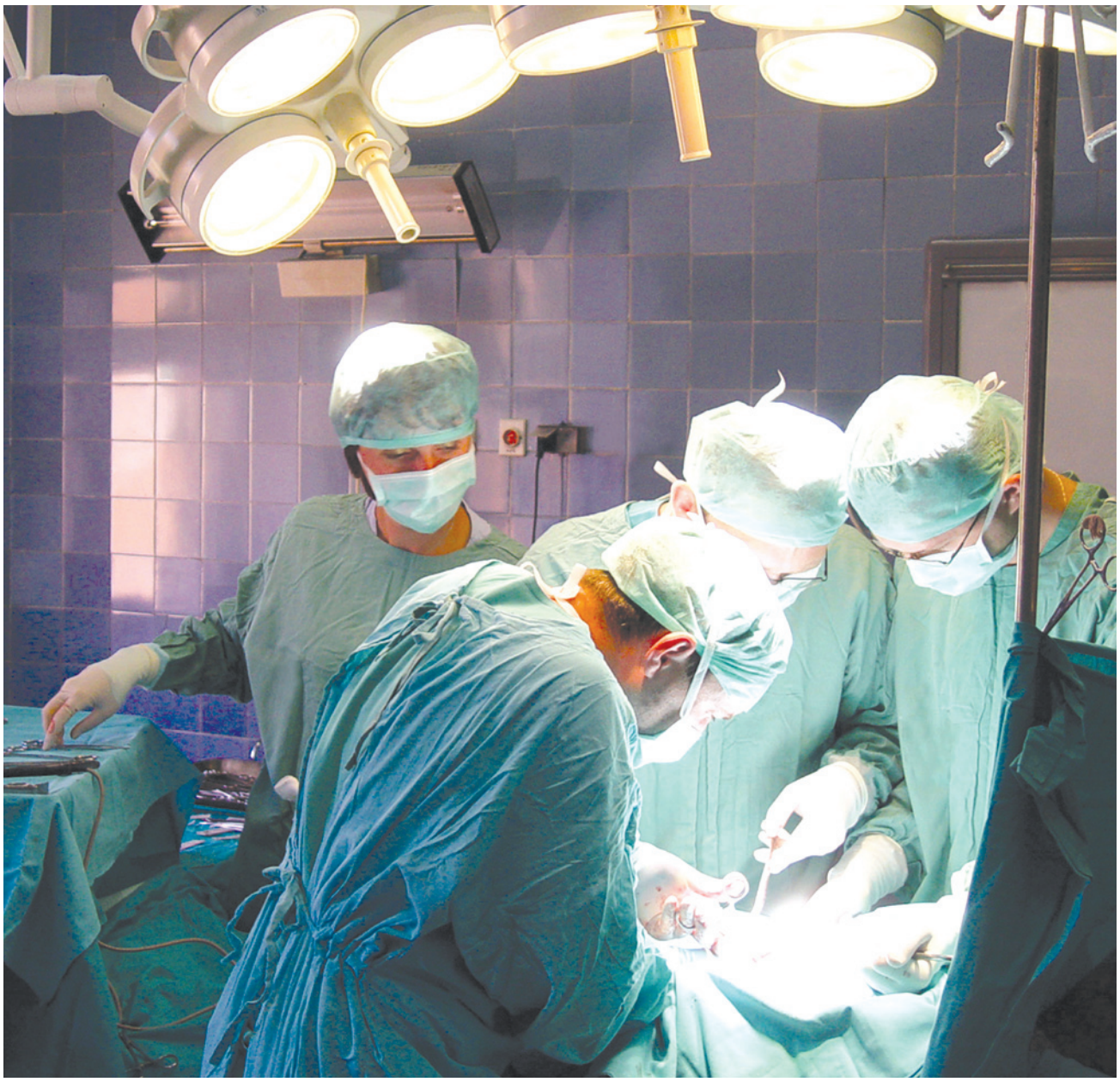

Adverse Health Care Events Reporting System:

What have we learned?

5-YEAR REVIEW

MINNESOTA MDH DEPARTMENT OF HEALTH

January 2009

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EXECUTIVE SUMMARY

In 2003, the Minnesota Legislature passed the Adverse Health Care Events Law, requiring hospitals and ambulatory surgical centers to report to the Minnesota Department of Health whenever one of 27 – now 28 - serious adverse health events occurred. This law is now in its fifth year of implementation. During that time, MDH has collected information on nearly 800 adverse events, including information about their causes and the steps being taken to prevent them from happening again.

The reporting law was envisioned as a system for enhancing both accountability and transparency in Minnesota. While counting events is important, the true strength of the adverse events reporting system has always been its focus on learning, sharing of information about root causes and best practices for prevention, and increased awareness of and transparency about adverse events.

An important goal of the reporting law was to serve as a mechanism for driving quality improvement in facilities across Minnesota, as part of a broader statewide vision of creating the safest healthcare system possible. In light of those goals, the Minnesota Department of Health undertook an evaluation of the adverse events system in 2008, to determine the extent to which it has been successful as a catalyst for improvement and learning.

The evaluation, conducted through focus groups, interviews, and surveys with reporting facilities from around the state, found that:

- 72 percent of responding facilities feel that the reporting law has made us safer than we were in 2003.
- A strong majority of reporting facilities say that patient safety is a higher priority now than it was in 2003.
- Adoption of best practices has improved dramatically since 2003, particularly in the areas of sharing of adverse events data with boards of directors, staff and other facilities, disclosing adverse events to patients and family members, leadership engagement, and assessment of each organization's safety culture.
- Facilities have made numerous changes in policies, processes, and approaches to prevention of the most common types of adverse events. Using a team approach to prevention of falls,

pressure ulcers, wrong site surgery, and retained objects is now much more widespread, as is the identification of 'champions' to help promote and implement new strategies.

- Despite feeling that the law has been a catalyst for change, facilities still struggle at times to understand which events are reportable, and to determine whether or not events were preventable.
- The reporting and review process, while useful for the majority of facilities, may need to be streamlined to ensure that it is easy to use, timely, and constructive.

The majority of facilities have implemented significant changes as a result of the law, with greater levels of engagement at all levels of their organization, and agree that the law has led to dramatic changes in each organization's processes and culture. But to ensure that we sustain and build upon these achievements, MDH and its partners should explore the following avenues in the coming year:

- Developing new methods for regularly sharing key learnings from individual adverse events, as well as information about overall trends, with reporting facilities.
- Implementing changes to ensure that the reporting system is as easy to use as possible, provides meaningful and constructive feedback on individual events and broader categories of events, and is timely.
- Encouraging regular administration of safety culture surveys by all healthcare organizations around the state, and providing assistance to facilities in how to act effectively on their findings, how to benchmark their results against similar facilities, and how to communicate findings to staff and to leadership.
- Working with administration/boards of directors to encourage adoption of active leadership strategies.
- Working with educators, clinical training sites, and healthcare providers to encourage integration of teamwork and interdisciplinary training, training about patient safety principles, and education about the role of organizational culture as a part of the education of all Minnesota physicians and other providers
- Working with professional organizations and practicing physicians to ensure that physicians and surgeons are fully engaged in patient safety initiatives.

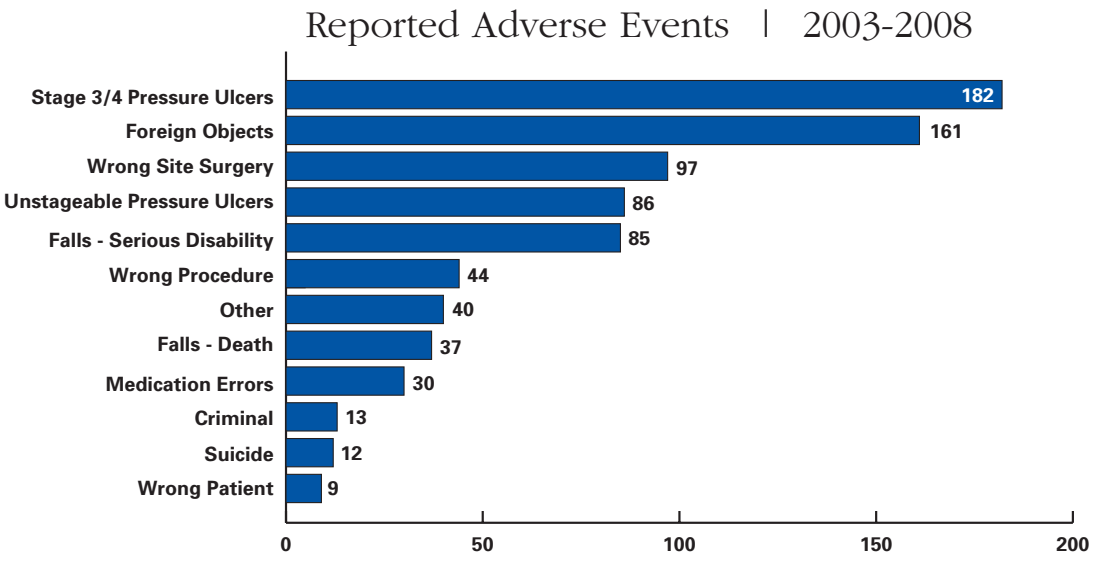
Patient safety is a complex and multifaceted concept, one that can be – and is – measured in many different ways by individual facilities and state/national organizations. In the last five years, Minnesota has taken great strides towards creating a statewide culture of safety, transparency, and learning, and the reporting law has been a crucial part of that process. Going forward, MDH and its partners will need to learn from the successes of the first five years, while also continually working to engage all stakeholders around this important issue, and making sure that patient safety remains a priority for all healthcare providers and consumers.

EVALUATION PROCESS OVERVIEW

In 2003, the Minnesota Legislature passed the Adverse Health Care Events 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 to expand or refine definitions of several other events. Reportable events under the Adverse Health Care Events Law include:

- Surgery or an invasive procedure on the wrong part of the body or the wrong patient, or performing the wrong surgery or invasive procedure on a patient;
- Foreign objects left in the body after surgery or an invasive procedure;
- Falls associated with death or serious disability;
- Serious pressure ulcers (bedsores);
- Medication errors associated with serious disability or death;
- Patient suicide or attempted suicide resulting in serious disability; and
- Criminal events such as sexual or physical assault.

Since 2003, nearly 800 adverse health events have been reported to MDH under the reporting law. Monitoring how often these adverse events occur is important, as changes over time in the frequency of serious adverse events can constitute one measure of patient safety.
The goal of the reporting system, though, from its inception, has been not just to count how often serious adverse events occur, but to facilitate quality improvement through evaluation of potential areas of risk or system failure, and to share learnings from adverse events with facilities around the state as a way of fostering system change. While counting the frequency with which adverse events occur, and reporting the results publicly, is very important, it is the focus on systems change and learning that is key to sustainable improvements in patient safety.



In January 2009, MDH released its fifth annual adverse health events report, providing information about 312 events that had happened during the previous reporting period and highlighting steps taken by facilities to prevent their recurrence. To coincide with the fifth annual report, MDH embarked on a five-year evaluation of the reporting system, seeking to answer six key questions (right).

To answer these questions, MDH convened a series of focus groups with patient safety officers from around the state, conducted a survey of patient safety leaders from reporting facilities around the state, and worked with the Minnesota Hospital Association to interview a sample of hospital CEO's.

Patient Safety Officer Survey

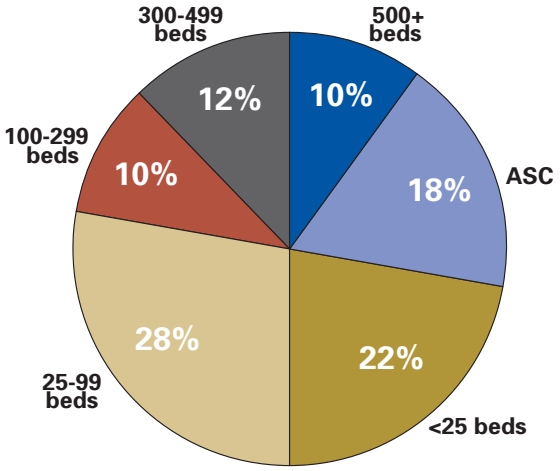
In November 2008, MDH conducted a survey of 178 patient safety officers, nurse managers, risk managers, and others involved in developing and implementing patient safety campaigns, reporting or analyzing adverse health events, and monitoring safety and quality measures within their facilities. A total of 60 individuals (34%) responded to the survey, which included the following questions:

- To what extent has your facility implemented broad changes related to data sharing, transparency, and surveys of patient safety culture since the passage of the AE law?
- To what extent has your facility implemented staffing, education, policy/procedure, or other changes in response to specific categories of adverse events?
- To what extent has the priority level of patient safety within your organization changed since the passage of the law?
- Are we safer now than we were five years ago?
- To what extent has your facility made use of adverse events-related resources available through MDH, MHA, or Stratis Health?
- What resources will be helpful for your facility going forward?

EVALUATION QUESTIONS

- **What are the most significant patient safety challenges facing reporting facilities today related to event reporting and process improvement?**
- **What have the biggest successes been?**
- **What changes have been implemented within reporting facilities as a result of the adverse events reporting law?**
- **How are we safer, or not safer, than we were five years ago?**
- **Does the AHE process help or hinder the patient safety journey? How could/should the process be modified to be more reflective or useful?**
- **What do reporting facilities need from MDH and other stakeholders in order to move forward on patient safety?**

Survey Responses by Facility Type



Survey respondents came from a wide variety of facilities; 18% represented ambulatory surgical centers, 22% came from hospitals with fewer than 25 beds, and 10% came from hospitals with more than 500 beds. Respondents were most likely to be Directors of Nursing or Quality Improvement Managers, patient safety managers/ officers, or risk managers.

Patient Safety Officer Focus Groups

MDH also conducted a series of patient safety officer/manager focus groups in October, 2008. A total of 18 hospitals and six ambulatory surgical centers participated in the focus groups, with representation from large and small facilities located throughout the state. Each focus group was asked the following questions:

1. What has been your biggest challenge in implementing the adverse events law?
2. How has your facility changed as a result of the adverse events law?
3. What would you consider your organization's biggest success as a result of the reporting law?
4. How would you rate your facility's overall success around patient safety?
5. How do we know if we're making a difference in patient safety, individually and at the state level? What are the indicators of progress?
6. Has the role of leadership within your organization changed since the law was passed?
7. What does leadership communicate about the role/priority level of patient safety?
8. How has the reporting system changed patient safety in MN? Are we safer now because of it, or less safe? What has its impact been?
9. What do you think has to happen next at your facility, and at the state level, to make care safer?
10. What's the most important thing MDH or MHA (MN Hospital Association) could do to make it easier for you to implement the law? To improve safety?

CEO Interviews

Five hospital CEO's representing hospitals of different sizes from different regions of the state were interviewed in November, 2008. Each CEO was asked a series of questions about their perceptions of the law at the time of its passage and currently, changes that have occurred as a result of the law, challenges related to implementation, and measuring the success of the law:

1. What did you think of the new law when it was signed?
    a. What did you think success would look like if the law were properly implemented?
    b. How did you think your organization would change as a result of the law?
2. Today, what do you think of the law?
    a. How has the law succeeded?
    b. How has your organization changed as a result of the law?
3. Has your organization used information from other hospitals' incidents to make changes?
4. Can you cite any specific changes in your organization that grew out of reported events or other information you learned through the law?
5. How has leadership and board work changed regarding patient safety?
    a. Has the structure of the board changed?
6. Since 2003, how has the investigation of incident reports/safety reports changed?
7. Before 2003, did you report out or have any improvement projects around any of the 28 adverse events?
8. How does your organization measure whether patient safety has improved?
9. Has the way you measure organizational culture changed in the last five years?
10. What has been the biggest challenge related to implementing the law?
11. What's the single most important action MHA/MDH could take in order to make the law more successful in reducing safety events? To make it easier for hospitals to implement the law?

The responses from focus group participants, survey respondents, and CEO interviews are summarized in this report. Comments and survey responses are organized into four categories:

1. The impact of the adverse health events reporting law
2. Measuring progress
3. The adverse events reporting system and review process
4. Resource use and future resource/training needs

This report concludes with a summary of recommendations and next steps for the Minnesota Department of Health, the Minnesota Hospital Association, the Minnesota Alliance for Patient Safety (MAPS), and other key stakeholders as we continue forward in our journey towards ensuring that the healthcare provided in Minnesota is the safest in the nation.

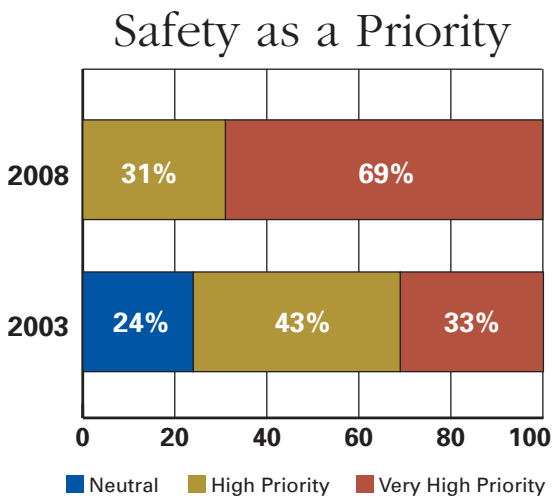
RESULTS: IMPACT OF THE REPORTING LAW

Evaluation participants shared a strong belief that the reporting system has been a catalyst for a great deal of change within their facilities and across the state. The most dramatic changes have been in the areas of board awareness, participation and leadership, in implementation of best practices, and in transparency and sharing of learning.

"The AHE law has succeeded in harnessing the attention of senior leaders and the Board on the key AHE topics. EVERYONE understands retained foreign objects, pressure ulcers, and wrong site/procedure events."

Safety as a Priority

A strong majority of survey respondents indicated that patient safety has always been a high priority within their organizations, even prior to the implementation of the adverse events law. But responding facilities indicated that its importance as a priority has grown substantially since the passage of the law.



Rating the priority level of patient safety since the passage of the law, 69 percent of respondents indicated that they felt patient safety was a very high priority, compared with 33 percent who indicated that it was a very high priority prior to the passage of the law. These results varied based on the type of facility; ambulatory surgical center and very small (< 25 beds) hospitals were more likely to classify patient safety as a "very high" priority than medium-sized and larger hospitals, who tended to indicate that it was a high priority both before and after the passage of the law. In every group, though, facilities reported that the priority level of safety has increased since 2003, a strong signal that the law has been effective in drawing attention to events that may have previously been seen as unavoidable complications of care.

"The law opened people's consciousness up to looking at things we wouldn't have looked at in a systematic way before."

This higher priority manifests itself in several ways, including the establishment of high-level patient safety/quality improvement committees, leadership involvement in root cause analyses, the addition of patient safety as a standing agenda item for governing board, leadership and staff meetings, and increased resources devoted to patient safety activities.

Biggest Changes in Facilities as a Result of the Law

Some changes that have come about as a result of the adverse events law are difficult to quantify, but provide strong evidence of a shift in the focus of organizations towards prevention, sharing of

information and learning. Changes in culture, frequency of staff assertiveness in risky or hierarchical situations, level of buy-in or support from leadership and from physicians, and increased transparency around adverse events and near misses are all changes that one would hope to see as a result of a statewide or facility-level safety campaign; all are changes that were cited by evaluation participants to varying degrees.

In some cases, these efforts may have been in place prior to the law, or would have been implemented even in the absence of the law. However, a clear theme that emerged from the responses is the idea that the law helped to focus attention on safety beyond what it might otherwise have been, and that it raised the sense of urgency about correcting the root causes of these events. Facilities noted that the law was a catalyst for:

- Increased awareness and involvement at the highest levels within the facility, particularly by the CEO and Board of Directors.
- Improved communication to not only discuss whether an event falls into the AE categories, but to report incidents that would not have been reported before.
- Increased focus on these events as usually preventable, and on analysis of their root causes.

As one evaluation participant said, the law has helped to shift the focus from responding to adverse events to prevention of them:

"There was a time that if no one was adversely affected the issue did not get the attention that it was due. There is a change in staff understanding so now potential and actual adverse events receive the same attention. The goal is to prevent."

"The biggest change for us was that our circulating nurses now feel that they have the authority to stop progress in the O.R. until the "Pause for the Cause" (pre-surgical time-out) has been successfully completed."

But while the public reporting aspect of the system has been a catalyst for many changes, and has increased the pace at which best practices are adopted, it also creates unique pressures on reporting facilities. Concerns about whether all facilities were using the same definitions to determine whether or not events were reportable were raised by several participants, as were concerns about the media focus solely on numbers rather than on the many positive changes that are happening. As one participant commented:

"As soon as leadership sends the message that we're having too much of something [reported adverse events], then we will have fewer reported – that's a tough balance."

"The biggest change is greater acceptance of transparency around adverse events, especially broadcasting our events and event patterns to the front-line. There is probably also a greater "pull" to learn from other facilities with the same challenges."

"(Our) focus was always on patient safety, however now safety efforts are better understood by more of our staff and we prioritize this work ahead of other work. The resources being provided assist us to further this work quicker. Data is helping us to create more sense of urgency for this work."

Leadership Involvement

One of the keys to a creating a safe culture is for executives and boards of directors to show – through resource allocation, seeking out and responding to data, and maintaining a physical presence in the facility through patient safety rounds or discussions with staff - that patient safety is a high priority. Evaluation participants strongly agreed that the reporting law has been an important driver for high-level change, which takes a number of forms:

- "(The report) certainly is a required conversation every CEO must have with the board every year. If there wasn't a good conversation about patient safety and quality with the board every year before, this required it."
- "I don't have any problem getting funds for events, safer technology, for example. I think the law has added support for getting resources."
- "The board spends as much time on safety as on finance."
- "I would never have broached that subject [patient safety] myself if the law hadn't been passed; I wouldn't have brought it to the board level."
- "At a board committee level, every month the first thing on the agenda is any adverse events. Our board members do safety rounds."

Beyond the board level, the law has helped executives focus on adverse events as well; and when safety is a high priority at the top, that sense of urgency tends to spread throughout the organization. As one CEO put it,

> *"Starting with myself, I've changed. Before this time, I thought we were doing a great job, we had a quality person in place. But I really sat up and paid attention to…what a difference this makes in the quality of care people receive. We're now talking about it at every level in the organization, everyone from housekeepers and dietary to leadership and board members."*

The fact that executives and board members are becoming more engaged in patient safety efforts, and more "hands on" in their approach to learning about potential safety hazards and successful solutions, is a very dramatic change compared with where Minnesota, as a state, was five years ago. While ideas, solutions, and energy for preventing adverse events can – and do – come from front line staff, those same staff will quickly lose that energy if they don't feel that patient safety is a priority for the entire organization, and that the issues they identify will be addressed. Developing more leaders who can serve as patient safety champions, and who can model the importance of high-reliability principles and a fair and just culture, will move us closer to the point where that approach will become the norm for all healthcare providers.

Physician Involvement

While attention to patient safety has increased at all levels in reporting facilities, making sure that physicians are engaged in and supportive of newly-implemented policies and practices, and that they are full partners in creating a culture in which all team members feel comfortable speaking up about safety risks remains a challenge in many facilities. Most participants who brought up

this topic agreed that the vast majority of physicians and surgeons are compliant with new standardized processes and safety measures, but that buy-in is not universal. And, as several noted, a lack of universal and enthusiastic buy-in from physicians and surgeons can have a dramatic effect on culture and attitudes, particularly within the operating room.

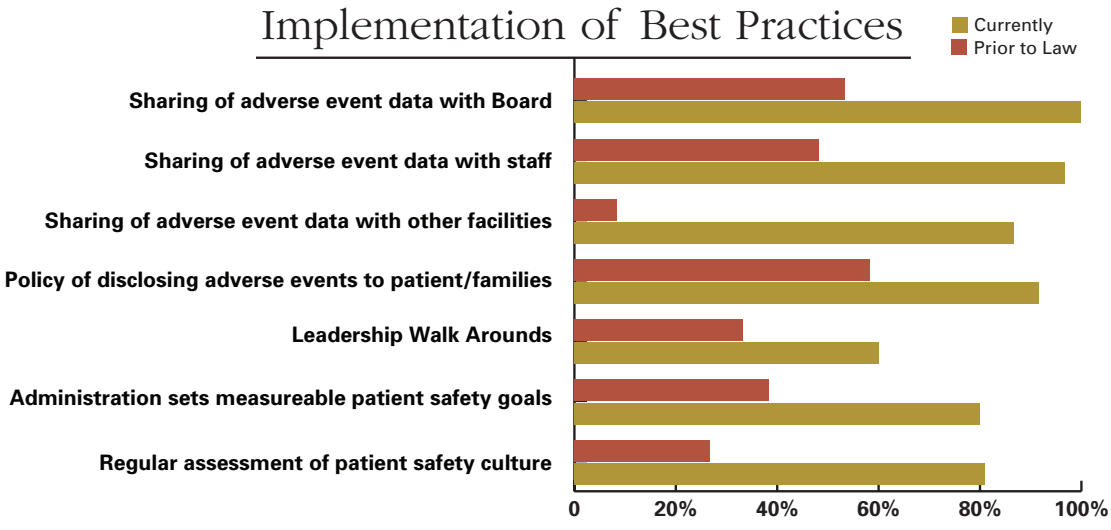
Respondents noted that the "captain of the ship" mentality still exists to an extent, with surgeons not always being open to being questioned about their decisions or choices. As a result, some OR team members are reluctant to speak up about issues of concern, or if they feel that a surgeon or other provider is about to make an error. One CEO noted that some physicians can be a "difficult sell" when a facility is trying to implement standardized processes such as site marking or time-outs for invasive procedures, and that the new emphasis on transparency is, for many, a dramatic change from the past.

"Certainly (a challenge) has been educating the providers. They grew up in the school of peer review, secrecy and protection, to now where they're being asked to disclose everything. That's been a leap for them."

Physicians are usually not employees of hospitals, but rather are independent practitioners who have privileges in one or more facilities. This means that making sure that they are included in all planning for adoption of new policies, and requiring participation in certain activities or processes, can be challenging. An additional complicating factor for certain facilities is that they may have physicians from neighboring states who also have privileges in their facility. If those states have different disclosure and reporting laws, different practices for pre-operative verification, or different approaches to addressing other issues, making that cognitive switch can be difficult for physicians. This can also be an issue when physicians practice in multiple facilities within Minnesota, highlighting the need for a consistent approach to prevention across facilities whenever possible, as in the area of time-outs.

Implementation of Best Practices

While progress on the journey towards the safest possible healthcare system can be measured in many ways, one very important factor is the extent to which facilities have created a culture that values transparency, sharing of learning about risks and solutions, setting goals, and supporting staff who speak up about risks. Survey respondents were asked about a number of best practices related to data sharing and transparency, to see whether or not the rate of adoption of these practices has increased over the last five years.



"Now I always ask the question, 'Have you talked to your colleagues around town about ways they've been successful in this area?' The ability to dialogue was made easier; it's no longer a taboo topic."

"(The reporting system) was able to identify issues before they happened so when … something had happened at five facilities but it hadn't happened at yours yet, it gave us an opportunity to address issues before they even occurred."

The results showed a very dramatic movement on all measures since 2003, to the point where adoption of the full set of best practices has become the norm across the vast majority of facilities rather than the exception. Many of these practices have a strong basis in patient safety research and literature, and form the foundation of a comprehensive patient safety program.

In 2003, when the adverse events reporting system was just beginning, it was unusual for facilities to share any information about their adverse events with staff or even boards of directors, and almost unheard of for a facility to share adverse events data with other facilities. This has been one of the areas that has seen the most dramatic growth, with more than 80 percent of facilities now sharing adverse events data with other facilities and all or nearly all sharing data and learnings with staff and boards of directors. This sharing of information is at the heart 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 before them. Often, facilities are able to implement new strategies proactively, having learned about an event in another facility that could affect them in the future.

The responses also provide more evidence of growing leadership involvement in patient safety. Executives and boards of directors are now twice as likely to set measurable goals for staff around patient safety as they were in 2003, and the percentage of facilities that have adopted "Leadership walk-arounds," or regular visits by executives or board members to clinical areas to learn about patient safety issues, has increased from just over 30 percent in 2003 to 60 percent in 2008.

While strategies to prevent adverse events often focus on education, new policies, and revised processes, these changes are less likely to be sustainable and effective in the long run if the organization's culture is not one in which patient safety is a high priority and staff feel safe talking about potential risks or behaviors that might compromise safety. Organizations should regularly assess their own culture, to see whether those fundamental principles are in place and that they are being as supportive as possible of staff who do speak up about risks or adverse events. Compared with 2003, many more facilities are now conducting regular culture assessments; adoption of this best practice has grown from less than 30 percent in 2003 to more than 80 percent in 2008 among responding facilities.

Finally, more and more facilities are putting disclosure policies into place, ensuring that patients and family members who experience an adverse event or other serious outcome are provided with information about the event, and about what the facility is doing to prevent it from happening again. Prior to the passage of the law, nearly sixty percent of facilities had disclosure policies; that figure has now grown to 90 percent.

Not all of these changes can be attributed solely to the adverse events law. Many of these practices have become much more widely supported nationwide, have been part of national initiatives such as the Institute for Healthcare Improvement's "100,000 Lives" campaign, and have a growing basis of support in literature. Given that context, some may have been adopted even in

the absence of the adverse health events law. However, focus group and survey respondents indicated that the law has pushed changes such as these to happen more quickly or more thoroughly than they might have otherwise.

Adoption of these best practices has accelerated greatly in the last five years, but there is still room for improvement. While the percentage of responding facilities that use leadership walk-arounds has increased to 60 percent, a number of facilities indicated that they still need ideas or assistance in engaging leaders in patient safety initiatives. Implementation of walk-around policies might be one strategy that could be explored by those facilities, along with providing additional training to boards of directors or using existing hospital leaders to serve as champions among their peers. Regular assessment of safety culture and the setting of measurable patient safety goals by facility administration also still hover around 80 percent, indicating that more support may be needed in those areas.

Sharing of information

One of the goals of the adverse health events reporting law, when it was first implemented, was to create a first of its kind system that encouraged sharing of adverse events information across facilities as a strategy for fostering learning. The theory was that if facilities could learn from the experiences of others, they would be more effective in preventing similar events from occurring in their own facilities, thus accelerating the adoption of change across the state. As noted above, evaluation participants agreed that this has been one of the key successes of the reporting system.

In particular, many participants highlighted the Minnesota Hospital Association's work in implementing statewide "calls to action" around the four most common adverse events as one of the most successful examples of data sharing and collaboration. In these campaigns, developed in response to data submitted through the adverse events system, CEO's agree to implement a series of evidence-based best practices and to report quarterly on their progress. As one participant noted:

> *"I feel the workgroups put together by MHA to address the most frequent adverse events have been an important step forward in improving care and patient safety. It has been very good to work with other hospitals in the state to improve patient safety, and invent one new "wheel," for example for the prevention of pressure ulcers, rather than everyone trying to reinvent their own individual wheel."*

However, evaluation participants also noted that there is room for improvement in the compilation, analysis, and sharing of data by MDH. Sometimes, the sheer volume of information available can be overwhelming, and participants expressed a need for MDH to find ways to break key learnings down into manageable blocks, focusing on root causes, successful corrective actions, and more guidance on where they should focus their attention. Others expressed a desire for more information about the "big picture," and a better sense of what we're learning on a large scale from the reporting system.

"There's an exorbitant amount of information. Part of the problem there is trying to filter that down to a useable tool that can be circulated to everyone. It's been difficult."

"(We) look at what's going on in other hospitals and if they see something unusual they'll make sure we're following it, like (preventing the) use of dangerous abbreviations, labeling, dangerous medication uses—we try to learn from what other hospitals are doing."

Process Improvements and Standardization

One of the keys to successful implementation of procedures or policies that are meant to prevent adverse events is consistency not only within but also, when feasible, across facilities. While complete standardization isn't usually possible in every situation due to differing patient needs, it's important to make sure that there are basic steps that are done the same way every time, whenever possible. Evaluation participants noted that the overall level of standardization of processes has increased, a key element in developing a highly reliable organization with clear expectations.

"It's not an option to not mark something down (in the surgery room)."

"Before we had some kind of processes, but now we have improved processes; we're closer to the standard now."

This standardization is particularly crucial in the operating room and in procedural areas. As recent events have highlighted, a lack of consistency in how facilities carry out pre-operative time-outs and site marking can increase the risk that an error will reach the patient. Often, a lack of standardization means that some team members don't understand how to implement a process correctly, and that it's more difficult for team members to spot situations in which other are drifting from the correct approach.

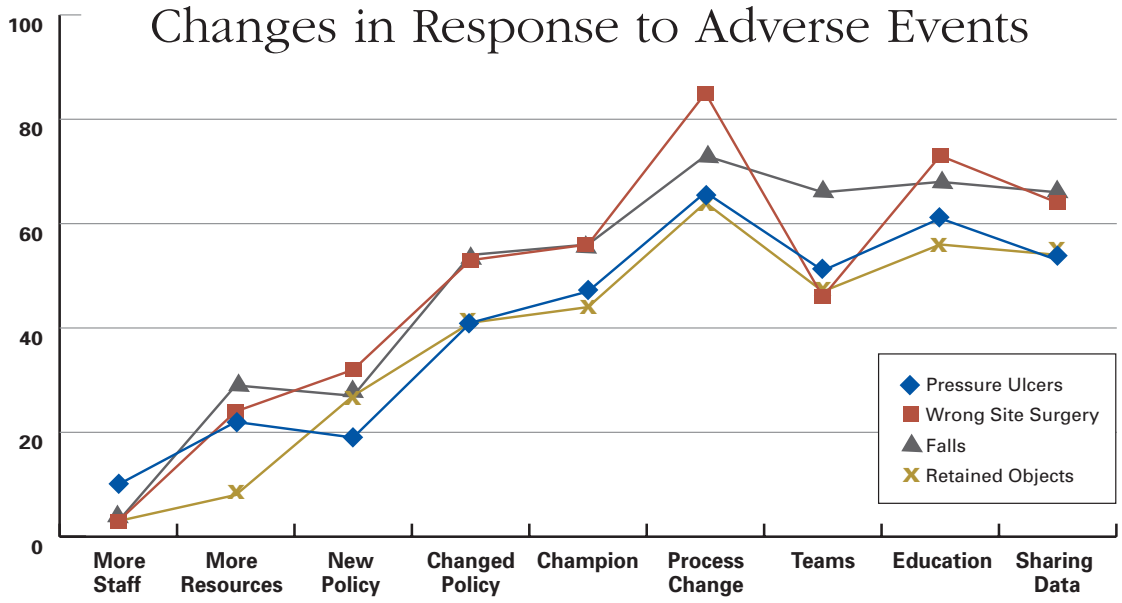
"Nurses know that the clipboard goes into the room with a marking pen; they explain that this is the site documentation process that we implement here."

Changes in clinical practice

Over the life of the adverse events reporting system, the most commonly reported events have been serious pressure ulcers (bedsores), wrong-site surgery, retained foreign objects, and falls. These four categories of events have accounted for more than 80 percent of all reported events across the five years that the system has been in effect. A particular focus of MDH's work, and that of the Minnesota Hospital Association, has been on defining best practices for prevention of these events, and helping facilities to implement those practices successfully.

Facilities learn about best practices through a variety of avenues. The four statewide Calls to Action are an important resource for many participants, providing them with a roadmap or bundle of steps that should be put in place in order to prevent events from recurring. But our growing understanding about how to prevent events also comes from analysis of individual events, feedback given through the review process, and consultation with clinical experts.

Evaluation participants noted that they have made a number of changes in their policies, processes and resource allocation in the four areas that are most commonly reported (falls, pressure ulcers, wrong site surgery, and retained foreign objects). Overall, the most common steps that facilities took in response to these events were implementing process changes, providing additional education to staff, sharing data across the facility, and creating topic-specific teams, such as organization-wide skin safety or falls teams.



The idea of identifying a 'champion' for a particular type of event, who can encourage peers to be engaged in the topic, help to educate about best practices, and serve as a very visible supporter of process changes, has begun to be more widely adopted across facilities, in part because of the Calls to Action. More than half of respondents had identified one or more champions for falls and pressure ulcers, and nearly half had done so for pressure ulcers and retained objects. Often, this type of peer-reinforcement and role-modeling position can help to minimize opposition to planned changes, particularly if the champion is someone who is widely seen as influential and knowledgeable.

The adoption of team approaches to analyzing and preventing adverse events has also caught on with many facilities. More than 60 percent of facilities had established falls teams, and roughly half had established teams to address pressure ulcers, wrong-site surgery, and retained objects. These teams can include a very broad group of caregivers, including physicians, nurses, therapists, dietary staff, aides, transport staff, technicians in procedural areas, and even maintenance staff, depending on the issue. This reflects a growing awareness that many of these issues can cross shifts, units, and disciplines, and that any corrective actions that do not involve all caregivers are less likely to be successful.

RESULTS: MEASURING PROGRESS

"While there has been a lot of activity, conversation, and policy changes, there is no proof that we have positively influenced the risk of these events. To some extent this is because the AHE law was never set up as a measurement system, there is no risk-stratification, there are no denominators, and we are continually modifying the definitions. So it is possible that there has been improvement but it has not been detected."

Patient safety is a complex and multifaceted concept, one that can be – and is – measured in many different ways by individual facilities and state/national organizations. Safety can be measured in terms of the absence of serious reportable events, the presence of a safe and transparent culture, the implementation of best practices, the perceptions of patients that they are receiving safe and high-quality care, or performance relative to state or national goals. As a result, many facilities struggle with the question of how best to measure the extent to which they are making progress, particularly in the area of adverse events.

Prior to the implementation of the law, there was no statewide system for assessing how frequently these events happened. While individual facilities tracked their own adverse or serious events, there was no policy in place requiring reporting of a consistent set of events to a central location, and no compilation or reporting of results across facilities. At the time the law was implemented, there was also no reliable way of predicting how many events were likely to be reported each year, how Minnesota might compare with other states, or how long it might take to learn from and ultimately reduce the frequency of these events.

"Certainly one gauge (of progress) is to monitor how many people are talking about it. In different meetings someone will always make a comment that before may not have been in the equation--it's so foremost on people's minds, you hear comments all the time."

The question of how progress should be measured was also discussed by stakeholders, with most agreeing that the best way to assess progress is to use multiple measures of success. When CEO's were asked what they thought "success" would look like at the time of the law's implementation in 2003, most noted that a reduction in adverse events should be a key goal of the law. But they also noted that increased collaboration among facilities around prevention of adverse events, transparency, and sharing of learning were also an important part of the definition of success for the reporting system.

"There is no way to really know how many incidents were happening before."

The first few years of the law have included changes and clarifications in definitions of reportable events, ongoing education about facilities' requirements under the law, and the development of strong systems for notifying facilities about changes in definitions. This start-up process has muddied the waters somewhat, making it difficult to know whether any year to year shifts in the number of events are due to definitional changes, improvements in compliance, a better understanding of the law, or statistical noise.

A few facilities noted that while they knew that numbers would probably go up before they went down, as a result of improved understanding of the law and increased compliance, they were experiencing some frustrations related to the fact that events continue to happen. Some

noted that while they had experienced multiple events in the same category, the events themselves were so different that sharing learnings or corrective actions between the events wasn't really possible:

> *"For some topics, such as medication errors, sexual assault, or infant abduction, they are so rare and the causative factors are so diverse that learning and application beyond the original event and site is almost impossible."*

This quote highlights another crucial aspect of the reporting system; its ability to allow facilities to learn how to more effectively prevent rare events that they may not have ever experienced. With events that happen so rarely, some facilities may have put processes into place that have not yet been tested by a real case. In that environment, spotting potential risks in a process or system can be more difficult. But by learning from facilities that have experienced these events, others are able to identify where their own systems have the potential to fail, and implement process improvements to prevent those failures.

Others commented that the human element is always unpredictable, even with the best-designed system. As one CEO put it:

"After the first year we put a bunch of procedures in place to prevent it, and the exact same thing happened again. And it all comes back to humans. You think you fix all the systems but it just takes one person, one time, one thing and that's a problem with healthcare. It's so people dependent; it's very difficult to get our arms around."

"Success would mean that people would actually work together to try to prevent these events across hospitals, and I think that's come to pass."

In many ways, this comment gets to the heart of the challenge that many facilities face when working to prevent adverse events. As the landmark Institute of Medicine report "To Err is Human" so clearly stated, the healthcare system is dependent on humans to deliver care, and those humans are fallible. We have a tendency to expect perfection, and to assume that every person is capable of complete vigilance in all situations at all times, even in an environment where patients' needs and conditions may be changing rapidly. We expect this even when we know that perfection is impossible.

And yet, healthcare providers have an obligation to ensure that the care they deliver is as safe as possible every time, and that they are putting redundancies and barriers in place to prevent the inevitable human errors from reaching – and harming – patients. They also have an obligation to manage their staff's behavioral choices and to make it easier for them to choose the safest option every time rather than taking shortcuts that may compromise care. That tension between expectations of perfect performance, the reality of human fallibility, and the human tendency to make things simpler sometimes results in frustration, both for leaders and for front-line staff.

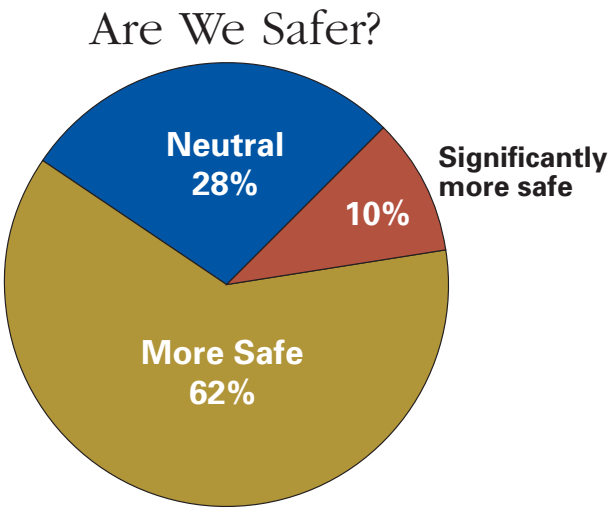
"We have had a large reduction of patient falls in our facility. Our pressure ulcers are minimal and our processes are taken seriously and have been instituted hospital wide from nursing through physicians."

"Our practices are more intentionally directed at patient safety - this is obvious by chart reviews, etc. However, we are not seeing significant changes in our numbers."

"The adverse events law was a catalyst for broader, organization-wide appreciation of instances previously viewed as a "complication" or the natural course of healthcare delivery to instances that could and should be preventable/avoidable- a catalyst for a paradigm shift. The law has also improved the sense of urgency around becoming safer."

Are we safer?

Over the five years that the adverse events reporting system has been in effect, a number of state and national campaigns have brought increased attention to specific patient safety issues. At the same time, changes such as the decision of certain payers to no longer pay for preventable events and increasing regulatory oversight of care providers have been catalysts for a number of safety-related initiatives.



Given that changing environment, separating out the impact of the adverse events reporting law itself can be difficult. However, a strong majority of facilities responding to the survey felt that the reporting law has made us safer than we were five years ago.

Respondents stated again that it can be difficult to know when an event has been prevented, and that we had no baseline prior to the law with which to compare current performance; they also noted that the adverse events law alone is not responsible for all safety improvements that have happened. As one focus group participant stated, the law is one driver for change – but not the only driver.

"I agree that the attention to safety is starting to move the culture. People are talking differently about safety and about teamwork."

However, evaluation participants agreed that in many facilities, the reporting law has helped to drive a greater degree of transparency, improved interdisciplinary teamwork, increased awareness of patient safety issues and risks, and changes to internal event review processes. Several participants also noted that the law has given added back-up or authority to their efforts. As one participant noted, "the law has given us the power to enforce."

Respondents also remarked that awareness and transparency alone will not make care safer, and that we still have a great deal of work ahead of us before we can definitively say that we've improved care in a measurable and

sustainable way. Several noted that the reporting system may lead to a diversion of attention or resources from other areas that are equally important, that transferable learning from rare events may be limited, or that a focus on implementation of best practices may mask continuing incidence of events.

"It's really raised the bar. I'm proud to say that."

Given the lack of a baseline, issues related to definitional clarifications or expansions, and the many dimensions along which progress can be measured, assessing whether or not the law has been successful in reducing the frequency of adverse events is difficult. Nearly all evaluation participants agreed that we are safer now as a result of the law, but many also agreed that counting the number of events that happen in any given year is not the only, or perhaps even the best, way to measure safety. As one CEO noted, there are many indicators of patient safety, including measures required or recommended by Medicare, Leapfrog, the Joint Commission, and other organizations. To truly measure progress, it's necessary to look at the incidence of adverse events, but also at progress on these other measures of success.

"The focus on these events by necessity diverts attention from other events that may be occurring more frequently in a given institution. Therefore, we may be simply "stepping on a balloon" in terms of overall safety. Still, the focus is helpful as it disciplines the organization to focus on its core processes."

RESULTS: REPORTING AND REVIEW PROCESS

"It's ironic that we're in the business of making systems work better for human beings – yet, as part of the reporting process (we) have to work with such a difficult system."

"The technical part of the process isn't really intuitive. It doesn't flow right. Trying to pick a classification (for a root cause) – you pick one because you have to, but it may not be what you would choose if there were other choices."

In the five years that the adverse events reporting system has been in place, it has evolved from a relatively simple web-based reporting system and review process to a much more comprehensive system that encompasses multiple reviews of every event, a larger amount 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. But the backbone of the system remains the reporting and analysis of individual adverse events. This process is designed to provide focused feedback to reporting facilities about each event, as well as a mechanism for moving them towards more robust analysis of the root causes of the event and the development of strong and effective corrective actions. On a larger scale, the review process is also a mechanism for analysis of trends and learnings across facilities, some of which have formed the basis for statewide campaigns to prevent the most common types of adverse events.

"We were JCAHO previously so root cause analysis was in place, and reporting on paper hasn't changed a lot. But what has changed is people don't see it as a paperwork compliance issue anymore, they take it to heart."

In practice, though, the system itself can sometimes pose challenges for reporting facilities. To facilitate analysis of trends across events, the web-based reporting system sometimes pushes facilities to fit the findings of their often far-ranging analyses into pre-determined boxes rather than submitting free-form responses. This can mean that more follow-up is necessary in order to get "the whole story" about an event, leading to delays in moving events through the review process to completion.

"(We have a) much more diligent process in analyzing events and actions for follow-up now."

As the number of reported and reportable events has grown, and as the number of potential reviews of any particular event has grown from two to three, the review process has experienced times of slower pass-through. Several participants said that it has taken several months before they received a review on their events. In some instances, those participants said their teams had already moved on by the time they received feedback on their event analysis (implementing corrective action plans, etc), and that it can be difficult to bring participants back to those events to further hone the analysis or to develop new fixes.

Both the relatively rigid framework of the reporting system and the sometimes slow-moving review process can lead to frustration for reporting facilities, as expressed by focus group participants. Focus group participants also expressed frustrations with the content of the review process, which attempts to balance constructive feedback on an event with the requirement

that each event "pass" on all review criteria. This balance of quality improvement and constructive criticism sometimes causes friction; participants indicated that the process sometimes feels more like regulation than quality improvement, and commented that it can feel discouraging to hear that they need to go back and make changes to a plan that they had considered complete. Overall, participants suggested that the process could be modified so that it has an increased focus on learning and coaching, rather than on pointing out insufficiencies.

Preventability

Another very common theme that emerged in focus groups and interviews was the issue of preventability. While the National Quality Forum's list of Serious Reportable Events in HealthCare, on which Minnesota's Adverse Health Care Event reporting law is based, is sometimes referred to as the "never events" list, there are situations in which events may not be preventable.

Particularly in the case of pressure ulcers, clinically complex patients with multiple co-morbidities can quickly develop pressure ulcers even with the best of care, as can patients who are undergoing long surgical procedures. In the area of falls, facilities occasionally encounter situations where even the best risk assessment and patient education programs can't prevent a patient from deciding not to use their call light to ask for assistance in a particular situation. Facilities also sometimes have to balance concerns of safety and patient privacy, as when a patient would like to use the bathroom by themselves but the care plan might indicate a need for closer observation.

"There are too many variables (that) make these events not preventable…a lot is out of our control."

While these situations are rare, they can lead to frustration, given that events must be reported regardless of whether the facility considers them preventable or not, and the public report does not distinguish between preventable and non-preventable events. Without the ability to share more information with the public about the circumstances surrounding each event, some facilities worry that non-preventable events will be viewed as within their control, making them appear less safe when they may not have had total control over the situation. These situations also raise the concern that, without standards for determining what makes a particular event preventable, the level of certainty required to make that determination may differ across facilities.

Dealing with staff perceptions that certain events are not preventable can add an additional layer of challenge. If front-line staff or leadership believe that, for example, pressure ulcers cannot be prevented, they may be less likely to look for potential areas of process improvement in more complex cases, or to view fixes designed to address these issues as unlikely to succeed.

The question of preventability will always be evolving. What we may consider to be non-preventable today may well be preventable in the future, as we continue to learn more about

"While the sharing of information throughout the healthcare facility population might spark and renew interest in the topics, the actual reporting of information is a data process only and has not seemed to influence the number of adverse events that are reported."

"(Falls and pressure ulcers) are not necessarily all avoidable because of patient choice."

"It's sort of an overriding consensus that pressure ulcers are not preventable."

where the risks lie and develop new strategies to reduce those risks. The challenge, with the issue of preventability, is to make sure that we are looking at all possible avenues for improvement, rather than viewing preventability as static, and working to reduce risk as much as possible.

Defining Reportable Events

Definitional issues and changes also pose an ongoing challenge for reporting facilities. While the Adverse Health Events Reporting Law defines 28 categories of reportable events, there has been an ongoing need to provide guidance to facilities on how to interpret reportability of individual events that may not fit neatly into one category, or where the statute may not have captured the full variety of possible scenarios.

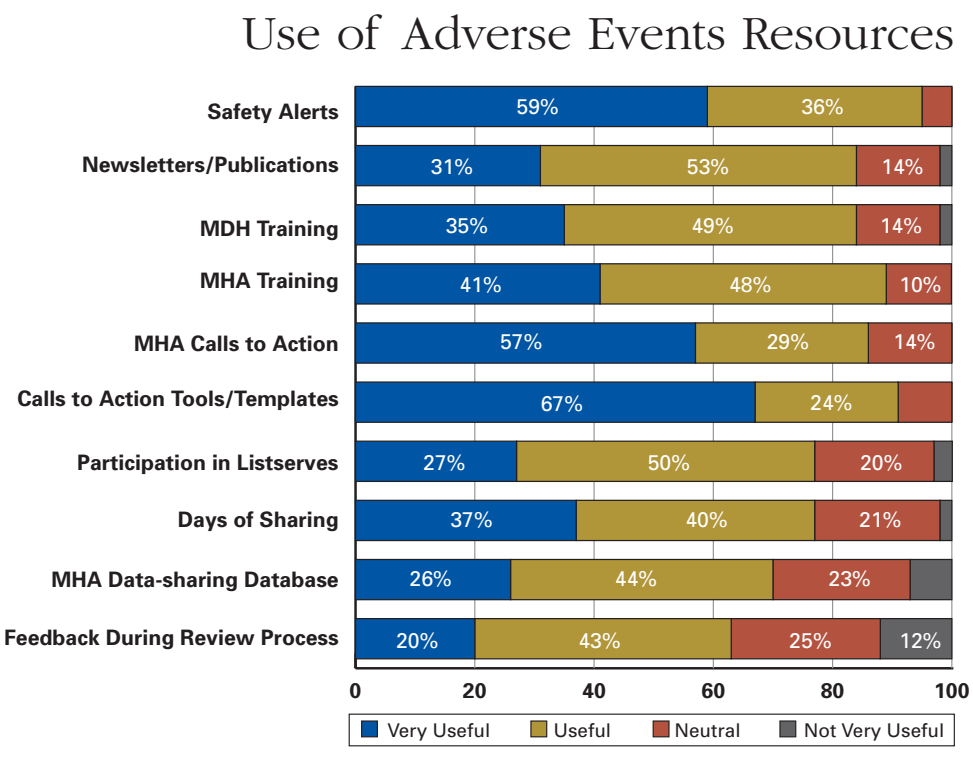
Over the five years that the reporting system has been in operation, clarifications or decision tools have been developed related to the definition of serious disabilities, when a surgery is considered complete for the purposes of identifying retained foreign objects, what is considered an invasive procedure, the difference between deep tissue injuries and pressure ulcers, and the definition of sexual assault, among other topics. The ongoing refining of event definitions has led to confusion for some reporting facilities, as well as a need to verify that the definitions are interpreted, and events reported, in the same way across facilities. It also makes it difficult to compare results from the early years of the reporting system to those from more recent years, after definitional guidance has been issued.

As one CEO noted, if reportability isn't viewed the same way across facilities, the report itself is less accurate, and it becomes less useful in painting a true picture of how often, and why, these events occur. If there are inconsistent definitions of events, facilities that are broader in their interpretation of what is reportable may also face the possibility of more negative media coverage or scrutiny when the annual report is released than those who use a narrower definition of reportability; in effect, this punishes those that are making a greater effort to find and report all events, even those for which reportability is unclear.

RESULTS: RESOURCE USE & FUTURE NEEDS

Through the reporting system and the collaborative efforts of the Minnesota Hospital Association, the Minnesota Department of Health, and Stratis Health, reporting facilities have access to a number of training opportunities, resources, and forums for sharing and learning from each other. Evaluation participants were asked about their use of available resources, and the degree to which they found them to be useful.

In general, respondents indicated that all of the available resources are useful to them; more than 60 percent of respondents indicated that every type of resource was useful, and the average across all categories was 82% indicating that the resource was very useful or useful. Matching what evaluation participants said in response to earlier questions, they indicated that the MHA-led Calls to Action on wrong site surgery, retained sponges in labor and delivery, falls, and pressure ulcers were the most useful tools/resources for their work. Participation in the campaigns themselves was very highly rated, as was the quality of the tools and templates that were made available to campaign participants. Additionally, survey respondents noted that the safety alerts that are periodically issued by MDH and MHA are very useful.



Again mirroring earlier responses, a smaller percentage of facilities indicated they found the feedback and comments that they received during the event review process to be useful, although this number was still over 60 percent.

Going forward, participants expressed a desire for a variety of resources, training, and data sharing tools from MDH and MHA, to help them work more effectively with leadership, engage patients and families, and draw out key points from the data collected by the adverse events system:

- Information about trends/patterns in submitted root cause analysis and corrective action plans
- Stories and case studies about successful practices implemented in other Minnesota facilities or in other states
- Summaries of relevant national research or publications
- Information about successful strategies for engaging leadership in patient safety
- Opportunities to share experiences or challenges related to specific types of adverse events or other topics
- Successful strategies for engaging leadership
- Information and resources related to patient/family engagement and disclosure
- Improved functionality in the web-based registry for running reports

RECOMMENDATIONS AND NEXT STEPS

The evaluation of the adverse health events reporting system revealed a number of clear messages about the success of the system. The reporting law has been a catalyst for dramatic improvements in adoption of best practices around transparency and disclosure, and in sharing of data and learning both within and across facilities. It has also been a driver for increased involvement/engagement in patient safety by board members and executives, as well as by staff at all levels. In the last five years, Minnesota has taken great strides towards creating a statewide culture of safety, transparency, and learning, and the reporting law has been a crucial part of that process.

But the responses of evaluation participants also point out that there is still room for improvement. As the reporting system moves into its next phase, there are a number of steps that the Minnesota Department of Health, its partners, and other stakeholders should take to ensure that the progress of the first five years is maintained, and that we are doing everything possible to support and assist facilities as they implement additional strategies for improvement.

Recommendations for next steps include:

- Developing new methods for regularly sharing key learnings from individual adverse events, as well as information about overall trends, with reporting facilities. With a sometimes overwhelming amount of information available, facilities need help to filter through large amounts of data and decide what will be most useful for them to accelerate learning/adoption of best practices.
- Monitoring the process for reporting and reviewing adverse events, and implementing changes to ensure that the reporting system is as easy to use as possible, provides meaningful and constructive feedback on individual events and broader categories of events, and is timely.
- Encouraging regular administration of safety culture surveys by all healthcare organizations around the state, and providing assistance to facilities in how to act effectively on their findings, how to benchmark their results against similar facilities, and how to communicate findings to staff and to leadership.
- Working with administration/boards of directors to encourage adoption of active leadership strategies such as executive/board walk arounds and the establishment of measurable safety goals for every facility, and cultivating executive or board-level "champions" who can educate peers about effective practices for creating and maintaining a safe culture.
- Working with educators, clinical training sites, and healthcare providers to encourage integration of teamwork and interdisciplinary training, training about patient safety principles, and education about the role of organizational culture as a part of the education of all Minnesota physicians and other providers
- Working with professional organizations and practicing physicians to ensure that physicians and surgeons are fully engaged in patient safety initiatives, and cultivating additional physician champions or leaders on specific clinical issues such as wrong-site surgery, retained foreign objects, and pressure ulcers.

APPENDIX A

144.7063 Definitions.

Subdivision 1. **Scope.** Unless the context clearly indicates otherwise, for the purposes of sections 144.706 to 144.7069, the terms defined in this section have the meanings given them.

Subd. 2. **Commissioner.** "Commissioner" means the commissioner of health.

Subd. 3. **Facility.** "Facility" means a hospital or outpatient surgical center licensed under sections 144.50 to 144.58.

Subd. 4. **Serious disability.** "Serious disability" means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual or a loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or (2) loss of a body part.

Subd. 5. **Surgery.** "Surgery" means the treatment of disease, injury, or deformity by manual or operative methods. Surgery includes endoscopies and other invasive procedures.

144.7065 FACILITY REQUIREMENTS TO REPORT, ANALYZE, AND CORRECT.

Subdivision 1. **Reports of adverse health care events required.** Each facility shall report to the commissioner the occurrence of any of the adverse health care events described in subdivisions 2 to 7 as soon as is reasonably and practically possible, but no later than 15 working days after discovery of the event. The report shall be filed in a format specified by the commissioner and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees, or patients involved. The commissioner may consult with experts and organizations familiar with patient safety when developing the format for reporting and in further defining events in order to be consistent with industry standards.

Subd. 2. **Surgical events.** Events reportable under this subdivision are:
(1) surgery 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 performed on the wrong patient;
(3) the wrong surgical 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 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 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.

Subd. 3. **Product or device events.** Events reportable under this subdivision are:
(1) patient death or serious disability 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 disability 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 disability 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.

Subd. 4. **Patient protection events.** Events reportable under this subdivision are:
(1) an infant discharged to the wrong person;
(2) patient death or serious disability associated with patient disappearance, excluding events involving adults who have decision-making capacity; and
(3) patient suicide or attempted suicide resulting in serious disability 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.

Subd. 5. **Care management events.** Events reportable under this subdivision are:
(1) patient death or serious disability 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 disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
(3) maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;
(4) patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;
(5) death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter;
(6) stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission;
(7) patient death or serious disability due to spinal manipulative therapy; and
(8) artificial insemination with the wrong donor sperm or wrong egg.

Subd. 6. **Environmental events.** Events reportable under this subdivision are:
(1) patient death or serious disability 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 disability associated with a burn incurred from any source while being cared for in a facility;
(4) patient death or serious disability associated with a fall while being cared for in a facility; and
(5) patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility.

Subd. 7. **Criminal events.** Events reportable under this subdivision are:
(1) any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care 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 significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Subd. 8. **Root cause analysis; corrective action plan.** Following the occurrence of an adverse health care event, the facility must conduct a root cause analysis of the event. Following the analysis, the facility must: (1) implement a corrective action plan to implement the findings of the analysis or (2) report to the commissioner any reasons for not taking corrective action. If the root cause analysis and the implementation of a corrective action plan are complete at the time an event must be reported, the findings of the analysis and the corrective action plan must be included in the report of the event. The findings of the root cause analysis and a copy of the corrective action plan must otherwise be filed with the commissioner within 60 days of the event.

Subd. 9. **Electronic reporting.** The commissioner must design the reporting system so that a facility may file by electronic means the reports required under this section. The commissioner shall encourage a facility to use the electronic filing option when that option is feasible for the facility.

Subd. 10. **Relation to other law; data classification.** (a) Adverse health events described in subdivisions 2 to 6 do not constitute "maltreatment," "neglect," or "a physical injury that is not reasonably explained" under section 626.556 or 626.557 and are excluded from the reporting requirements of sections 626.556 and 626.557, provided the facility makes a determination within 24 hours of the discovery of the event that this section is applicable and the facility files the reports required under this section in a timely fashion.
(b) A facility that has determined that an event described in subdivisions 2 to 6 has occurred must inform persons who are mandated reporters under section 626.556, subdivision 3, or 626.5572, subdivision 16, of that determination. A mandated reporter otherwise required to report under section 626.556, subdivision 3, or 626.557, subdivision 3, paragraph (e), is relieved of the duty to report an event that the facility determines under paragraph (a) to be reportable under subdivisions 2 to 6.
(c) The protections and immunities applicable to voluntary reports under sections 626.556 and 626.557 are not affected by this section.
(d) Notwithstanding section 626.556, 626.557, or any other provision of Minnesota statute or rule to the contrary, neither a lead agency under section 626.556, subdivision 3c, or 626.5572, subdivision 13 , the commissioner of health, nor the director of the Office of Health Facility Complaints is required to conduct an investigation of or obtain or create investigative data or reports regarding an event described in subdivisions 2 to 6. If the facility satisfies the requirements described in paragraph (a), the review or investigation shall be conducted and data or reports shall be obtained or created only under sections 144.706 to 144.7069, except as permitted or required under sections 144.50 to 144.564, or as necessary to carry out the state's certification responsibility under the provisions of sections 1864 and 1867 of the Social Security Act.
(e) Data contained in the following records are nonpublic and, to the extent they contain data on individuals, confidential data on individuals, as defined in section 13.02:
(1) reports provided to the commissioner under sections 147.155, 147A.155, 148.267, 151.301, and 153.255;
(2) event reports, findings of root cause analyses, and corrective action plans filed by a facility under this section; and
(3) records created or obtained by the commissioner in reviewing or investigating the reports, findings, and plans described in clause (2).
For purposes of the nonpublic data classification contained in this paragraph, the reporting facility shall be deemed the subject of the data.

144.7067 Commissioner duties and responsibilities.

Subdivision 1. **Establishment of reporting system.** (a) The commissioner shall establish an adverse health event reporting system designed to facilitate quality improvement in the health care system. The reporting system shall not be designed to punish errors by health care practitio-

ners or health care facility employees.

(b) The reporting system shall consist of:

(1) mandatory reporting by facilities of 27 adverse health care events;

(2) mandatory completion of a root cause analysis and a corrective action plan by the facility and reporting of the findings of the analysis and the plan to the commissioner or reporting of reasons for not taking corrective action;

(3) analysis of reported information by the commissioner to determine patterns of systemic failure in the health care system and successful methods to correct these failures;

(4) sanctions against facilities for failure to comply with reporting system requirements; and

(5) communication from the commissioner to facilities, health care purchasers, and the public to maximize the use of the reporting system to improve health care quality.

(c) The commissioner is not authorized to select from or between competing alternate acceptable medical practices.

Subd. 2. **Duty to analyze reports; communicate findings.**
The commissioner shall:

(1) analyze adverse event reports, corrective action plans, and findings of the root cause analyses to determine patterns of systemic failure in the health care system and successful methods to correct these failures;

(2) communicate to individual facilities the commissioner's conclusions, if any, regarding an adverse event reported by the facility;

(3) communicate with relevant health care facilities any recommendations for corrective action resulting from the commissioner's analysis of submissions from facilities; and

(4) publish an annual report:

(i) describing, by institution, adverse events reported;

(ii) outlining, in aggregate, corrective action plans and the findings of root cause analyses; and

(iii) making recommendations for modifications of state health care operations.

Subd. 3. **Sanctions.** (a) The commissioner shall take steps necessary to determine if adverse event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner. The commissioner may sanction a facility for:

(1) failure to file a timely adverse event report under section 144.7065, subdivision 1; or

(2) failure to conduct a root cause analysis, to implement a corrective action plan, or to provide the findings of a root cause analysis or corrective action plan in a timely fashion under section 144.7065, subdivision 8.

(b) If a facility fails to develop and implement a corrective action plan or report to the commissioner why corrective action is not needed, the commissioner may suspend, revoke, fail to renew, or place conditions on the license under which the facility operates.

144.7069 Interstate coordination; reports.

The commissioner shall report the definitions and the list of reportable events adopted in this act to the National Quality Forum and, working in coordination with the National Quality Forum, to the other states. The commissioner shall monitor discussions by the National Quality Forum of amendments to the forum's list of reportable events and shall report to the legislature whenever the list is modified. The commissioner shall also monitor implementation efforts in other states to establish a list of reportable events and shall make recommendations to the legislature as necessary for modifications in the Minnesota list or in the other components of the Minnesota reporting system to keep the system as nearly uniform as possible with similar systems in other states.

For More Information:

Minnesota Department of Health
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