analysis of events and the ability to identify focused improvement opportunities to address specific issues.
- Hospitals and surgical centers reported the AHE system works well in the current healthcare environment in Minnesota and would like the same commitment to transparency, learning and public reporting spread to all settings of care, including: cosmetic surgery centers, long term care facilities and clinics.
- Facilities have put many policies/procedures to improve patient safety in place since 2003, including policies to disclose events to patients/families, regular assessment of organizational culture and sharing AHE data with the board and throughout the facility.
- The number of deaths has declined overall since the first year of the system and events that result in serious disability are on a downward trend as well.
- Some rates of reported events that have had consistent definitions during all 10 years, such as stage III or IV pressure ulcers, have seen a reduction. However, rates of reported events as a whole have remained consistent over the 10 years (accounting for definitional changes).

- The reporting system was designed as a learning system and analysis of the data across the reporting years demonstrates this primary goal of the system is being met. For example, after Safety Alerts are issued, typically the number of reported events related to the alert increase as awareness about reporting and preventing those types of events has increased. Then numbers begin to decline as identified practices are implemented across the state.
- AHE data indicates that hospitals and surgical centers are very responsive to learnings from the system. An impact on the number of reported events is demonstrated in the data in a very short period of time following the issuing of alerts or best practice recommendations.
- Some facilities still struggle to engage physicians/surgeons and other staff members in certain safety initiatives (usually surgical safety), and would like assistance developing physician/surgeon champions to build support for safety initiatives.

In the upcoming year, MDH and its partners will take steps to address the key learnings from the annual report as well as this 10-year evaluation in order to improve patient safety in Minnesota, including:

- Developing additional methods, tools or resources for data sharing across facilities. This includes sharing learnings from events as well as near misses.
- Improved functionality in the current data sharing database for running reports and data mining.
- Developing additional education/training opportunities on most frequently reported events (falls, pressure ulcers and surgical/procedural events).
- Developing physician/surgeon champions to build support for safety initiatives.
- Working with stakeholders throughout the state to expand the same commitment to transparency, learning and public reporting to all healthcare settings in Minnesota.

## Evaluation Overview

In January 2014, MDH released its 10th annual adverse health events report, providing information about 258 events that occurred during the previous reporting period and highlighting steps taken by hospitals and surgical centers to prevent future events. Along with this work in 2013, MDH embarked on a 10-year evaluation of the reporting system, seeking to answer questions including, but not limited to:

- Are we safer, or not safer, than we were 10 years ago?
- What changes have facilities put in place since 2003?
- How does the AHE process help or hinder the patient safety journey?
- What are the most significant patient safety challenges facing reporting facilities today related to event reporting and process improvement?
- How can the AHE process evolve to continue to advance patient safety forward in Minnesota?

To answer these questions, MDH convened a series of focus groups with patient safety managers from hospitals and surgical centers around the state, conducted a survey of staff and leaders from reporting facilities, and worked with the Minnesota Hospital Association (MHA) and Stratis Health to analyze data from the 10 years of the reporting system.

### Facility Survey

In August 2013, MDH conducted a survey of more than 200 hospital and surgical center CEOs/administrators, patient safety managers, directors of nursing, risk managers, and others involved in reporting/analyzing adverse health events, and monitoring safety and quality measures within their facilities. The survey included the following questions:

- In your opinion, is your facility safer, or not safer, than it was 10 years ago?
- How would you rate patient safety as a priority within your organization?
- What are the priorities for your organization and where does your organization spend time with regard to those priorities?
- What resources will be helpful for your organization going forward?

Survey respondents represented a wide variety of facilities: 12 percent represented ambulatory surgical centers, 38 percent came from hospitals with fewer than 25 beds, and seven percent came from hospitals with more than 500 beds. Respondents were most likely to be patient safety/quality managers, although CEOs, directors of nursing and risk managers were also well represented (Figure 2).

**FIGURE 2:**  
Facility survey respondents

Respondent Type	Percent of respondents	Number of Respondents
Patient Safety/Quality manager	37.70%	50
Other	18.50%	25
Director of Nursing	16.20%	22
CEO/Administrator	15.40%	23
Risk Manager	10.80%	20
Physician	0.80%	2
Staff nurse	0.80%	2

### Data Analysis

Throughout 2013, MDH, Stratis Health and MHA worked to analyze data across the 10 years of reporting. Throughout the data analysis, two different types of data were analyzed:

- Process measure data, such as: how quickly facilities report their events, type of root causes reported and how often facilities cite that there is no root cause for an event.
- Outcome measure data, such as: rates of falls, number of retained foreign objects (RFO) in various settings and frequency of medication errors.

Since the data that the online system collects has evolved significantly over the years, some data was not easily compared across the full 10-year span; however, trends and patterns were evaluated across as wide a range of years as possible given the available data. The goal of the data analysis was for MDH to look at the reporting system as a whole and identify which aspects of the system have worked well and which can be improved in the future, as well as paint a 10-year picture of data gathered through the system.

## Patient Safety Manager Focus Groups

To evaluate and improve the Adverse Health Events program, MDH held four focus groups in September 2013 and one community conversation in October, consisting of patient safety managers/officers working in ambulatory surgical centers and hospitals across the state of Minnesota. Two of the four focus groups and the community event were held in St. Paul while the other two focus groups were held in greater Minnesota: Redwood Falls and St. Cloud.

Focus group participants were randomly selected by staff at MDH and no incentives were given to participants. The community event participants were invited by MDH, in collaboration with the Minnesota Alliance for Patient Safety (MAPS), to discuss the impact of the reporting law and the future of adverse health events reporting. Minnesota Management Analysis & Development facilitated the focus groups and community event.

Critical access hospitals were the largest group represented in the focus groups, followed by ambulatory surgical centers and mid-sized hospitals. Other facility types represented were large academic medical centers, a multiple hospital multiple clinic system, a large urban hospital, an integrated health system and a healthcare system corporate office.

Focus group participants were asked the following questions:

### Domain: AHE Reporting Impact

1. How has your facility changed as a result of the AHE law? Positively or negatively.
2. Where has the requirement to report adverse health events reprioritized safety improvements to those types of events? What safety improvements have been deprioritized as a result?

### Domain: Data Reliability and Reporting

3. How do you track adverse health events at your facility?
4. How are you tracking your progress in safety more broadly?
5. What steps do you take to ensure full and accurate reporting?

6. In the event of employee turnover, how does the transfer of knowledge occur to ensure continued reporting?
  - a. How can MDH/Stratis/MHA support that?

### Domain: AHE Categories

7. We continue to focus most of our time and energy on the top 3-4 categories of reported events: falls, pressure ulcers and surgical events. If it were up to you, where would you put the focus? Why is that?

### Domain: Current AHE Program Practices

8. For large frequency events like pressure ulcers, the program moved to sampling events for review by Stratis Health. In your experience, how effective has this approach been? How could we apply this approach to other types of events?
9. Minnesota's Adverse Health Event law is linked to the National Quality Forum (NQF). How does it, or doesn't it, enhance the overall program? How would you change it? Why is that? If it continues to be linked to NQF, what events should we be capturing?

### Domain: Future

10. What should the next generation of AHE look like? Should it include new settings or facility types? Should it include new events? Are there events which we should no longer capture?

### Domain: Support

11. What resources and training do you need from MDH/MHA/Stratis Health that could help you in your work?
12. What else would you like to say about the AHE reporting program that hasn't been discussed?

The responses from focus group participants and survey respondents, along with data analysis results, are summarized in the following sections.

# Impact of the Reporting Law

This section of the evaluation focused on a series of questions related to the patient safety best practices that have been implemented over the last 10 years, the degree to which the reporting law has led to broader changes within facilities, and the priority patient safety takes at facilities. The ultimate question with regards to the AHE system is whether or not it has made patient care safer, and met its goal of supporting a system of learning and transparency that will lead to fewer adverse events and lower levels of harm.

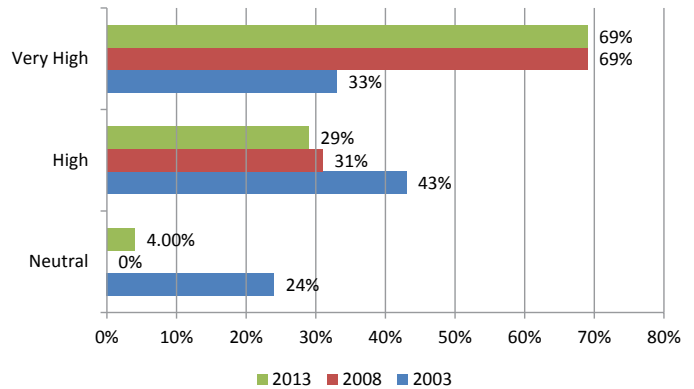
## Are We Safer?

Patient safety is a complex and evolving concept, one that is measured in many different ways by individual facilities and state/national organizations. Examples of safety measures include: the rate or number of reportable adverse health events, the number of healthcare acquired infections or conditions, overall rates of harm, or performance relative to state or national goals. As a result, many facilities report finding it challenging to answer the question of how best to measure the extent to which they are making progress, particularly in the area of adverse events.

### Survey Data Analysis

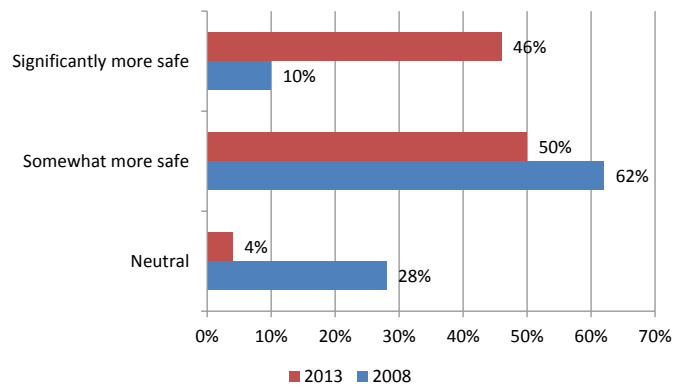
Healthcare facilities have to balance a number of high-priority issues, such as: financial sustainability, implementation of state and federal health care delivery and payment reforms, and new or evolving reporting systems for quality, cost and patient experience. In recognition of these issues, survey participants were asked to rate the priority level of patient safety in their organization; 98 percent reported patient safety as a high or very high priority at their organization (Figure 3). This is a strong indicator of the amount of time and resources invested in patient safety and quality in Minnesota healthcare organizations. When compared to responses to the same question in 2008 and 2003, results were similar in 2008, but much improved since 2003.

**FIGURE 3:**  
Safety as a priority, 2003–2013



Similarly, respondents were asked if they felt that Minnesota was safer than it was at the start of the reporting system in 2003. A strong majority of survey respondents (96 percent) reported that they felt their facility was somewhat safer or significantly safer than 10 years ago (Figure 4). In 2008, during the five year evaluation of the reporting system, MDH asked the same question of reporting facilities. The percent of respondents that reported feeling “significantly safer” in 2013 is four times higher than the level reported in 2008; the percent of respondents stating a neutral response has declined sharply as well.

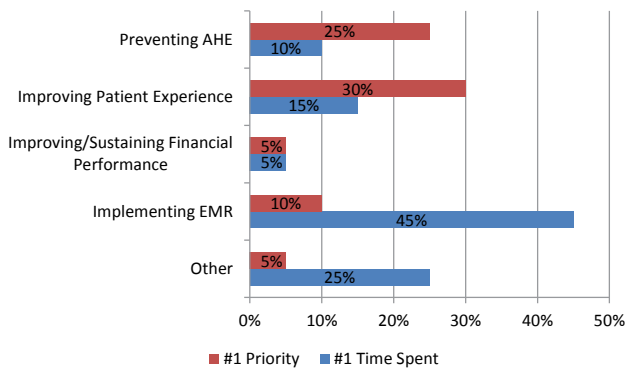
**FIGURE 4:**  
Are we safer?



### Patient Safety as a Priority

Survey participants were asked to rank nine different common priorities for facilities from one to nine (one being the highest priority) and then to do the same for the amount of time that is spent in each of those areas. Overall, CEOs/administrators chose ‘preventing AHE’ as their number one priority 25 percent of the time, followed by improving patient experience at 30 percent. However, when asked to rank the priority areas in relation to time spent, 45 percent stated the majority of their time is spent implementing or optimizing their electronic health records (EHR) and only 10 percent stated the majority of their time is spent on preventing AHE (Figure 5).

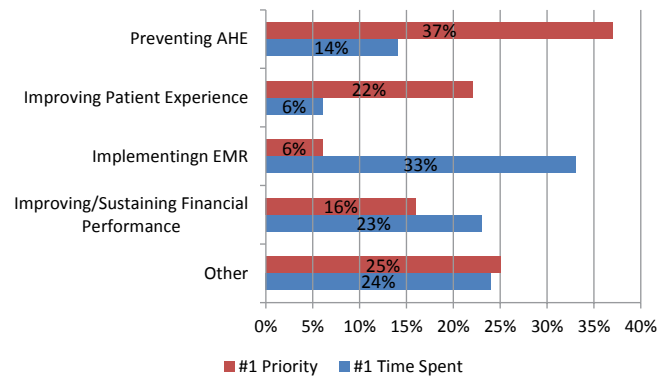
**FIGURE 5:**  
CEO/administrator priorities vs. time spent, 2013



When looking at the same questions for patient safety and quality managers, the results were similar to those of CEO/administrators, with 37 percent stating that preventing AHE is their number one priority, but only 14 percent spending the majority of their time in that area. Also of note, patient safety and quality managers noted spending the majority of their time implementing or optimizing their EHR (Figure 6).

In a complex healthcare environment with many financial challenges, a shifting landscape of healthcare reform and increasing reporting requirements, facilities are often challenged to prioritize their time and balance their resources. As can be seen through this survey, facilities are spending a significant amount of time on implementation and optimization

**FIGURE 6:**  
PS/quality managers priorities vs. time spent, 2013



of their electronic health record systems, which may lead to unanticipated outcomes as resources are stretched elsewhere.

In the upcoming year, MDH and its partners will continue to work with facilities to ensure that they are aware of patient safety opportunities and risks associated with electronic health records, and that they are aware of and using the resources that are available to assist in planning and implementing EHRs. Some facilities are currently using innovative approaches to align these two areas by using their EHR for things such as early sepsis warnings or capturing fall injury risk assessment. MDH will continue to work with innovative users of this type of technology to spread learnings.

### Adverse Events Data Analysis

While one way to measure the level of safety in Minnesota hospitals and surgical centers is to look at qualitative data such as the survey responses and focus group answers, another way is to look at event specific data such as rates of retained foreign objects, level of harm to patients from these events and pressure ulcer rates. Analyzing this type of quantitative data is a challenge for the AHE system as a whole, as it only captures a relatively small subset of events and some definitions have changed over time, making it difficult to interpret increases or decreases in numbers.



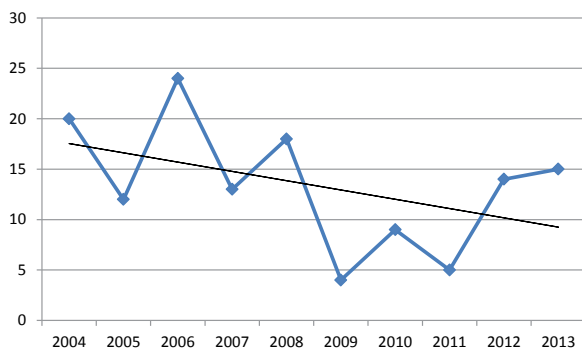
Prior to the implementation of the law, there was no statewide system for assessing how frequently these events happened, making it hard to retroactively compare where we are now with where we were then. While some individual facilities tracked their own adverse or serious events, there was no law in place requiring reporting of events publicly or collectively. This has also made quantifying the progress in the past 10 years somewhat of a challenge. However, the data do show some patterns of progress that are highlighted in this section of the report.

### Level of Harm

Under the reporting law, some event categories are reportable regardless of level of harm (e.g., retained objects or wrong body part procedures). Other categories, such as a burn or medication error, are only reportable if the event results in a patient death or serious disability. Still other events have evolved over the life of the reporting law, such as the addition of the reporting of falls resulting in serious disability in 2008 (prior to 2008, only falls resulting in a patient death were reportable).

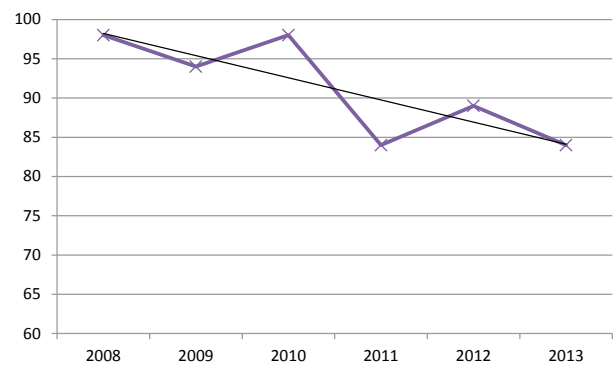
However, reportable events resulting in death of a patient have been reported consistently throughout the 10 years, making it possible to analyze trends across the full decade of reporting. Analysis of the number of deaths from reportable adverse events per year shows that the overall number of deaths associated with AHE has varied from year to year, but has declined as a whole (Figure 7).

**FIGURE 7:**  
Deaths per year, 2004–2013



Trends associated with events resulting in serious disability are harder to quantify with the addition of falls associated with serious disability in 2008. However, when looking at the data from the last six years since that category was expanded, there is a slow, yet steady downward trend in the number of events reported with serious disability (Figure 8).

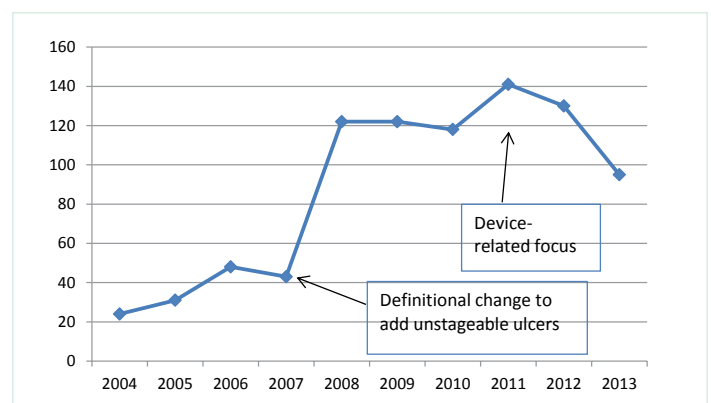
**FIGURE 8:**  
Events resulting in serious disability, 2008–2013



### Pressure Ulcers

Over the course of 10 years, pressure ulcers have been the most commonly reported event, and are reportable regardless of level of harm to the patient. A definitional change in 2007 added ‘unstageable’ pressure ulcers to the list of reportable events and since those types of pressure ulcers are more frequent, the number of events increased substantially at that time (Figure 9).

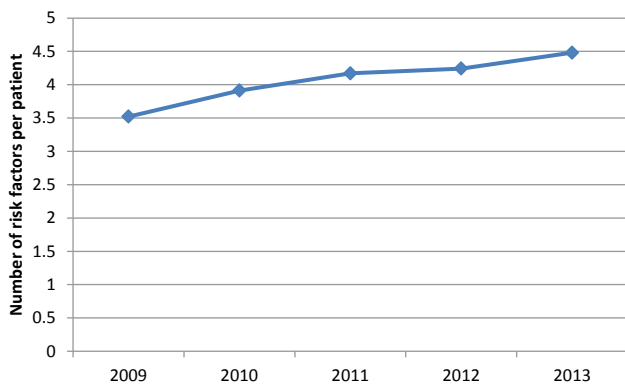
**FIGURE 9:**  
Reported pressure ulcers, 2004–2013



Staff from reporting facilities often state that through the MHA ‘SAFE SKIN’ Call to Action, they have put best practices in place to prevent many types of pressure ulcers, but are still struggling with critically ill patients, often those in intensive care units. Typically these patients’ conditions are tenuous and may prevent staff from repositioning them to relieve pressure.

To examine this issue, the evaluation looked at whether patients in Minnesota hospitals are ‘sicker’ than they were 10 years ago. One way of doing that is to look at the number of risk factors (e.g., diabetes, clinical malnourishment, kidney failure, respiratory failure) reported for each patient who acquired a pressure ulcer. This data has been collected in the registry system since 2009. The data shows that the average number of pressure ulcer risk factors per patient has increased by about 12 percent over the last five years (Figure 10). While pressure ulcers are still nearly always preventable, the data shows that facilities have had increasing challenges with regard to the overall health of their patients and preventing pressure ulcers from forming in the most complex patients.

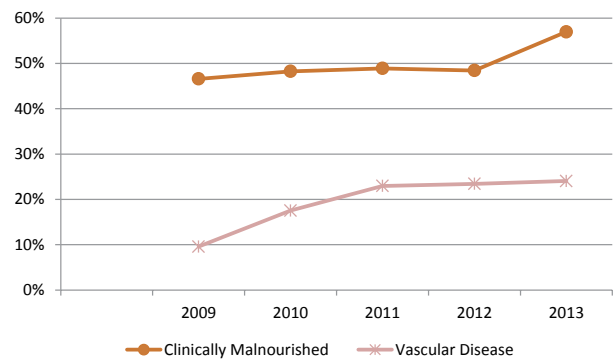
**FIGURE 10:**  
Average number of pressure ulcer risk factors per patient



When looking closer at individual risk factors, the percentage of patients who acquired a pressure ulcer and were clinically malnourished has increased over the past five years, and increased 10 percent in year 10 alone. These patients are especially complex, as low body mass and malnourishment make the skin more difficult to protect from pressure related injury. Similarly, the percentage of patients with vascular

disease has also increased (Figure 11). These are patients whose perfusion (blood flow) is not optimal to their tissues and skin, causing increased risk for pressure ulcers.

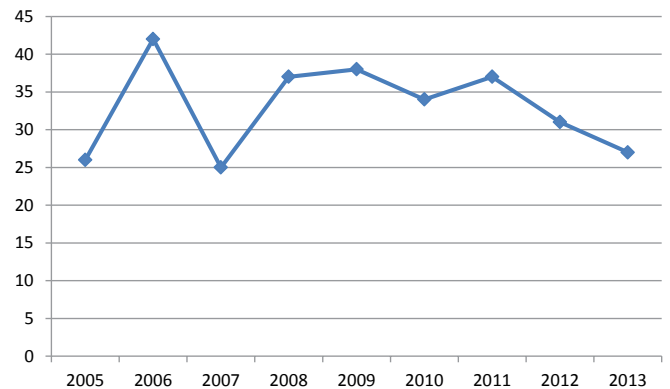
**FIGURE 11:**  
Pressur ulcer risk factors, 2009–2013



### Retained Foreign Objects

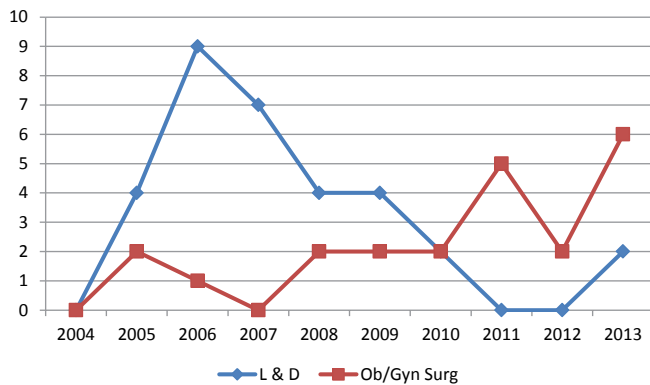
Overall numbers of retained foreign objects (RFO) have declined steadily for the past three years (Figure 12), as much work has been done through the MHA ‘SAFE COUNT’ Call to Action on best practices for counting and accounting for all items used during surgical or invasive procedures.

**FIGURE 12:**  
Retained foreign objects, 2005–2013



Looking specifically at vaginal packing (sponges, or gauze intentionally placed during a surgical procedure with the intent to remove before discharge) in the early years of the reporting system, there were many of these cases reported in labor and delivery (L&D). In response to those findings, MHA developed a Call to Action, 'SAFE COUNT', to address the issues surrounding accounting for items in labor and delivery. After this campaign began, there was a sharp decline in the number of retained foreign objects found in L&D and in 2011 and 2012 there were no RFO reported in that area (Figure 13). This was regarded as a large success for a Call to Action campaign and 'SAFE COUNT' was retired in 2012 with 97 percent of facilities reporting having implemented all of the best practices. However, in 2013, there were two cases of retained objects in L&D, causing MDH and its partners to remind facilities to review the 'SAFE COUNT' practices to ensure best practices remain in place.

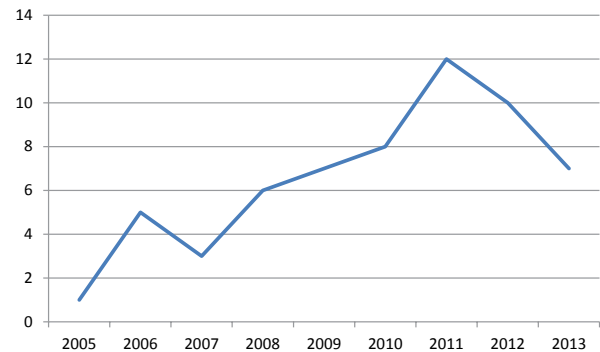
**FIGURE 13:**  
RFO (vaginal packing) by location, 2004–2013



Due to the increase in retained objects in gynecological surgery, MHA developed 'SAFE ACCOUNT 2.0' in 2013 to address new issues of vaginal packing in gynecological surgery. This campaign was rolled out in December of 2013 with 111 facilities participating and reporting data on their rates of implementation of best practices on a quarterly basis.

Another type of retained foreign object is a broken piece or fragment of an item used during a surgical procedure. Most commonly these are pieces of needles or tips of instruments. In 2009, due to an increase in these types of events, MDH and its partners issued a Safety Alert to all Minnesota facilities around accounting for items being intact before and after procedures. In the past two years, facilities have begun to see success in this area and the numbers of these types of reportable events are on the decline (Figure 14). This type of decline, seen after the issuance of a Safety Alert, demonstrates that the AHE system in Minnesota is one of learning and improvement.

**FIGURE 14:**  
Retained foreign objects (broken items)



# Biggest Changes in Facilities as a Result of the Law

Throughout the evaluation participants were asked to share the biggest changes in their facilities as a result of the AHE law. Some changes that have come about as a result of the adverse health events law are difficult to quantify, but provide strong evidence of a shift in the focus of organizations towards safety. Even so, a clear theme that emerged through the evaluation is the idea that the law helped to focus attention on safety beyond what it might otherwise have been.

Focus group participants stated that the law has brought attention and awareness to events that in the past may have been seen as “inevitable” and are now seen as nearly always “preventable.” This has shifted the emphasis away from accepting events such as pressure ulcers and falls as inevitable, to learning how events occur and implementing interventions to prevent them in the future. Focus group participants also stated that this is a significant shift from the ‘way of thinking’ prior to 2003 and has been a gradual but profound cultural shift in the past 10 years. Participants stated that because the AHE process is standardized and required across all hospitals and ambulatory surgical centers, it has introduced a level of rigor and structure where employees understand the process to report and how to attempt to prevent these events. Many participants remarked how this standardized approach has resulted in a higher quality of care for patients and how patient safety and evidence-based best practices are a community standard in Minnesota and allow all reporting facilities to consistently public report and improve patient safety.

## Root Cause Analysis Investigations

One component of the AHE law requires facilities to perform a Root Cause Analysis (RCA) after each reportable event and report those findings into the registry system. An RCA is a method of problem solving that attempts to identify the root causes of events, typically looking deeper than human error and looking for systems issues. Many focus group participants reported having broadened the use of RCA beyond reportable events and say that the AHE law has helped facilities to look at all their events (or near misses) in terms of identifying patterns and trends and being able to mitigate those risks. Participants reported that this practice was not common 10 years ago and has allowed for a more robust investigation of events and near misses.

## Implementation of Best Practices

Survey respondents were asked about a number of other best practices related to patient safety and quality to see whether or not the rate of adoption of these practices has increased over the past 10 years and to evaluate the current rate of adoption. In particular, use of adverse event learnings from other facilities and regular assessment of patient safety culture are now much more widely adopted than they were five years ago (the most recent data available).

The responses reveal that some of these practices were in place even prior to the implementation of the reporting law. In particular, policies requiring disclosure of adverse health events to patients or family members were in place in over half of respondents’ facilities, as was the practice of having CEOs or other leaders participate in ‘leadership walk rounds’ (where executives walk through the facility in order to see areas for improvement and talk with staff). Facilities also report assessing organizational culture in 2008 as well, although typically this was more staff satisfaction than patient safety culture (Figure 15).

**FIGURE 15:**  
Policies in place

Policy/Procedure	2008	2013 HSPTL	2013 ASC
Sharing AHE data with board		94%	93%
Sharing AHE Stories with board		73%	80%
Sharing AHE data with staff		94%	100%
Sharing AHE learnings with other facilities		66%	53%
Use of AHE learnings from other facilities		82%	80%
Regular use of FMEA		53%	40%
Policy of disclosing AHE to pt/families	60%	94%	60%
Leadership WalkRounds	60%	79%	73%
Leadership/C-Suite measurable goals related to PS		69%	66%
Regular assessment of organizational culture	80%	91%	66%
Teamwork training for staff		72%	93%
Good Catch program/system for front line staff		71%	53%

The current responses show that the policy of disclosing AHE to patients/families has been implemented in almost all hospitals, but only 60 percent of ambulatory surgical centers have implemented this policy. Other differences of note are that hospitals appear to do regular assessments of organizational culture more often than ambulatory surgical centers, while surgical centers report sharing AHE data with staff 100 percent of the time compared to 94 percent for hospitals.

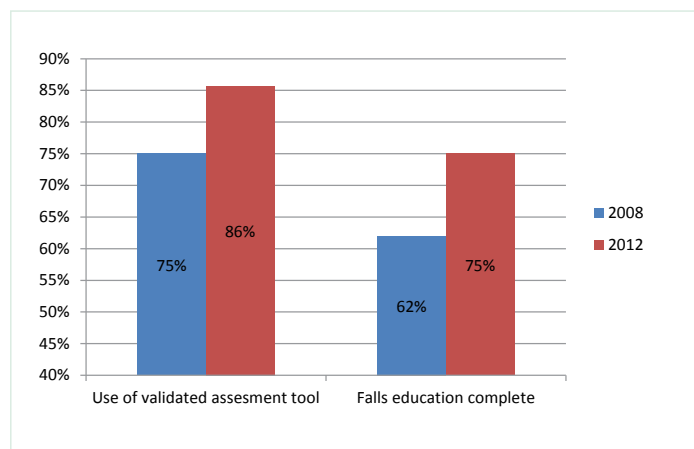
Anecdotally it is known that prior to the adverse health events system, it was unusual for facilities to share any information about their adverse events within their own facilities, and almost unheard of for a facility to share adverse events data with other organizations. Currently, 80 percent of facilities report using shared learnings in their facilities. This sharing of information is at the foundation of the adverse events reporting system, and it has been a catalyst for many facilities to try new approaches or solutions that have been tested by others to prevent future events.

Another of the most frequently reported events is falls. Falls have continually been a challenge to facilities in Minnesota, as they have implemented many best practices to prevent falls, but falls still occur and patients still sustain injuries from those falls. In the fifth year of the adverse events system, MDH began collecting data on types of best practices and if they were in place when a patient fell and was injured severely or died. Examples of best practices include: completing a falls risk assessment upon admission, completing education on falls with the patient, and placement of a visual indicator of falls risk in the patient's room.

When comparing 2008 data to 2012 (the latest year of available data), the use of a validated assessment tool to assess patients for fall risk increased by 11 percent and staff completing falls education with patients increased by 13 percent (Figure 16). These are best practices that were outlined in the 'SAFE from FALLS' roadmap and are evidence that facilities have worked hard to put these practices in place.

While some of these changes can be tied closely to the adverse health events law, many of these practices have become more widely supported nationwide, have been part of national initiatives such as The Centers for Medicare and Medicaid Services' 'Partnership for Patients' program

**FIGURE 16:**  
Falls best practices



and have a growing evidence base in literature. However, many participants felt that the law itself has pushed for swifter change in Minnesota and that Minnesota is often times on the forefront of change and adoption of best practices.

Overall, participants noted the following overarching improvements that the reporting law has helped to drive:

- Increased awareness of patient safety at the highest levels within the facility, particularly by the CEO and Board of Directors.
- Increased awareness of patient safety by all staff at the facility, especially front-line staff. Patient safety is now considered "everyone's responsibility."
- Increased focus on analyzing and investigating events to prevent them in the future.

# Learning from Events

Analysis of reported events across the 10 years of AHE reporting demonstrates a system of learning and improvement. As trends are identified in the data, aggregate information from the event information, including findings from the root cause analyses and action plans, are communicated to hospitals and ambulatory surgical centers in the form of safety alerts and/or incorporated in best practice recommendations, such as MHA ‘Calls to Action.’

**FIGURE 17:**  
Unstageable pressure ulcers for med/surg, 2007–2013

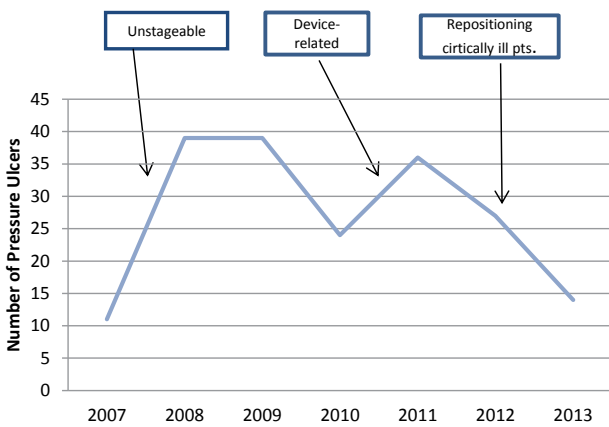


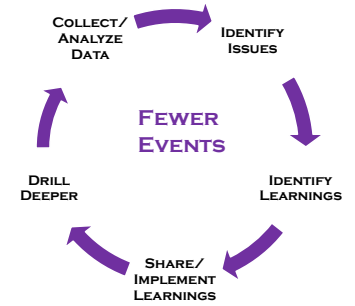
Figure 17 illustrates this system of learning and improvement for pressure ulcers in which trends were identified and communicated, awareness increased, resulting initially in an increase in reports related to the type of event involved, and best practices were implemented, resulting in a gradual decrease in the specific type of events being targeted.

In October 2007, unstageable pressure ulcers were formally added to the list of reportable pressure ulcers. Prior to that time, the vast majority of pressure ulcers were either Stage III or IV ulcers. The sharp increase in reported unstageable pressure ulcers in 2008 reflects that change. At that same time, Minnesota facilities began participating in a statewide initiative, ‘SAFE SKIN’, to collectively implement best practices to prevent pressure ulcers. Following the statewide implementation, there was a decrease in pressure ulcers.

Several years later, ongoing review of reported events identified a number of pressure ulcers resulting from medical devices such as oxygen tubing, oxygen masks and cervical collars. In 2010, these findings were communicated to facilities,

which raised awareness of this issue and initially increased the number of reported device-related pressure ulcers as staff become more proficient in finding these types of ulcers. However, after best practices were put in place around the state, another decrease was noted.

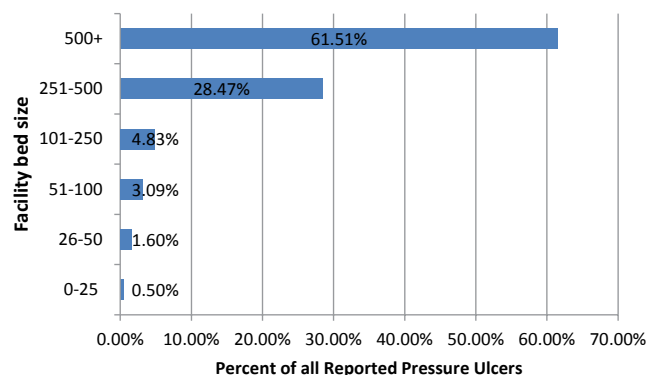
## How do we learn?



Learnings from these events were used as a foundation for best practice recommendations and were incorporated into the next iteration of the statewide initiative, MHA ‘SAFE SKIN 2.0’, which began in early 2011, and included best practices for repositioning critically ill patients. Since facilities have been working on implementing best practices from this initiative, pressure ulcers have been declining.

Improvement opportunities for pressure ulcer prevention may vary by facility bed size. Data shows that large hospitals with over 250 beds account for 90 percent of the pressure ulcers that have been reported over the past 10 years (Figure 18). This is likely due to the more critical nature of the patient population served by these hospitals given that a higher number of pressure ulcers occur in intensive care units than elsewhere in the facility. It may also be due to the fact that these facilities account for a larger percentage of beds and therefore patients in the state.

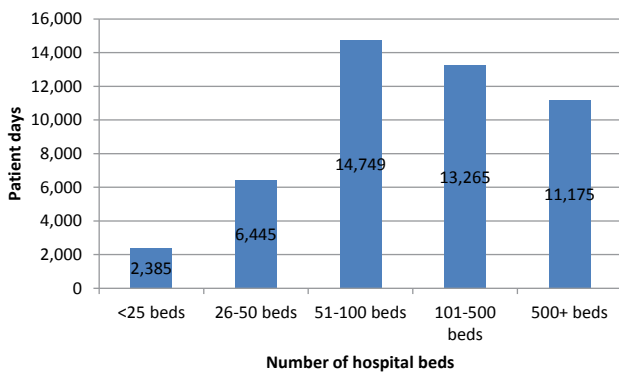
**FIGURE 18:**  
Percentage pressure ulcers reported, 2003–2013



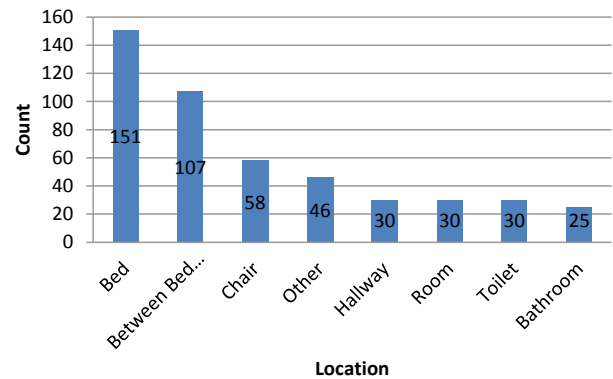
## Falls

Improvement opportunities for other types of events, such as falls, also may vary by the size of the facility. The data demonstrates that after adjusting for the number of patient days across reporting years, small hospitals are experiencing a higher rate of falls resulting in serious injury than larger hospitals (Figure 19). This is shown by looking at the days between events (the lower the number, the more frequently falls are occurring). This could be due to the data showing a higher average age for patients who fall in smaller hospitals; and elderly patients are at greater risk for falling and sustaining an injury from a fall. This is an area that MDH and its partners could target for improvement with smaller facilities in the future.

**FIGURE 19:**  
Patient days between falls by hospital size



**FIGURE 20:**  
Location of falls, 2004–2013



As the reporting system has matured and more knowledge has been gained across the different reporting categories, there are opportunities to enhance the system for more effective and efficient data analysis. For example, looking at location information for falls, this data has shown that patients are more likely to fall from the bed, from the chair or fall between the bed and the bathroom (Figure 20). This data has not changed substantially over the reporting years and does not provide detailed information about why the patient was attempting to get out of the bed or the chair, or why they fell between the bed and bathroom. This may require the collection of more detailed information to move to a deeper level of analysis and learning.

## Sharing of Information

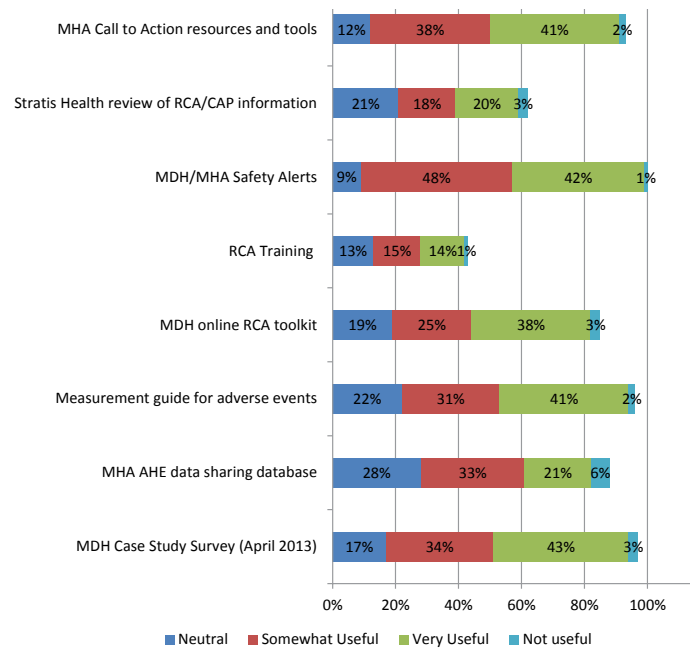
Since the inception of the reporting law, MDH and its partners have held numerous education and training events for reporting facilities on such topics as falls, pressure ulcers, safe surgical practices, suicide risk assessment and prevention, and root cause analysis. This education is based on the learnings that come from the reported events in the Patient Safety Registry and is a crucial element in supporting the program's goal to create a learning healthcare system.

Resources provided through the AHE system include, but are not limited to:

- MHA 'Calls to Action' on five topics with an average of 110 hospitals participating per campaign
- Eighteen 'Safety Alerts' on topics such as: implant verification, fall injury risk and suicide prevention
- Semiannual Root Cause Analysis training(s) done throughout the state since 2007, with an average of 40 participants per training
- An online Root Cause Analysis toolkit with resources compiled nationally and at a local level
- Measurement for Adverse Health Events Guide developed by Stratis Health
- Regional training/education sessions on safe surgical practices and how to audit pre-surgical Time Outs
- Two suicide prevention trainings

Many participants in the focus groups and survey stated that one of the most valuable parts of the AHE program are the training and resources that have been made available, in particular the MHA 'Calls to Action.' In these campaigns, developed in response to data submitted through the adverse events system, facilities agree to implement a series of evidence-based best practices and to report quarterly on their progress. Participants described feeling supported in their patient safety efforts with this education and training as well as hundreds of resources and toolkits that have been made available online for all facilities. When asked about the resources that are available to them, participants responded that most of the resources were useful and or very useful (Figure 21). \*Note, Figure 21, does not include respondents who answered "not applicable."\*

**FIGURE 21:**  
Use of Adverse Event Resources, 2013



This approach of training/education and sharing all resources publicly has helped facilities by allowing them to use those resources instead of creating their own tools at individual facilities, which is time consuming and can be cost prohibitive. Participants also reported a benefit to attending training and education with other facilities throughout the state and sharing learnings and best practices with one another in-person. They state that these sharing sessions can sometimes be the most beneficial to them, providing innovative and outside the box ideas.

Although event information is shared between hospitals that have agreed to share their data in a de-identified manner, and key learnings are incorporated into statewide improvement initiatives, facilities are interested in continuing to expand their ability to learn from each other. Often facilities will use the database after an event, in order to gain perspective from other facilities that have experienced similar events and look at what types of corrective action plans may have put into place and how successful those were.



## Reporting and Review Process

In the 10 years that the adverse events reporting system has been in place, it has evolved from a basic web-based reporting tool and review process to a much more comprehensive system that involves reviews of reported events, a higher level of granularity of data that is required for each event, and alerts and campaigns based on best practices and other issues identified through the reporting and review process.

The reporting and review process is designed to support reporting facilities in using RCA to review the systems they use to provide care for breakdowns or contributing factors related to the event and to assist with development of strong and effective corrective action plans.

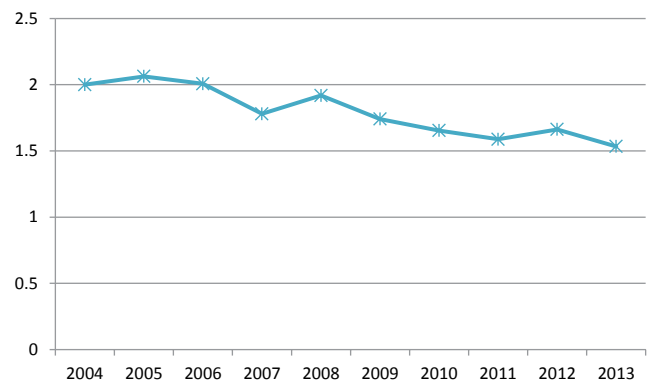
During this evaluation, MDH sought input on the reporting and review process from participants. The vast majority of participants stated that the web-based reporting system is effective and works well within their facility. However, participants that rarely use the web-based tool reported confusion and burden with the use of the system. Through the years, MHA has worked closely with MDH and reporting facilities to refine the web-based system and make its use as intuitive as possible, including changes to make its use easier and quicker and to add additional categories for data collection in order to accommodate changing practice.

One key aspect of the reporting system is the review process that allows the State to assess the quality of the RCAs and corrective actions that are submitted in response to adverse events. A team of clinical and quality improvement experts from Stratis Health reviews a sample of pressure ulcer events and 100 percent of all other events. Root causes and corrective action plans are reviewed against a set of criteria that serves as an evaluation of the information submitted. The goal of the review is to assess that the information in the registry is clear and thorough, and provides a summary of the event and root cause finding (or explanation for lack of a root cause finding) of systems breakdown, and that the corrective action plan is appropriate and reflective of the finding(s) of the root cause analysis. Through the review process, a reporting facility is given individualized feedback on the information submitted to the registry; the facility is asked to provide updates or clarification to the information so that it can be used for analysis and potential future event prevention efforts.

Each event can go through this review process up to three times. MDH and its partners continually work with facilities that bring issues with the review process forward or that need assistance with reporting. This assistance and continued work at making the system and the reported data more robust has led to a 24 percent decrease in the number of times that an event has to go through the review process (Figure 22).

At the inception of the reporting system, the majority of submitted root cause analyses, corrective action plans or measurement methodologies were found to have deficits. In fact, in 2005 (the first year this data is available) only 15 percent of events passed on the first review. In year 10 of the reporting system, 52 percent of reported events are passed by the independent reviewer following the first review, indicating the information submitted was clear and sufficient for use in objective aggregate analysis. This reduction in average reviews per event can be attributed, again, to the learning nature of the system.

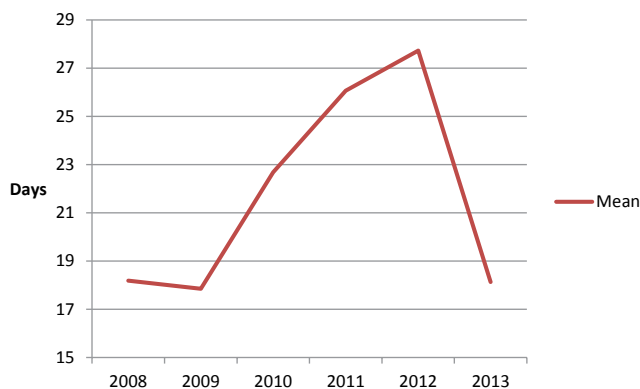
**FIGURE 22:**  
Average reviews per event, 2004–2013



As issues are brought forth, MDH and its partners work to resolve them and similarly, facilities have worked to make their RCA process and reporting process much more robust over the past 10 years. A five year evaluation completed by MDH revealed that participants thought the review process should be modified so that it has an increased focus on learning and coaching, rather than on pointing out insufficiencies. During this 10 year evaluation, those concerns were not noted and the majority of participants reported satisfaction with the review process overall and many felt that it had helped them to dive deeper into their root cause analysis than previously.

One requirement of the AHE law is that facilities enter the event into the Patient Safety Registry (PSR) within 15 working days of discovering the event occurred. Over the years, this average time frame was increasing as the requirements for reporting other data increased on facilities. In the past year, MDH and its partners have worked with facilities on consistently reporting their events in a timely fashion, not only to meet the requirements of the law, but so that data can be analyzed and learnings can be disseminated as quickly as possible statewide. In the past year, the mean days it took to report the event into the system decreased by over 60 percent to an average of 18 days (Figure 23).

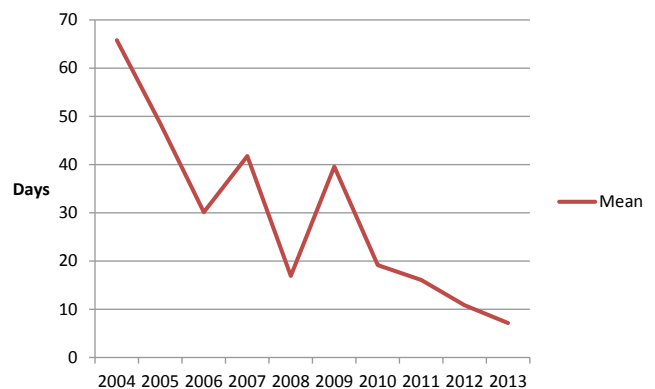
**FIGURE 23:**  
Time between discovery date and PSR, 2008–2013



Also of note, the time between when an event occurred and when it was discovered has decreased steadily (Figure 24), which could be attributed to increased awareness of patient safety and heightened emphasis on reporting and mitigating events. In the case of pressure ulcers, this decrease may be related to the ways in which pressure ulcers are identified. When the reporting system began, facilities were doing prevalence and incidence studies on a quarterly basis and would identify the majority of pressure ulcers retrospectively, even if they had occurred much earlier. Over the course of the 10 years of reporting, facilities have moved toward concurrent identification and reporting of pressure ulcers and are able to identify and treat pressure ulcers much sooner.

*Note: With some categories of events, such as retained foreign objects, the event may not be discovered the same day it occurs or may be discovered at a later date or clinic visit.*

**FIGURE 24:**  
Time between event date and discovery date, 2004–2013

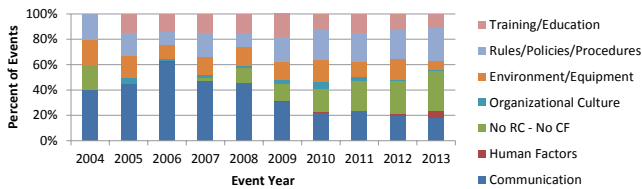


### Root Cause Analysis/Corrective Action Plans

One of the pillars of the AHE system is that facilities investigate their events by completing a root cause analysis. MDH has been collecting data on the type of root causes identified by facilities for each event since the inception of the law.

Root cause categories have shifted and changed slightly over the years, but overall have remained mostly consistent. The percentage of times that facilities choose ‘Communication’ as the root cause of an event has steadily decreased over time, while the percentage of times that facilities had a finding of no root cause or contributing factor (CF) has increased (Figure 25).

**FIGURE 25:**  
RCA categories, 2004–2013

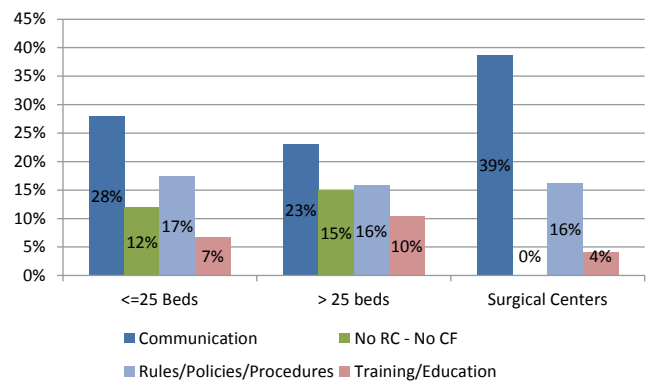


The ‘Communication’ category includes all forms of communication, such as: verbal, electronic, communication of test results, etc. and is often reported as communication of important information to the incorrect person, lack of communication of important information or lack of team work during a stressful situation.

Many facilities in Minnesota have started to perform teamwork training for all staff as a way of preventing communication errors and increasing a culture of patient safety. Much of this work has come out of the MAPS “SAFE CULTURE” roadmap. Also of note is an increase in facilities choosing ‘Rules/Policies/Procedures’ as a root cause since the first few years of the reporting system. This is often reported as lack of a policy/procedure or an ineffective policy/procedure in place. Of note, ‘Human Factors’ as a root cause was not an option in the reporting system until 2012.

When this data is broken down by type of facility, it shows that surgical centers identify ‘Communication’ as a root cause more often than hospitals of any size and surgical centers on average do not conclude a finding of no root cause following their analysis of the adverse event (Figure 26). This could be due to the subset of events that surgical centers encounter, or for other reasons, such as training or education differences. When comparing small hospitals to larger hospitals, both types of facilities choose similar root causes equally.

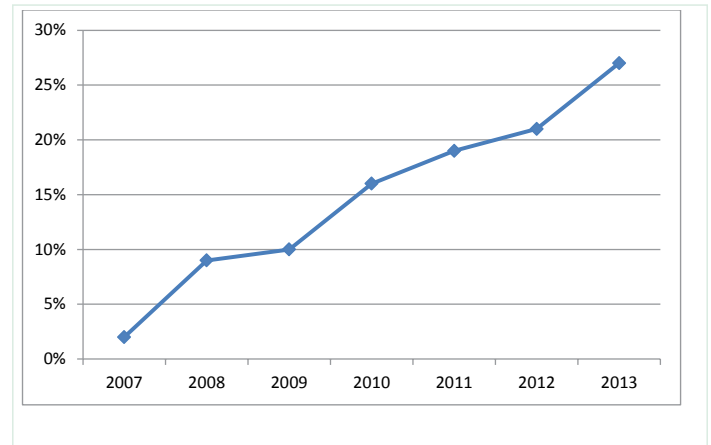
**FIGURE 26:**  
RCA categories by facility type



As noted above, facilities are increasingly reporting an inability to identify a root cause or contributing factor for their events. In 2007, only two percent of events had no identified root cause, whereas in 2013 over a quarter of events were reported without an identified root cause or contributing factor (Figure 27). The vast majority of events with no root cause or contributing factor were pressure ulcers and falls.

Through the AHE system, facilities are required by law to complete a RCA, however, those findings may conclude there was no root cause (system breakdown) or contributing factor (any possible factors that could have played a role aside from system breakdowns) or that the event could not have been prevented. The challenge with the issue of preventability is to assure that facilities are looking at all possible avenues for improvement, rather than looking at preventability, and working to reduce risk as much as possible. The fact that these types of events with no identified root cause or contributing factors are increasing is of note and MDH will be working with facilities to increase the rigor with which they recognize and strive to reduce risks and look for opportunities for improve safety in the upcoming year. This may take the form of additional training, resources or education for reporting facilities.

**FIGURE 27:**  
Percentage of events with no root cause, 2007–2013



## Recommendations and Evolution of the System

As MDH and its partners embarked on this 10-year evaluation of the adverse health events system, MDH explicitly sought ideas about ways to change the system. Input from stakeholders across the state went into the evaluation and all participants were asked "How should the AHE system evolve in the future?" The consensus was that the system as a whole is functioning well as one of learning and sharing, however, there are some minor changes and additional resources needed. The system will continue to evolve as new information becomes available and through the learnings from reported events.

Key findings from the 10-year evaluation include:

- The AHE law was a catalyst for advancing patient safety throughout Minnesota. It has helped to bring patient safety to the forefront and has increased awareness of patient safety risks as well as best practices for prevention of adverse events.
- The number of deaths has declined overall since the first year of the system and events that result in serious disability are on a downward trend as well.
- Some rates of reported events that have had consistent definitions during all 10 years, such as stage III or IV pressure ulcers, have seen a reduction. However, rates of reported events as a whole have remained consistent over the 10 years (accounting for definitional changes).
- Facilities are submitting more robust data and root causes than at the inception of the system. This has led to more in-depth analysis of events and the ability to put systems in place to prevent them in the future.
- The reporting system was designed as a learning system and analysis of the data across the reporting years demonstrates this primary goal of the system is being met. For example, after Safety Alerts are issued, typically the number of reported events related to the alert increase as awareness about reporting and preventing those types of events has increased. Then numbers begin to decline as identified practices are implemented across the state.
- The AHE system works well in the current healthcare environment in Minnesota, but facilities would like the same commitment to transparency, learning and public reporting

spread to other settings of care, including cosmetic surgery centers, long term care facilities and clinics.

- Facilities have put many policies/procedures to improve patient safety in place since 2003, including policies to disclose events to patients/families, regular assessment of organizational culture and sharing AHE data with the board and throughout the facility.
- MDH needs to investigate other ways for facilities to share learnings with one another in addition to the MHA Data Share Database, safety alerts and the sharing that occurs within the statewide Calls to Action.

The majority of stakeholders from hospitals and surgical centers, as well as long term care organizations, would like to see the same commitment to transparency and public reporting (similar to this system) expanded to include clinics and long term care facilities in Minnesota. Current reporting facilities feel very strongly that the AHE system and its commitment to learning and transparency has been a catalyst for change and has made the care patients in those settings receive much safer. Reporting facilities also feel that expanding a similar system to other settings would even the playing field in some cases. For example, ambulatory surgery centers that are licensed by MDH are subject to the reporting law; however, the majority of cosmetic surgery centers in Minnesota are not licensed by MDH and therefore are not subject to the law. In addition, clinics that are licensed under a hospital are required to report under the AHE law, however independent clinics are not currently required to report. Surgery centers feel that this offers an opportunity to spread the learnings of the AHE system to new settings and further improve the safety of care.

In the upcoming year, MDH will convene discussions with stakeholders, including state regulators, long term care associations, hospitals, clinics, surgery centers and other invested parties to begin discussing the idea of expanding a similar adverse health events system across other settings of care in the state. Movement toward expanding to other settings is complex and involves many stakeholders and therefore, may be a lengthy process. But it is a conversation that a wide range of partners are committed to exploring.

Additional recommendations for next steps include:

- Develop new methods, tools or resources for data sharing across facilities. This includes sharing learnings from events as well as near misses.
- Improve functionality in the current data sharing database for running reports and data mining.
- Develop additional education/training opportunities on most frequently reported events (falls, pressure ulcers and surgical/procedural events).
- Work with all providers, including physicians, to encourage adoption of best practices in patient safety.

Hospitals and surgical centers have been on a journey with MDH and its partners through the adverse health events system for 10 years now. Progress toward eliminating adverse health events has been made, however, the work continues and will be an ongoing process, defined by new types of events and evolving best practices and shared learnings throughout the state. Facilities have committed many resources and are beginning to see progress. They should be proud of the work that they have invested in improving patient safety and quality in Minnesota and therefore providing a higher level of care to their patients. However, based on responses by evaluation participants, MDH and its partners are committed to taking steps to ensure that the progress from the first 10 years of the reporting system continues to advance.

# Appendix A: Reportable Adverse Health Events

Below is a list of the events that hospitals and licensed ambulatory surgical centers are required to report to the Minnesota Department of Health.

The language is taken directly from Minnesota statutes 144.7065. *Changes enacted during the 2013 legislative session, which will first appear in the 2014 annual report, are shown here.*

## Surgical Events

1. Surgery or other invasive procedure performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;
2. Surgery or other invasive procedure performed on the wrong patient;
3. The wrong surgical or other invasive procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent;
4. Retention of a foreign object in a patient after surgery or other invasive procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and
5. Death during or immediately after surgery or other invasive procedure of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

## Product or Device Events

1. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product;
2. Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Device includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators; and
3. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

## Patient Protection Events

1. A patient of any age, who does not have decision-making capacity, discharged to the wrong person;
2. Patient death or serious injury associated with patient disappearance, excluding events involving adults who have decision-making capacity; and
3. Patient suicide, attempted suicide resulting in serious injury, or self-harm resulting in serious injury or death while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

## Care Management Events

1. Patient death or serious injury associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;
2. Patient death or serious injury associated with unsafe administration of blood or blood products
3. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;
4. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy;
5. Stage 3, 4 or unstageable ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission;
6. Artificial insemination with the wrong donor sperm or wrong egg;
7. Patient death or serious injury associated with a fall while being cared for in a facility;
8. The irretrievable loss of an irreplaceable biological specimen; and
9. Patient death or serious injury resulting from the failure to follow up or communicate laboratory, pathology, or radiology test results.

## Environmental Events

1. Patient death or serious injury associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock;
2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
3. Patient death or serious injury associated with a burn incurred from any source while being cared for in a facility;
4. Patient death or serious injury associated with the use of or lack of restraints or bedrails while being cared for in a facility.

## Potential Criminal Events

1. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;
2. Abduction of a patient of any age;
3. Sexual assault on a patient within or on the grounds of a facility; and
4. Death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

## Radiologic Events

1. Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area.



## Appendix B: Background on Minnesota's Adverse Health Events Reporting Law

In 2003, Minnesota became the first state in the nation to establish a mandatory adverse health event reporting system that included all 27 serious reportable events identified by the National Quality Forum and a public report that identified adverse events by facility. The law covers Minnesota hospitals and licensed outpatient surgical centers.

Momentum toward a system for mandatory adverse event reporting began with the publication of the Institute of Medicine (IOM) report "To Err is Human" in 2000. While the issue of medical errors was not a new one for health professionals, Americans reacted strongly to the idea that preventable errors could contribute to the deaths of up to 98,000 people per year. The public and media attention that followed the report's publication started a national conversation about the reasons why such errors occur. A primary focus of the discussions was the concept of systemic causes for errors.

In the past, discussions of medical errors often focused on identifying and punishing those who had caused the error. While individual accountability for behavior that could put patients at risk is very important, the IOM report confirmed that most errors were not the result of the isolated actions of any one care provider, but rather of a failure of the complex systems and processes in health care. Given that knowledge, the old 'blame and train' mentality, wherein individual providers were blamed for mistakes and provided with training in the hopes of preventing future slip-ups, has to make way for a new approach that encompasses a broader view of accountability and learning from errors or near misses.

Every facility has processes for dealing with individual providers who exhibit dangerous or inappropriate behavior or who knowingly put patients at risk. Disciplining, educating or dismissing an individual provider will always be an option in those cases. But the focus of the reporting system is on using focused analysis of events to develop broader opportunities for education about patient safety and best practices – solutions that can be applied across facilities. Responses focused on an individual provider may or may not prevent that provider from making a mistake again, but changing an entire system or process to eliminate opportunities for error, whether by building in cross-checks, establishing a 'stop the line' policy, or using automation to prevent risky choices, will help to keep all patients safer.

From the beginning, the reporting system has been a collaborative effort. Health care leaders, hospitals, doctors, professional boards, patient advocacy groups, health plans, MDH, and other stakeholders worked together to create the reporting law, with a shared goal of improving patient safety. The vision for the reporting system is of a tool for quality improvement and education that provides a forum for sharing best practices, rather than a tool for regulatory enforcement.

In 2007, the Adverse Health Care Events Reporting Law was modified to include a 28th event and to expand the definitions of certain other events. The most significant change was an expansion of reportable falls to include those associated with a serious disability in addition to those associated with a death. At the same time, the pressure ulcer category was expanded to include 'unstageable' pressure ulcers.

ADVERSE HEALTH EVENTS

10 Year  
Program  
Evaluation

