Due to the unprecedented COVID-19 pandemic, many state employees have been redeployed to assist with pandemic response. This has impacted our ability to release certain legislatively-mandated reports, including the annual Adverse Health Events (AHE) report. Prior to COVID-19, MDH had spent over a year gathering input on how to advance the system to better support safe patient care in a rapidly evolving, complex health care environment. Through extensive outreach, the project's steering team had identified some high-level themes and recommendations that will help to guide our work to evolve the system. A discussion of that work, and the resulting recommendations, is a strong focus of this report. However, with COVID-19 continuing to strain our health care delivery system, individuals, and communities, it is likely that the new landscape of health care will look different, in significant ways, than it did prior to the pandemic. MDH is committed to re-convening our partners post-pandemic to assess how these recommendations for evolution apply in this new environment, and whether they need to be modified.

The 2021 annual Adverse Health Events report will also not be released in the same manner as in the past. For the 2021 annual report, the data will be released with little or no accompanying narrative. Throughout 2020, MDH has continued to contract with the Minnesota Hospital Association and Stratis Health to manage the patient safety registry, analyze data and trends in adverse health events, and review submitted events to ensure reporting, root cause analysis, and follow-up requirements are being met. There has been no lapse in the reporting requirements for hospitals and ambulatory surgical centers.

Minnesota Department of Health
Health Policy
www.health.state.mn.us

12/14/2020

To obtain this information in a different format, call: 651-201-3560

Adverse Health Events in Minnesota

16TH ANNUAL PUBLIC REPORT

MARCH 2020

DEPARTMENT OF HEALTH

Adverse Health Events in Minnesota
Annual Report |March 2020

Minnesota Department of Health
Division of Health Policy
P.O. Box 64882
Saint Paul, MN 55101
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www.health.state.mn.us/patientsafety

As requested by Minnesota Statute 3.197: This report cost approximately $8,000 to prepare, including staff time, printing and mailing expenses.

Upon request, this material will be made available in an alternative format such as large print, Braille or audio recording. Printed on recycled paper.

DEPARTMENT OF HEALTH

February 28, 2019

The Honorable Michelle Benson, Chair
Health and Human Services Finance & Policy Committee
Minnesota Senate
3109 Minnesota Senate Building
95 University Ave W.
Saint Paul, MN 55155-1606

The Honorable Rena Mora, Chair
Health and Human Services Policy Committee
Minnesota House of Representatives
575 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd
Saint Paul, MN 55155-1606

The Honorable Jim Abeler, Chair
Human Services Reform Finance & Policy Committee
Minnesota Senate
3215 Minnesota Senate Building
95 University Ave W.
Saint Paul, MN 55155-1606

The Honorable Tina Liebling, Chair
Health and Human Services Finance Committee
Minnesota House of Representatives
477 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd
Saint Paul, MN 55155-1606

Dear Honorable Chairs

As required by Minnesota Statutes, Section 144.706, this report provides an overview of events reported under Minnesota's Adverse Health Event Reporting Law during the most recent reporting year. This law requires that all hospitals and licensed surgical centers in Minnesota report to MDH any time one of 29 'events' occurs. These events include things like serious falls, wrong site surgeries and suicides.

This report provides an analysis of the data collected through the adverse health event (AHE) system for the period from October 7th, 2018-October 6th, 2019. The report shows 366 adverse health events reported during this period, with 143 serious injuries and 12 deaths. This represents a slight decrease in these events with a slight increase in number of events resulting in serious injury to the patient. The most common type of reportable events are pressure ulcers (bedsores) and falls resulting in serious injury. A highlight of this reporting year is that MDH and its partners have embarked on a formal project to evolve the Adverse Health Events system in the coming years to better protect patients and to better improve safety in our health care facilities in Minnesota. The AHE system started over 16 years ago, and through our work with hospitals and surgery centers, we know a lot more about where the greatest risks to patients are now then we did back in 2003. Given that changing environment, our approach to reporting on and improving patient safety may need to evolve to match. Formal recommendations to MDH on ways to evolve the program are expected in late spring 2020.

Questions or comments on the report may be directed to Rachel Jokela of the Adverse Health Events program at (651) 201-5807.

Sincerely,

Jan K. Malcolm
Commissioner
PO Box 64975
St. Paul, MN 55164-0975

CONTENTS

EXECUTIVE SUMMARY

In any given year, millions of people receive care in a Minnesota hospital or ambulatory surgical center. When you are a patient, or when you are providing support for a loved one who is receiving care, you need to know that you will be safe from harm.

One way that we can help create a health care system that is as safe as it can be, and as successful as possible in avoiding incidents of preventable harm to patients, is by collecting data on how often serious, often avoidable events happen and using that data to promote learning and prevention. Since 2003, Minnesota has required all hospitals and surgery centers to report whenever a serious adverse health event occurs and conduct an analysis on the reasons for the occurrence. Since then, more than 4,500 adverse health events (AHE) events (list of events) have been reported to the Minnesota Department of Health (MDH).

In 2019, the total number of reported events was 366, a slight decrease from the prior year. Over the last five years, an average of roughly 350 events have been reported each year. Once again, falls and pressure ulcers were the most commonly reported types of events, accounting for 53 percent of all events reported (197 events). There were 12 deaths and 143 serious injuries that resulted from the reported events. While the overall number of events has been relatively flat in the last five years, the number of events resulting in harm has continued to rise, from 109 in 2015 to 155 in 2019.

A system like this, that uses data to drive learning and prevention, is a key part of creating the safest possible health care system. Without quality data, and a focus on learning and transparency, reporting systems risk contributing to a culture of blame, shame and secrecy. But this system has its limits. We know that these events represent only a portion of the situations that can lead to unintended harm to patients: it does not capture all possible risks to patients' safety. And, of course, people receive care in many other settings, not just in hospitals and surgical center.

In recognition of the limitations of the current system, and the fact that patients may face different risks as a result of evolving technologies, changes in care delivery models and settings of care, and increasing clinical complexity, MDH has spent the last year gathering input on how to advance the system to better support safe patient care in a rapidly evolving, complex health care environment.

The following sections of this report, and accompanying documents, provide an overview of the events that were reported during the last reporting year, and the activities that MDH and its partners led to promote shared learning and next steps for improvement.

HIGHLIGHTS OF 2019 ACTIVITIES

The Minnesota Adverse Health Events Law directs the Commissioner of Health to review all reported events, root cause analyses, and corrective action plans, and provide direction to reporting facilities on how they can improve patient safety. In this work, MDH works closely with a variety of stakeholders including the Minnesota Hospital Association (MHA), and Stratis Health. Highlights of the 2019 activities include:

CONFERENCES AND LEARNING EVENTS

- MHA hosted a 'Healthy Moms and Babies' summit where all MN birthing hospitals attended to share and learn about neonatal quality improvement initiatives;
- MHA hosted a falls and pressure injury conference where 80 in person participants and 120 virtual participants learned about preventing falls and pressure injuries through early mobility and nutrition and ways the patient safety registry can be used a learning tool for prevention efforts;
- MHA held a medication safety conference where 125 attendees learned about safe practices involving opioid medication administration as well as anticoagulant therapy;
- MDH and its partners held an annual Case Study Review webinar in order to educate on the reportability of certain event types and look more deeply into root causes and corrective action plans of current events; and,
- MDH and its partners continued an Adverse Health Events (AHE) webinar series covering a range of topics, including surgical safety, as well as root cause analysis and corrective action development.

NEW TOOLS AND RESOURCES

- MHA, together with surgical experts from around the state and MDH, launched a new 'Time Out Surgical Checklist' toolkit to further prevention efforts in surgical/procedural areas across Minnesota. The checklist identifies 22 critical elements that should be included either in the Time Out or during a pre-procedure briefing.

TECHNICAL ASSISTANCE AND CONSULTATION

- For the last three years, reporting organizations have had the option to request one-on-one consultation or technical assistance related to the root cause analysis process, developing strong action plans, and/or approaches for monitoring improvement. MDH and its partners can also reach out to organizations to initiate a follow up discussion. The purpose of the follow up discussion can be to learn more from the representatives about the root causes and how the corrective actions will mitigate risk, or to share information about resources or best practices

- In this reporting year, 114 events (31 percent) received some form of consultation; most commonly, this was for falls, surgical events, or biological specimen events. Of these cases, 99 involved hospitals and 15 involved ambulatory surgery centers. The consultation included exploring lessons learned across similar events, seeking to understand preceding causes to events, sharing information on best practices or available resources, connecting organizations with subject matter technical experts, and identifying the most effective methods to evaluate the impact of corrective actions.

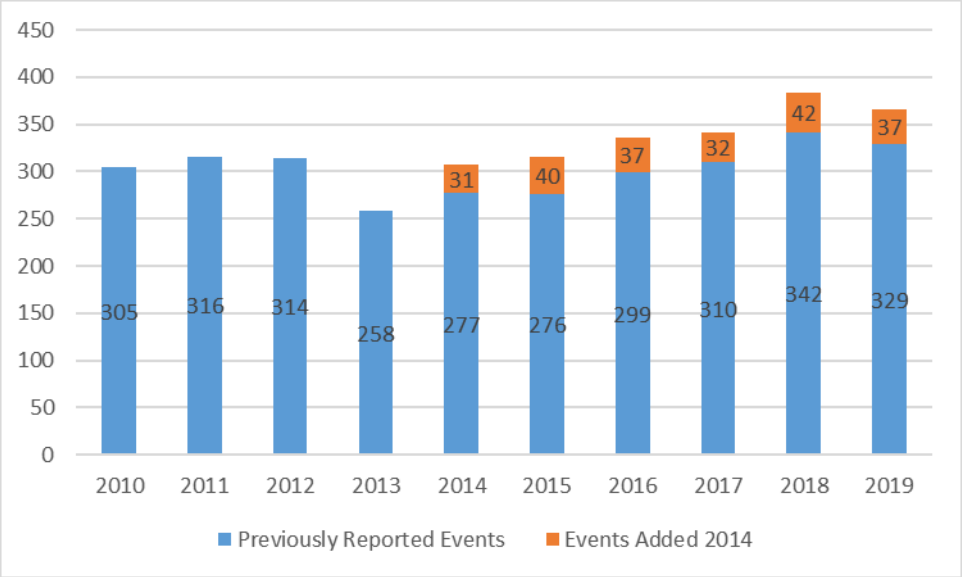
OVERVIEW OF REPORTED EVENTS & FINDINGS

In the 16 years of public reporting of adverse health events, the Minnesota Department of Health has collected detailed information on more than 4,500 events. MDH and its partners have used the findings from those events to identify ways to improve patient safety in Minnesota and support a system of shared learning across all participating facilities.

This annual report provides an overview of what the most recent year of data can teach us about the risk points for adverse health events and the best approaches for preventing them, with a highlight on the most commonly reported events. For those who with to learn more about the most frequently reported of events, such as falls, pressure ulcers, surgical events, and biological specimen events, companion documents that provide more detailed information are available here: .

Hospitals and ambulatory surgical centers that are licensed by MDH are required to report adverse health events under this law. Federally licensed facilities, such as those operated by the Veteran's Administration or the Indian Health Service, are not covered by the law.

Figure 1: **Reported Adverse Health Events 2010-2019**



FREQUENCY OF EVENTS

Between October 7, 2018, and October 6, 2019, hospitals and surgical centers reported 366 adverse health events to MDH (Figure 1). In the most recent reporting year there was a slight decrease in overall numbers of reported events, but an increase in the percent of events resulting in harm.

PATIENT HARM

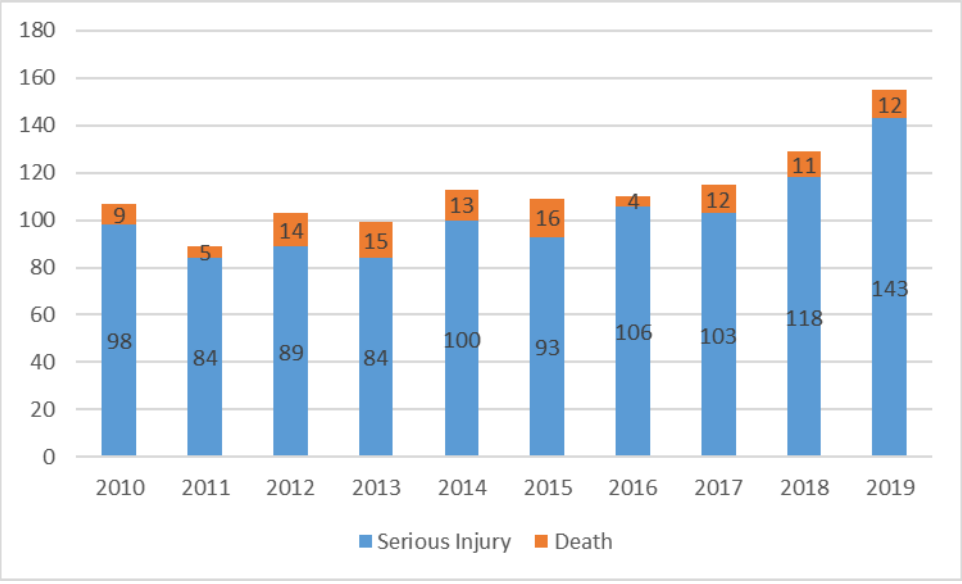
Of the reports submitted during this reporting period, 143 events (39 percent) resulted in serious injury, while 12 events (three percent) led to the death of the patient (Figure 2). While the number of deaths is similar to previous years, the number of serious injuries increased in 2019. While this represents the highest number of events associated with harm since the system began, it appears that a significant portion of the increase may be due to a change in how data for retained foreign objects (RFO) are reported.

The most commonly reported injury severity level for RFO is 'treatment required.' However, in 2019 MDH made a change to automatically categorize injury severity level as "serious injury" if a second procedure was required. This resulted in more events receiving the classification of "serious injury" than in previous years. In this reporting year, there were 20 RFO's that resulted in serious injury, compared to one the previous year. See the RFO section for more information.

Over the life of the reporting system, falls, medication errors and neonatal events have been the most common causes of serious patient injury or death. The pattern was similar in 2019; six of the 12 deaths were associated with falls, three with the death of a neonate and one each as the result of a medication error, suicide and an air embolism.

It is important to note that not all of the events under Minnesota's adverse health events reporting law have a threshold for the level of harm required to be reportable. Some events, such as pressure injuries or the loss or irretrievable biological specimen, are required to be reported regardless of the level of patient harm. However, all of these events are indicators of potential system issues that could lead to harm.

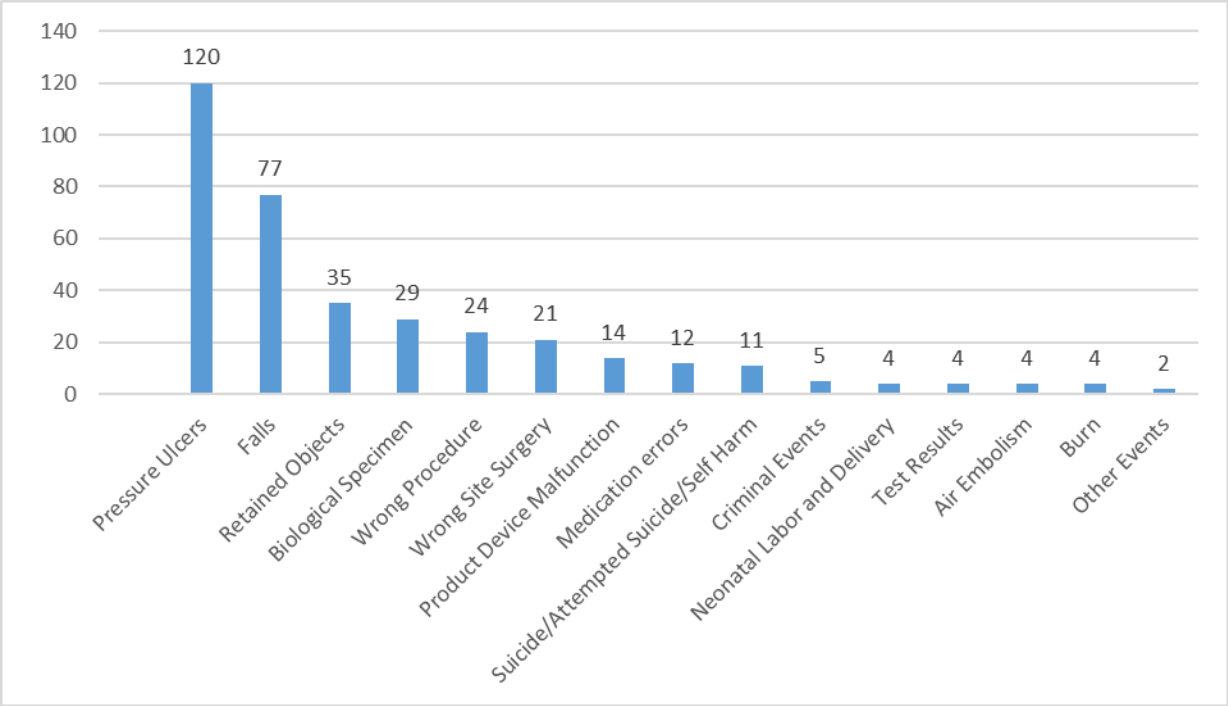
Figure 2: **Events with Harm 2010-2019**



TYPES OF EVENTS

As in previous years, falls and pressure ulcers were the most commonly reported types of events, accounting for 53 percent of all events reported (197 events). The four event types that make up the surgical/invasive procedure category accounted for another 22 percent of events, with 81 (Figure 3). More detailed information about the number of events reported in each category over the life of the system is available here:.

Figure 3: **Events by Category 2019**

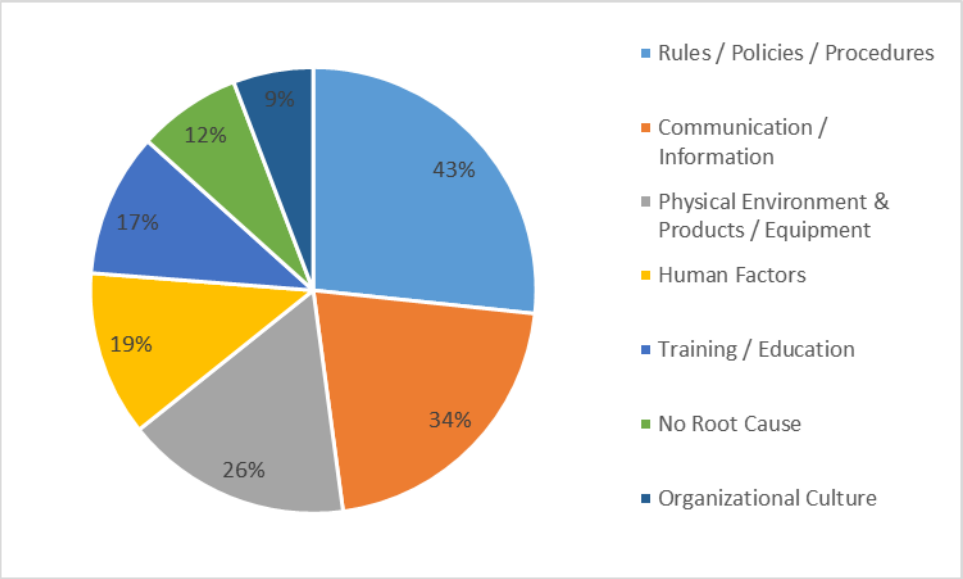


ROOT CAUSES OF ADVERSE EVENTS

When a reportable adverse event occurs, facilities are required to conduct a root cause analysis (RCA). This process involves gathering a team to closely examine the factors and circumstances that led to the event. These factors can include miscommunication, inadequate training, failure to follow policies/procedures or confusion about roles and responsibilities. The process of completing an RCA is a critical step in determining exactly what happened and why. Only after the RCA can organizations can put concrete steps in place to prevent a similar event in the future.

As in previous years, the majority of adverse health events are tied to root causes in one of the three areas: rules/policies/procedures, communication and environment/equipment (Figure 4). However, it is important to note that not all root causes fit neatly into these categories, and in many cases the causes are closely intertwined and there may even be more than one root cause or contributing factor.

Figure 4: **Root Causes of Events 2019**



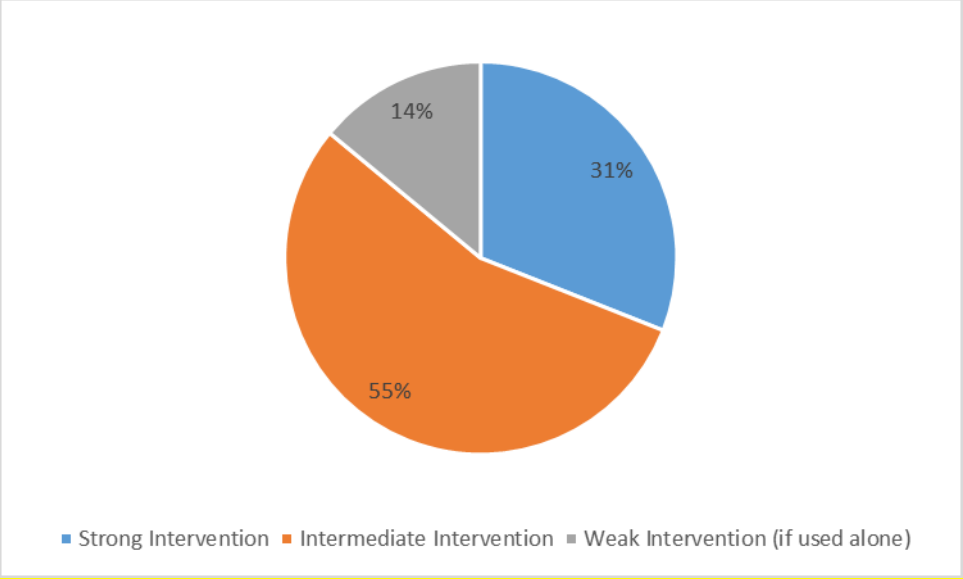
Of note, in this reporting period, 12 percent of the time facilities were unable to identify a root cause, this is down nearly 20 percent from recent years. The highest number of events with no identified root cause were pressure ulcers. In these events, the organizations usually identified that all intended preventive interventions were in place at the time of the pressure injury and a system breakdown was not identified. Ensuring that facilities know how to conduct a robust root cause analysis to assure that the causes for these events are identified properly has been a focus area for training and technical assistance in recent years. The decrease in the number of events without a root cause is potentially a sign that work and those training sessions are beginning to bear fruit.

CORRECTIVE ACTION PLANS

After the organization identifies a root cause, they are also required to put a corrective action in place to prevent future events from happening. MDH collects data on those corrective action plans; corrective action plans are then tiered by strength and the degree to which they minimize risk of human error. Certain actions, such as training (when used alone), are considered "weak" actions (as they typically do not lead to change that is hardwired). Physical plant or architectural changes are "strong" actions, because they are less prone to fail due to human error. Enhanced documentation or similar changes are considered "intermediate" actions. While it may not be possible for every event to have a strong corrective action associated with it, MDH works with reporting facilities to take an in-depth look at the root cause and attempt to pair the strongest action plan with it.

In this reporting period, 31 percent of reported corrective action plans were ranked as strong (Figure 5), 55 percent as intermediate and 14 percent as weak interventions. The number of weak interventions put in place during this reporting year is down from 20 percent in the year prior and subsequently, the percent of strong interventions rose in 2019 as well. This is encouraging progress, as facilities implementing stronger action plans could potentially lead to less events or less harm in the future. Over the coming year, MDH will continue to work with reporting facilities on increasing the strength of their action plans through providing technical assistance outreach to facilities.

Figure 5: **Corrective Actions by Strength, 2019**



ADVERSE HEALTH EVENTS: SYSTEM EVOLUTION

In 2019, MDH and its partners, Stratis Health, MHA and the Minnesota Alliance for Patient Safety, (MAPS), embarked on a formal project to examine how the AHE system could evolve to better meet the challenges of today's health care system. The ideal system would be focused on the areas of greatest risk for patient harm, promote transparency and learning, and avoid unnecessary administrative burden. The information that comes from the system should lead to meaningful and measurable actions to reduce harm to patients, wherever they receive care.

The project included a formal literature review, facilitated discussions with stakeholder groups, key informant interviews with state and national patient safety leaders, and analysis of other sources of information to inform the shape and focus of the potential future system. More details on the sources of information gathered are below.

The group did nearly 20 key informant interviews of state and national experts on patient safety and healthcare delivery. Input was sought from these informants on the biggest safety risks nationally, the trajectory in which the nation is moving with safety and quality and how MN could improve our system to better protect patients.

- Minnesota Board of Medical Practice
- Pennsylvania Patient Safety Authority
- Institute for Healthcare Improvement
- Emergency Care Research Institute (ECRI)

Facilitated discussions with stakeholder groups to generate ideas about what is possible for AHE in MN. Groups include:

- Consumer focus group with participants from consumer advocacy groups, as well as former patients/families who had experienced a patient safety event.
- Current patient safety registry users (hospital and ambulatory surgery center safety/risk team members)
- Minnesota Alliance for Patient Safety board members including:
    - Commissioner Health for MDH
    - President of Leading Age Minnesota
    - President of Aging Services of Minnesota
    - CEO, Minnesota Medical Association
    - Chief Quality Officer, Minnesota Department of Human Services
    - CEO, MMIC Insurance
    - Chief Quality/Safety Officers from numerous MN hospitals and health systems

Through this extensive input and discussion phase, the project's steering team identified several high-level themes that will guide the next phase of the work:

- Include other settings of care, namely long-term care and other ambulatory surgery settings
- Balance accountability and transparency with a non-punitive learning environment
- Expand the data collected to include other patient safety events with the potential to cause harm, outside the 29 events currently captured
- Consider utilization of technology to decrease duplicative reporting and improve the ease of data collection
- Re-scope when an root cause analysis and corrective action plan must be submitted to MDH
- Better allow for shared learning dissemination statewide

In the coming months, MDH and the project steering team will continue to work with a broad group of stakeholders to gather input on the initial recommendations, shape and revise them as necessary in response to that input, and identify steps needed to move towards implementation of the recommendations.

CONCLUSION

It is crucial that the millions of Minnesotans who receive care in a hospital or ambulatory surgery center in Minnesota get safe, timely and effective care. One way to ensure safer healthcare delivery is to collect data on incidents that occur that cause harm or have the potential to cause harm. The current way of collecting that data has shown to be an important tool to identify key issues from reported events, leading to the development of new best practices and statewide activity to implement those practices.

Though MDH has collected data on over 4,500 events in 16 years, we know that these events represent only a portion of the situations that can lead to unintended harm to patients: it does not capture all possible risks to patients' safety. It also does not capture all settings where healthcare is delivered in the state.

In the past several years, it has become clear that those limitations of the current system need to be addressed. Therefore, MDH has spent the last year identifying gaps in the current system and working to develop a system that would address them. Formal recommendations to MDH on ways to evolve the program are expected in late spring 2020.

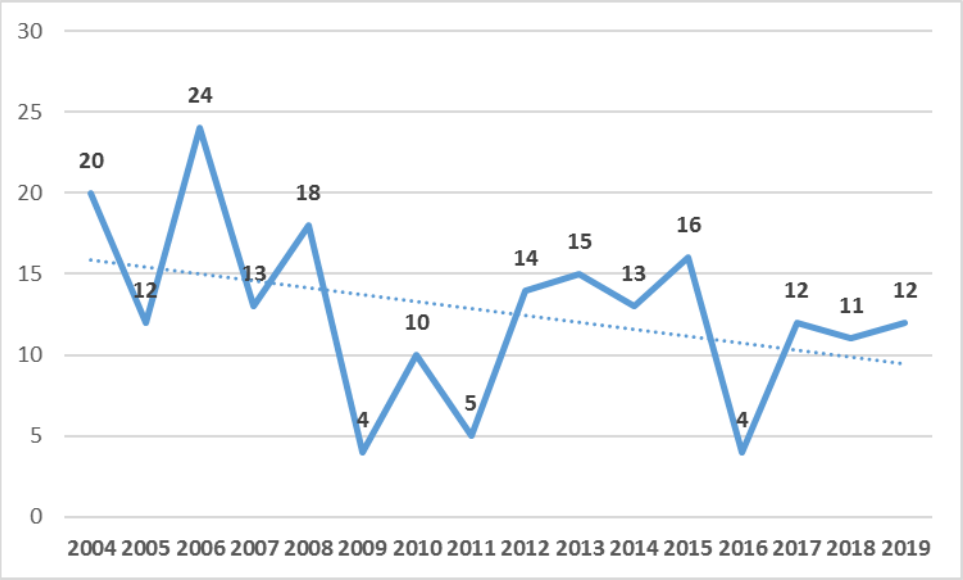
For each reporting facility, an online searchable database shows the number of events reported in each category and the level of severity of each event between October 7, 2018 and October 6, 2019. That database can be found at the website below.

https://www.health.state.mn.us/facilities/patientsafety/adverseevents/adverseselect.html

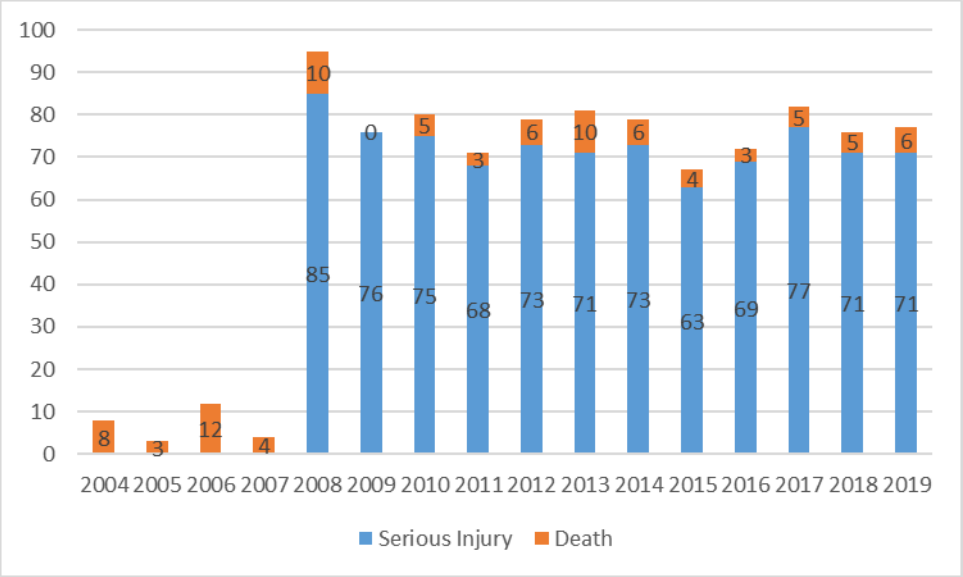
APPENDIX B: ADVERSE EVENTS DATA, 2003-2019

Hospitals began reporting adverse health events data to the Minnesota Department of Health in 2003, with ambulatory surgical centers joining the list of required reporting facilities in December 2004.

Deaths per Year, 2004-2019

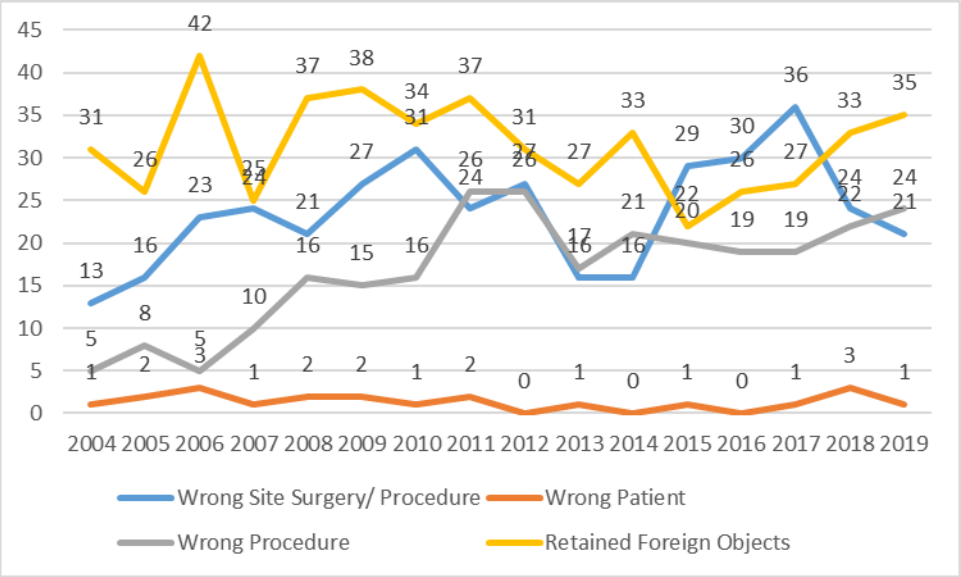


Falls per Year, 2004-2019

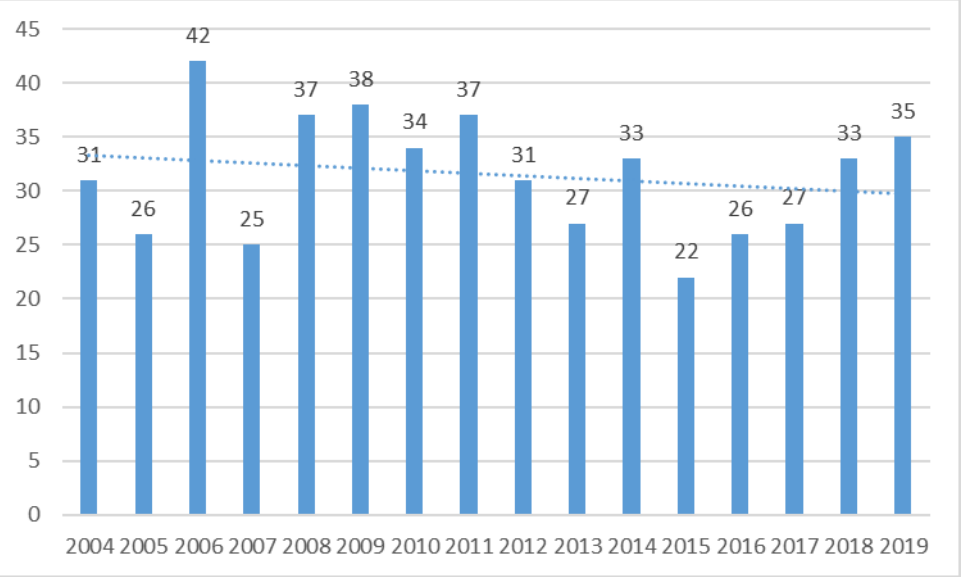


*Note, prior to 2008, facilities were only reporting falls that resulted in patient death. In 2008, the law was expanded to include falls resulting in serious injury as well.

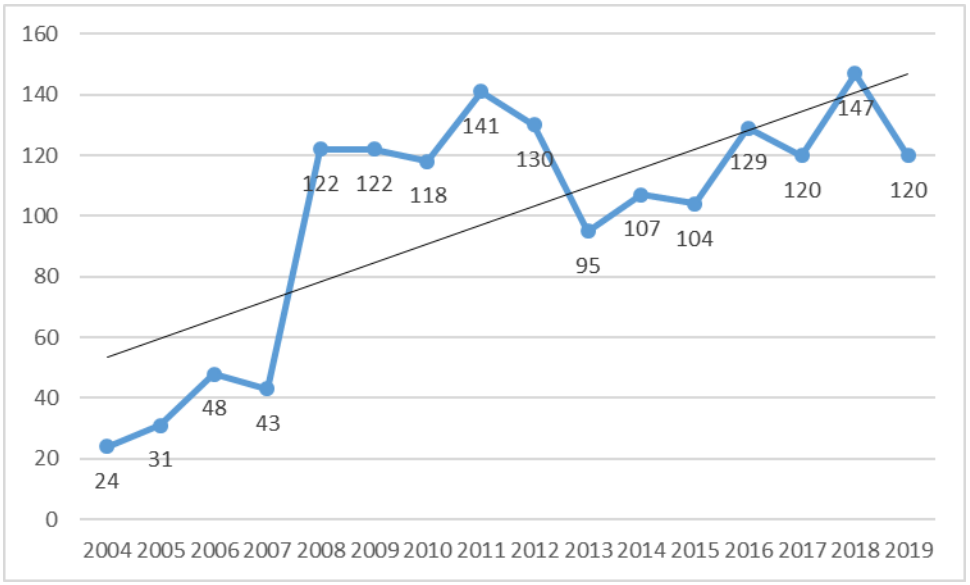
Surgical Events, 2004-2019



Retained Foreign Objects, 2004-2019 Retained Foreign Objects, 2004-2019



Reported Pressure Ulcers, 2004-2019



*Note, prior to 2008, facilities were only reporting “stage III and IV” pressure ulcers. In 2008, the law was expanded to include “unstageable” pressure ulcers.

OVERALL STATEWIDE REPORT

REPORTED ADVERSE HEALTH EVENTS: **ALL EVENTS**
(OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Surgical Events	81 Events	Death: 0, Serious Injury: 21, Neither: 60
2. Product or Device Events	19 Events	Death: 1, Serious Injury: 18, Neither: 0
3. Patient Protection Events	11 Events	Death: 1, Serious Injury: 10, Neither: 0
4. Care Management Events	246 Events	Death: 10, Serious Injury: 89, Neither: 147
5. Environmental Events	4 Event	Death: 0, Serious Injury: 4, Neither: 0
6. Potentially Criminal Events	5 Events	Death: 0, Serious Injury: 2, Neither: 3
Total for All Events	**366 Events**	**Death: 12 , Serious Injury: 143 , Neither: 211**

STATEWIDE REPORTS BY CATEGORY

DETAILS BY CATEGORY: **SURGICAL EVENTS**
(OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Wrong body part	21 Events	Death: 0, Serious Injury: 0, Neither: 21
2. Wrong Patient	1 Events	Death: 0, Serious Injury: 0, Neither: 1
3. Foreign object	35 Events	Death: 0, Serious Injury: 20, Neither: 15
4. Wrong surgical/invasive procedure performed	24 Events	Death: 0, Serious Injury:1, Neither: 23
Total Events	**81 Events**	**Death: 0, Serious Injury: 21, Neither: 60**

DETAILS BY CATEGORY: **PRODUCTS OR DEVICE EVENTS** (OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Product or device malfunction	14 Events	Death: 0, Serious Injury: 14, Neither: 0
2. Air embolism	4 Events	Death: 1, Serious Injury: 3, Neither: 0
3 Contaminated drugs, devices or biologics	1 Event	Death: 0, Serious Injury: 1, Neither: 0
Total Events	**19 Events**	**Death: 1, Serious Injury: 18, Neither: 0**

DETAILS BY CATEGORY: **PATIENT PROTECTION EVENTS** (OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Patient elopement	0 Event	Death: 0, Serious Injury: 0, Neither: 0
2. Patient suicide or attempted suicide resulting in serious injury	11 Events	Death: 1, Serious Injury: 10, Neither: 0
3. Discharge to wrong person	0 Event	Death: 0, Serious Injury: 0, Neither: 0
Total Events	**11 Events**	**Death: 1, Serious Injury: 10, Neither: 0**

DETAILS BY CATEGORY: **CARE MANAGEMENT EVENTS** (OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. A medication error	12 Events	Death: 1, Serious Injury: 11, Neither: 0
3. Labor or delivery in a low-risk pregnancy (neonatal)	4 Events	Death: 3, Serious Injury: 1, Neither: 0
4. Fall while being cared for in a facility	77 Events	Death: 5, Serious Injury: 72, Neither: 0
5. Stage 3, 4 or unstageable pressure ulcers (with or without death or serious injury)	120 Events	Death: 0, Serious Injury: 0, Neither: 120
6. Irretrievable loss of an irreplaceable biological specimen	29 Events	Death:0, Serious Injury: 1, Neither: 28
7. Patient death or serious injury resulting from the failure to follow up or communicate laboratory, pathology, or radiology test results	4 Events	Death: 0, Serious Injury: 4, Neither: 0
Total Events	**246 Events**	**Death: 10, Serious Injury: 89, Neither: 147**

DETAILS BY CATEGORY: **ENVIRONMENTAL EVENTS** (OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Death or serious injury associated with a burn	4 Events	Death: 0, Serious Injury: 4, Neither: 0

Total Events	**4 Event**	**Death: 0, Serious Injury: 4, Neither: 0**

DETAILS BY CATEGORY: **POTENTIALLY CRIMINAL EVENTS** (OCTOBER 7, 2018 – OCTOBER 6, 2019)

CATEGORY	QUANTITY	SEVERITY
1. Sexual assault on a patient	3 Events	Death: 0, Serious Injury: 0, Neither: 3
2. Death or serious injury of patient or staff from physical assault	2 Events	Death: 0, Serious Injury: 2, Neither: 0
Total Events	**5 Events**	**Death: 0, Serious Injury: 2, Neither: 3**