Maryland
DEPARTMENT OF HEALTH

Public Health Services Administration

Maryland Hospital Patient Safety Program Annual Report State Fiscal Year 2023

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Contents

Executive Summary

This is the Maryland Hospital Patient Safety Program's (MHPSP) Annual Report for Fiscal Year 2023, the 19th year of the program. The trend of increased reported events continued in FY23. This continues to be an after effect of the COVID-19 pandemic[1]. The pandemic exposed many vulnerabilities in the healthcare system, which continue to contribute to challenges that allow adverse events to occur. Adverse events are life-and function-threatening for patients. They can have a significant financial impact on hospitals and adversely affect the emotional and physical health of a hospital's workforce, leading to suboptimal performance or personnel loss.

There is a national call for a total systems approach to promote patient safety holistically. Under this total systems approach, leaders lead, the culture is strengthened, learning systems drive improvement, and patients and the workforce are safer. Just as there is a call for a total systems approach nationwide, there must be a total systems approach to improve the safety of hospitals in Maryland. The MHPSP continues to receive adverse events that are the result of poorly designed processes, workforce challenges, and environments that lack transparency in accordance with just culture principles.

Key findings in this report include:

- In FY 23, 957 adverse events were reported, including 808 Level 1 events.
- Reported Level 1 events increased by 5% from the previous year.
- Hospitals reported that 118 of 808 Level 1 events resulted in death. Of the 118 Level 1 events resulting in death, hospitals attributed only 49 of those to the reported event.
- Pressure injuries were the most frequently reported Level 1 event for FY 23, but were down 2% from FY 22.
- Falls are the second most reported event in FY 23, with a 22% increase from FY 22.

These key findings have informed the recommendations contained in this report, including:

- Ensure a workforce environment where staff feel empowered to speak up at every level.
- Ensure a just culture striving for zero harm.
- Prioritize safety using a total systems approach utilizing tactics and strategies proposed by the National Steering Committee for Patient Safety (NSC).

Patient safety is based on a just culture that emphasizes process improvement, identifies the root of the problem, and develops the best solutions. Solutions focus on improving the system rather than the person who made the error. With a just culture, staff report issues, organizations are aware of system issues, systems are optimized, and patients are less likely to be harmed during care. While the increase in adverse events is concerning, a just culture encourages reporting of these events, giving us the opportunity as a state to address these findings to improve patient safety across the state.

Tennile Ramsay MS, RN, CNL, CPPS, Nursing Program Consultant, MHPSP

[1] National Steering Committee for Patient Safety. *Declaration to Advance Patient Safety*. Boston: Institute for Healthcare Improvement; May2022. (Available at www.ihi.org)

Advancement of Patient Safety

A Call to Advance Patient Safety

In May of 2022, the Institute for Healthcare Improvement (IHI) released the Declaration to Advance Patient Safety. The declaration is the result of the collaboration of 27 national organizations committed to hospital safety that form the National Steering Committee for Patient Safety (NSC). The declaration provides guidance for organizations to strengthen the systematic improvement of safety for patients. The report is in response to worsening health outcomes nationwide that have persisted since the COVID-19 pandemic. The COVID-19 pandemic exposed vulnerabilities in a complex healthcare system. These vulnerabilities impact four functional areas that should be prioritized for improving safety across the health care continuum.[2] These include:

1. Culture, Leadership, and Governance
2. Workforce Safety
3. Patient and Family Engagement
4. Learning System

Improvement efforts across these four functional areas form a total systems approach to safety. These components support learning systems by establishing a culture of transparency along with continuous learning and improvement. The Culture, Leadership, and Governance component demonstrates leadership commitment to safety through enrichment of patient safety culture. The culture is strengthened by the addition of engagement with patients and families. Patient and Family Engagement is essential to ensure a care partnership that optimizes system design, care delivery, and patient-centered operational excellence. Organizations must ensure the safety of staff for a thriving and resilient healthcare workforce. This engagement supports and protects workers while ensuring an environment that is conducive to exceptional care delivery and a strong safety culture.

In addition to the four functional areas, the NSC identified a need to evaluate the relationship between patient safety and health equity. There is evidence that inequities exist with concentrations of harm in specific population groups surrounding race, ethnicity, sexual orientation, gender, age, disability, and income. These factors should be considered when taking a total systems approach to improving safety.

Under the total systems approach, leaders are asked to review the 17 recommendations and strategies developed by the NSC, identify senior leadership sponsors, and establish specific strategies and measurements to improve the organization's safety. A total systems approach is needed in Maryland that spans across all hospitals.

[2] National Steering Committee for Patient Safety. *Declaration to Advance Patient Safety*. Boston: Institute for Healthcare Improvement; May2022. (Available at www.ihi.org)

Since the inception of the MHPSP in March 2004, the program has tracked patient safety events reported by Maryland hospitals. During the COVID-19 pandemic, Maryland hospitals navigated challenges with changes in workflow, limited supplies, and a declining workforce.[3] Both the volume of patients, acuity, and diagnoses also changed. Many of the quality and risk professionals who worked in the hospital's patient safety program were called upon to serve on the front lines to provide patient care. Despite these additional duties, these patient safety professionals made time to report events to the MHPSP. The reported events in Maryland and across the nation demonstrate worsening patient safety since the COVID-19 pandemic. This reporting brings visibility and the opportunity to address these safety issues in accordance with a just culture approach.

Workforce Safety

There have been numerous surveys and reports of clinician burnout and depression since the COVID-19 pandemic started. A 2022 survey of more than 13,000 physicians and 29 specialties reported that 47 percent of the respondents identified as feeling burned out, and 21 percent reported suffering from depression. Additionally, burnout among healthcare workers in the United States has been reported at rates up to 76 percent. One survey noted that 75 percent of nurses reported feeling stressed, and 62 percent reported feeling overwhelmed.[4] Compared to data from 2019, in 2021, Press Gainey identified a performance decline in staffing and reasonable job stress measures[5]. From an equity standpoint, a national study identified the highest stress scores during the pandemic among females and racial minorities. Much of this is due to a declining workforce amidst high patient acuity in the health care system.

In August 2022, the Maryland Hospital Association released the State of Maryland's Healthcare Workforce report.[6] The report noted that one in every four hospital nursing positions is vacant. By 2035, it is anticipated that an additional 13,800 nurses are needed in Maryland. The report indicated 62 percent of Maryland Board of Nursing's licensees and certificate holders that were surveyed have considered leaving nursing due to burnout, feeling overworked, and feeling unappreciated. In alignment with the national work force survey, the Maryland statistics indicate the need to promote workforce well-being, physical safety, and psychological safety.

Workplace violence can often be a concern for the healthcare workforce. According to the Bureau of Labor Statistics, healthcare workers are the second highest occupation to experience workplace violence, next to law enforcement.[7] Many national organizations have identified workplace safety as a priority. The National Quality Forum (NQF) defines death or serious injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of health care setting as a “never event”. The American Hospital Association (AHA)

[3] psnet.ahrq.gov/perspective/ahrq-psnet-annual-perspective-impact-covid-19-pandemic-patient-safety#
[4] ihi.org/initiatives/national-steering-committee-patient-safety/national-action-plan-advance-patient-safety
[5] ihi.org/initiatives/national-steering-committee-patient-safety/national-action-plan-advance-patient-safety
[6] mhaonline.org/docs/default-source/default-document-library/2022-state-of-maryland-s-health-care-workforce-report.pdf
[7] Bureau of Labor Statistics, U.S. Department of Labor, *The Economics Daily*, Workplace violence: homicides and nonfatal intentional injuries by another person in 2020
bls.gov/opub/ted/2022/workplace-violence-homicides-and-nonfatal-intentional-injuries-by-another-person-in-2020.htm

noted an increase in workplace violence experienced by the healthcare workforce. AHA advocates for federal protections for workforce safety.[8] In January 2022, The Joint Commission (TJC) required organizations to develop and enforce a workplace violence prevention program. Workforce safety emerged as ECRI's number two priority of patient safety concerns in 2023.[9] As the national patient safety steering committee noted, healthcare workers who are safe are more likely to think, act, and practice in a safe way which ensures the safety of patients across the health care continuum.

Culture, Leadership, and Governance

The NSC recommends governing boards and CEOs of healthcare organizations establish a strong culture of safety by engaging patients and families along with the health care workforce. One of the key strategies recommended by the NSC is to build a strong safety culture by implementing the practices of a just culture. A just culture is a system of shared accountability in which organizations are accountable for the systems and working environment while the staff are accountable for their actions.[10] This model of accountability, developed by David Marx[11]focuses on three behaviors:

1. Human error: inadvertently completing the wrong action; a slip, a lapse, or mistake.
2. At-risk behavior: behaving in a way that increases risk, not recognizing risk, or mistakenly believing that a risk is justified.
3. Reckless behavior: choosing to consciously disregard a substantial and unjustifiable risk.

Each of the three types of behaviors has a corresponding response. Under the just culture model, human error is consoled, risk behavior is coached, and reckless behavior is disciplined.

A just culture emphasizes process improvement, which helps to identify the root of the problem and develop the best solutions. Solutions focus on improving the system rather than the person who made the error. Process improvement recognizes that a similar person of equal experience and training in the same circumstance could make the same mistake. Having a just culture related to patient safety does not preclude individual discipline. Without a just culture, staff do not report issues, organizations are not aware of system issues, the system isn't optimized, and patients are more likely to be harmed during care.

The MHPSP regulations require hospitals to designate an employee as the Patient Safety Coordinator. Patient safety requires a hospital-wide effort that starts with the Board of Directors. The Code of Maryland Regulations (COMAR) 10.07.06.03.B(3) requires a hospital's governing body to develop a process to review the hospital's patient safety program and to determine its effectiveness. Both the Centers for Medicare & Medicaid Services (CMS) and TJC require that the medical staff and governing body are included in hospital-wide patient safety and quality activities.

[8] aha.org/fact-sheets/2023-04-19-fact-sheet-workplace-violence-and-intimidation-and-need-federal-legislative-response
[9] ecri.org/top-10-patient-safety-concerns-2023-special-report
[10] ahrq.gov/hai/cusp/modules/apply/ac-cusp.html
[11] justculture.com/david-marx-j-d/

A hospital's leadership must demonstrate a commitment to patient safety by:

- Providing executive sponsorship to address adverse events;
- Providing regular reports regarding adverse events to the Board and other executive level committees;
- Telling patient stories by describing what happened or failed to happen that resulted in harm;
- Celebrating successes and adverse events that were avoided or mitigated;
- Educating staff and leaders at all levels about the hospital's patient safety program;
- Emphasizing the importance of reporting potential and actual harm;
- Establishing patient safety goals and monitoring the hospital's performance; and
- Supporting staff alignment with just culture principles.

The quality activities listed above from COMAR 10.07.06.03B(3) align with the recommendations and strategies listed in the national action plan to advance patient safety.

Learning Systems

Learning systems foster improvement by systematically evaluating data, assessing best practices, and considering the latest scientific evidence to improve care. The NSC urges organizations to commit to continuous learning by promoting transparency and collaborative learning in accordance with high reliability principles. High reliability principles include a preoccupation with failure, reluctance to simplify, sensitivity to operations, deference to expertise, and commitment to resilience.

Preoccupation with failure refers to everyone in the organization being aware of and considering potential failures that can occur throughout the health system. No matter their role, everyone has a heightened sense of awareness. People within the organization consider what can go wrong and are more likely to identify events that could have occurred but did not. Organizations view such situations as an opportunity to learn and to improve before a situation occurs and impacts a person.

Reluctance to simplify refers to the level of willingness to collect, analyze, and act on all warning signs that something may be wrong and to avoid making unwarranted assumptions regarding the causes of failure.

Organizations that are sensitive to operations understand and appreciate the organization's complexity. They are aware of the state of the systems and processes that impact patient care, thereby enabling the timely identification of errors and improved processes throughout the organization.

High reliability organizations recognize that the people closest to the job are the most familiar with the processes that they work under. They defer to expertise by seeking out the most knowledgeable people regarding those processes, regardless of seniority or career level.

When things fail, high reliability organizations are prepared to change course and adapt because of their commitment to resilience. They anticipate problems and respond quickly to situations to minimize errors and harm.

Defining Adverse Events in Maryland

COMAR 10.07.06.02B(2) defines an "adverse event" as an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition. COMAR defines "near miss" as a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

Maryland Classification of Adverse Events

The MHPSP describes three levels of events:

- Level 1: an adverse event that results in death or serious disability;
- Level 2: an adverse event that requires a medical intervention to prevent death or serious disability; and
- Level 3: an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability.

Serious disability is defined as a physical or mental impairment that substantially limits one or more of the major life activities of an individual, lasting more than seven days or that is still present at the time of discharge.

Level 1 events traditionally have included the NQF's “Serious Reportable Events,”[12] also known as “never events” in the taxonomy of adverse events. This nationally recognized classification system, which several states use, enables MHPSP to compare its data with other state reporting systems. Because the MHPSP focuses on patient outcomes and does not define or limit the types of events reported by hospitals, it has supplemented the NQF list with other types of frequently reported events. These additional classifications include:

- Death or serious disability related to the use of anticoagulants;
- Death or serious disability resulting from an unanticipated complication; and
- Death or serious disability related to a delay in treatment.

Level 1 adverse events also include TJC's definition of a sentinel event. A sentinel event is a patient safety event that may result in death, permanent harm, severe temporary harm, and intervention required to sustain life.[13] TJC identifies 18 sentinel events.[14] Organizations accredited by TJC may voluntarily report sentinel events. However, organizational culture and leadership influence whether the organization reports these events to TJC. Therefore, the MHPSP's mandatory reporting of Level 1 events plays an important role in ensuring the safety of patients.

[12] qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre4
[13] jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf
[14] jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

Overview of the Maryland Hospital Patient Safety Program

In response to the Institute of Medicine report To Err is Human,[15] Maryland established the MHPSP in March 2004. Health-General Article, §§19-308 and 19-319, Annotated Code of Maryland, authorized the development of regulations to establish and implement a hospital patient safety program. COMAR 10.07.06 focuses on creating a safe patient care environment. Hospitals must identify adverse events and are expected to report near misses. The MHPSP additionally requires disclosure to patients and families.

The MHPSP website is at health.maryland.gov/ohcq/Pages/Patient-Safety.aspx and includes links to patient safety forms, hospital tools, clinical alerts, and annual patient safety reports.

The hospital's patient safety coordinator or members of the risk management team review and triage reported events to determine the level under the MHPSP. Events are classified as Level 1, Level 2, Level 3, near miss, or not reportable. COMAR 10.07.06.09A requires hospitals to self-report any Level 1 adverse event by submitting the initial notification to the MHPSP within five days of the hospital's knowledge that the event occurred.

Root Cause Analysis

COMAR 10.07.06 requires a hospital to submit a root cause analysis (RCA) for all Level 1 events to the MHPSP within 60 days. An RCA is a process improvement tool defined by COMAR 10.07.06.02 as a medical review committee process for identifying the basic or contributory causal factors that underlie variations in performance associated with adverse events or near-misses.[16] The RCA includes an in-depth review of the event by a multi-disciplinary team of individuals. COMAR 10.07.06.06 states:

> "C. The root cause analysis shall examine the cause and effect of the event through an impartial process by:
> (1) Analysis of human and other factors;
> (2) Analysis of related processes and systems;
> (3) Analysis of underlying cause and effect systems through a series of "why" questions; and
> (4) Identification of risks and possible contributing factors."

Consistent with a just culture environment and Maryland regulations, RCAs and any other medical review committee information are not discoverable, disclosable, or admissible as evidence in civil actions. COMAR 10.07.06.09C states:

> "C. Any root cause analysis and any other medical review committee information submitted to the Department and the identity of individuals appointed to the interdisciplinary root cause analysis team are confidential under Health Occupations Article, §1-401, Annotated Code of Maryland and are not discoverable, disclosable, or

[15] Institute of Medicine. 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. https://doi.org/10.17226/9728.
[16] COMAR 10.07.06.02(B)(10).

admissible as evidence in any civil action or available under the Maryland Public Information Act."

Hospitals may submit RCAs using their chosen framework that complies with the requirements in COMAR. This may be the TJC RCA framework or one that the organization has developed internally. The submitted RCA must include the following components:

- Timeline;
- Framework;
- Cause-and-effect diagram (such as an Ishikawa or fishbone diagram);
- Process flow documents showing what happened, what should have happened, and the plan to fix it;
- Clearly identified root cause and contributing factors; and
- An action plan with measurable action items.

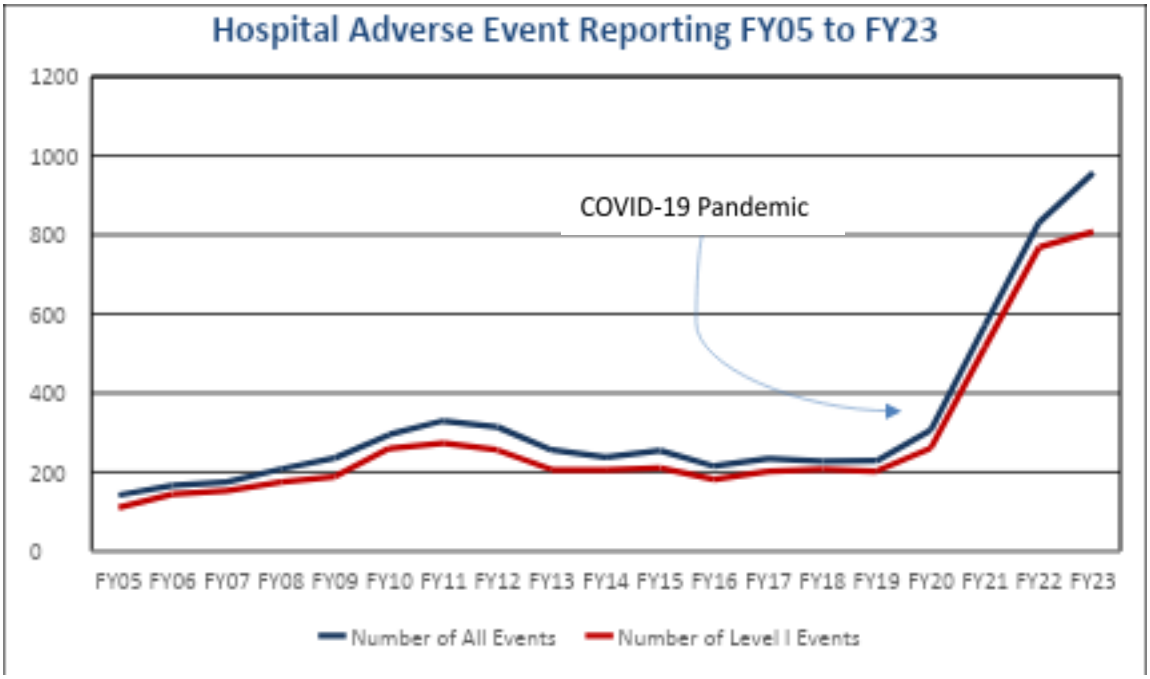
MHPSP provides RCA short forms for high frequency events, including hospital acquired pressure injuries (HAPI) and falls. A hospital may use the short form in lieu of their own RCA. If an RCA fails to meet one or all of the requirements of COMAR 10.07.06, MHPSP may send the hospital an extended RCA review that identifies specific areas of noncompliance with COMAR requirements and provides guidance for improving the quality of future RCAs.

FY23 Adverse Event Reporting

FY23 Summary of Reported Events

Since 2020, the number of reported events to the MHPSP has increased each year. See Figure 1 below. There was a 5% increase in Level 1 reporting in FY23 compared to FY22. There was a significant increase in reported events during the COVID-19 pandemic, with a 91% increase in FY21 and a 56% percent increase in FY22. In FY23, hospitals reported 957 events, with 808 of the events meeting the criteria for a Level 1 event. Hospitals reported that 118 of the 808 Level 1 events resulted in death. Of the 118 Level 1 events where the patient died, hospitals attributed only 49 of the deaths to the reported event.

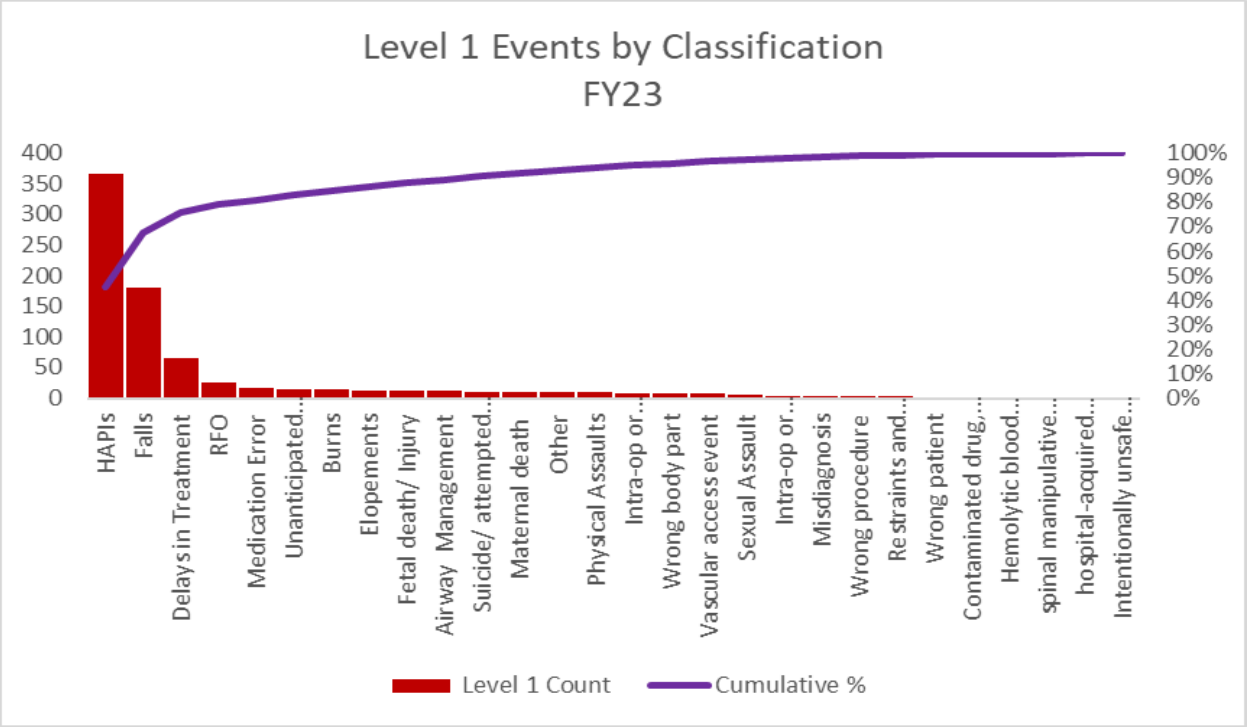
Figure 1: Hospital Adverse Event Reporting FY05 to FY23



Classification of Events

In FY23, 80 percent of the events were categorized as (1) HAPIs, (2) falls, (3) delays in treatment, (4) retained foreign objects, and (5) medication errors. Since the start of the COVID-19 pandemic, pressure injuries, falls, and delays in treatment have consistently been in the top three most frequently reported events. This is the first year since the start of the COVID-19 pandemic that medication errors have fallen within the top five categories. HAPIs, falls, and delays in treatment constitute the vast majority of reported events, as seen in Figure 2.

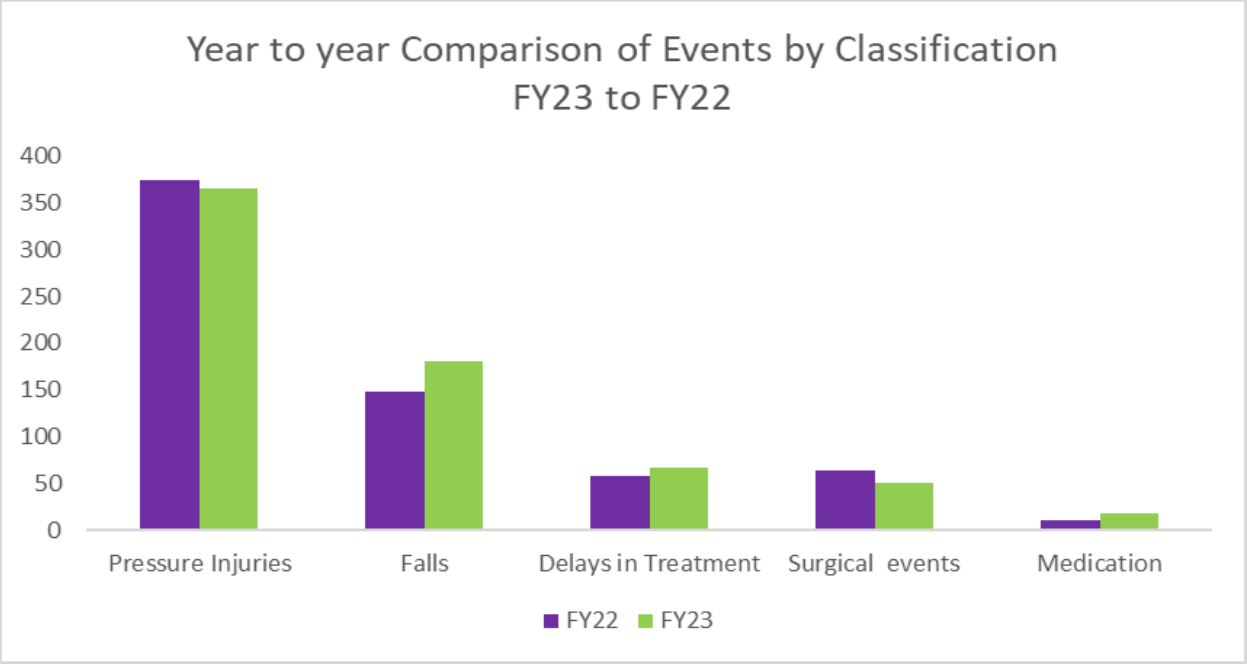
Figure 2: Level 1 FY23 Events by Classification



Comparison of Event by Classification in FY22 and FY23

As compared to FY22, in FY23, there was a 2% percent decrease in reported pressure injuries; a 22 percent increase in the number of reported falls; and a 16 percent increase in the number of reported delays in treatment.

Figure 3: FY22 to FY23 Comparison of Top 5 Events by Classification



Pressure Injuries

Since the start of the COVID-19 pandemic, there has been an increase in pressure injuries in healthcare settings. This is multifactorial but is driven largely by the COVID-19 pandemic that resulted in staffing challenges, supply chain issues, patients with multiple comorbidities, and higher patient acuity. Of note, improved reporting of unstaged pressure ulcers also contributed to the increase in pressure injuries reported. Additional reinforcement of the pressure injury reporting requirements has occurred at the OHCQ update at each Maryland Patient Safety Conference and the Maryland Healthcare Education Institute (MHEI) since April 2021.

Turning and positioning has long been a key strategy in pressure injury prevention. The National Pressure Injury Advisory Panel (NPIAP) published a position paper discussing unavoidable pressure injuries during COVID-19. Patients with COVID-19 may experience hypercoagulopathy and corresponding skin changes. These skin changes appear discolored and can quickly become necrotic. They mimic the appearance of deep tissue pressure injury (DTPI), especially when they occur under medical devices or over tissue exposed to pressure and/or shearing, such as the sacrum, buttocks, and heels. In addition, NPIAP discusses true pressure injuries that rapidly deteriorate from microvascular thrombosis caused by the COVID-19 virus.

The NQF considers a HAPI to be a never event. A HAPI is “any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission or presentation to a health care setting.” The criteria for reportable HAPIs under the MHPSP are based on the NQF definition. Hospitals must report all HAPIs except:

- Injuries that progress from wounds identified at admission and acquired pre-admission;

- Deep tissue injuries (DTIs), unless these evolve into or are debrided into Stage III or IV open wounds; and
- Kennedy ulcers that arise during the hypo-perfusion state in the 24 to 48 hours prior to death.

The MHPSP's definition is based on the NQF definition for a serious reportable event (never event), which includes Stage 3, Stage 4, and unstageable pressure injuries. Stage 3 and Stage 4 pressure ulcers are defined by wound depth relative to the underlying structure of bone and tendon. Unstageable pressure injuries are serious reportable events because they are Stage 3 or Stage 4 pressure injuries obscured by slough or eschar.[17] Note that in FY22, there was an increase in the number of reported HAPIs that was in part due to educating hospitals about pressure ulcer terminology.

Common Factors in HAPI Events

Common factors in HAPI events include:

- Failure to turn and reposition patients with limited mobility.
- Failure to use preventative measures.
- Failure to utilize barrier creams.
- Failure to use devices to offload pressure with devices or equipment, such as a specialty hospital bed.
- Failure to assess skin under devices.
- Failure to address the patient's nutrition status.
- Failure to consider the impact of comorbidities on the skin, including COVID-19.

Lessons learned and considerations for hospitals include:

- Thorough skin assessments are required, including assessing the skin under tubing and devices.
- Medical tubes and devices cause 30 percent of in-hospital pressure injuries.[18] Proper positioning and securing of medical tubes and devices is crucial to pressure injury prevention.
- Placing multi-layer foam dressings on bony prominences, such as forehead, chin, cheekbones, bridge of the nose, collarbones, hips, and knees prior to proning reduces risk of pressure injury.

Falls

The Agency for Healthcare Research and Quality (AHRQ) reports that more than one-third of hospital falls result in injury, including serious injuries such as fractures and head trauma. Fall prevention in a hospital is a balance between managing a patient's underlying fall risk factors and enabling the patient to maintain autonomy while adapting to the unfamiliar hospital

[17] https://cdn.ymaws.com/npiap.com/resource/resmgr/online_store/npiap_pressure_injury_stages.pdf

[18] Bakarat-Johnson, M., Carey, R., Coleman, K., Counter, K., Hocking, K., Leong, T., Levido, A., Coyer, F. (2020). Pressure injury prevention for COVID-19 patients in a prone position. *Wound Practice and Research.* Vol. 28(2).

environment. Common risk factors for falls include difficulty with walking, need for assistance with transfers, medication side effects, confusion, and frequent toileting needs.

Falls are multifactorial, but can be associated with deficits in assessment of patient risk, tailored interventions, communications, or human factors, such as staff forgetting to implement or re-engage interventions. Frail and impaired patients may overestimate their physical capability in the hospital environment. Fall event reporting increased from 148 in FY22 to 180 in FY23.

Fall with Subdural Hematoma

A patient was transferred from an outside hospital with acute leukemia, a stable subdural hematoma, and disseminated intravascular coagulopathy (DIC). Nursing staff assessed the patient as a standard fall risk. The patient had no prior falls history. The patient had sudden urinary and fecal incontinence while walking to the bathroom, then slipped and fell. The patient struck the back of the head on a closet door. When the nurse returned to the room to obtain labs and assess vital signs, they found the patient on the floor. An immediate post fall assessment was completed and a Computed Tomography (CT) of the head was ordered. There was a 30-minute wait for CT scanner availability. During CT testing, the patient demonstrated increased neurological deficits, becoming nonverbal and only responding to painful stimuli. An initial read of the CT revealed a worsening left-sided intracranial hemorrhage with likely new acute left frontal hemorrhage and new midline shift. The patient's spouse was notified.

The RCA noted that the patient was inaccurately assessed as a standard fall risk. The patient was high-risk due to their diagnosis, comorbidities, and medications. The patient had an IV running, and it was believed the IV pole was a factor in the fall. Since the patient's risk for falls was not assessed accurately, appropriate interventions were not in place, such as a room closer to the nursing station or the use of a bed alarm.

Lessons learned and considerations for hospitals include:

- The initial fall risk assessment is crucial in determining appropriate preventive measures and interventions for the patient.
- Engage the patient and family in the fall prevention process.
- Head injuries may require serial diagnostics as they may not be originally detected.
- Interventions must be tailored to the patient. Staff should ensure that the right strategies are used for each patient.
- In care planning, include strategies to be used when traveling off the unit if a tele-sitter is in use.
- Ensure beds, alarms, and other equipment are operational.

Delays in Treatment

Delays in treatment are the third highest reported event to the MHPSP. These may occur due to inadequate assessments, communication failures, or human factors, such as timely diagnostic testing, labs, and imaging. The ECRI Institute identified a missed or delayed diagnosis as the number one patient safety concern in 2020. In 2023, ECRI listed delayed identification and

treatment of sepsis as the number 5 patient safety concern. ECRI noted that 1.7 million Americans develop sepsis with a 30 percent mortality rate.

In a systematic review of 40 years of autopsy reports, the Agency for Healthcare Research and Quality (AHRQ) identified that 9 percent of patients died from an undiagnosed condition.

Diagnostic errors or omissions have various cognitive and systemic causes. They are influenced by communication, access to pertinent information, and decision support systems. MHPSP has found that, like most adverse events, diagnostic and treatment delays are multidisciplinary and multifactorial. These should generally be viewed as system or process defects, instead of the responsibility of an individual provider.

Delay in Treatment

A patient presented to the Emergency Department with intermittent chest pain and elevated cardiac markers. The patient was diagnosed with non-ST elevation myocardial infarction (NSTEMI). A subsequent EKG indicated ST-elevation myocardial infarction (STEMI). The Emergency Department provider consulted with a cardiologist, who did not feel that the activation of the cardiac catheterization team was needed at that time. The Emergency Department provider ordered medications that were appropriate for the patient, but there was a two-to-three-hour delay in administering medication.

The patient had further EKG changes that were not communicated to the cardiologist. The patient went into cardiogenic shock and was urgently taken to the cardiac catheterization lab (cath lab). The patient experienced a cardiac arrest in the cath lab and was transferred to another facility for a higher level of care.

The RCA revealed a staff call out resulted in a nurse not being assigned to the patient in the Emergency Department. With no assigned nurse, there was a delay in medication administration in the Emergency Department. While the original Emergency Department provider recognized the evolving STEMI, subsequent providers did not. Based on the patient's EKG changes, cardiology should have been re-consulted by the subsequent emergency provider.

Lessons learned and considerations for hospitals include:

- Communicate changes in condition timely.
- Ensure that every patient has an assigned nurse.
- Ensure that all necessary information is included in the handoff of patients.
- Foster an environment and culture where staff are comfortable to speak up and escalate through the chain of command if needed.

Retained Foreign Objects and Other Surgical Events

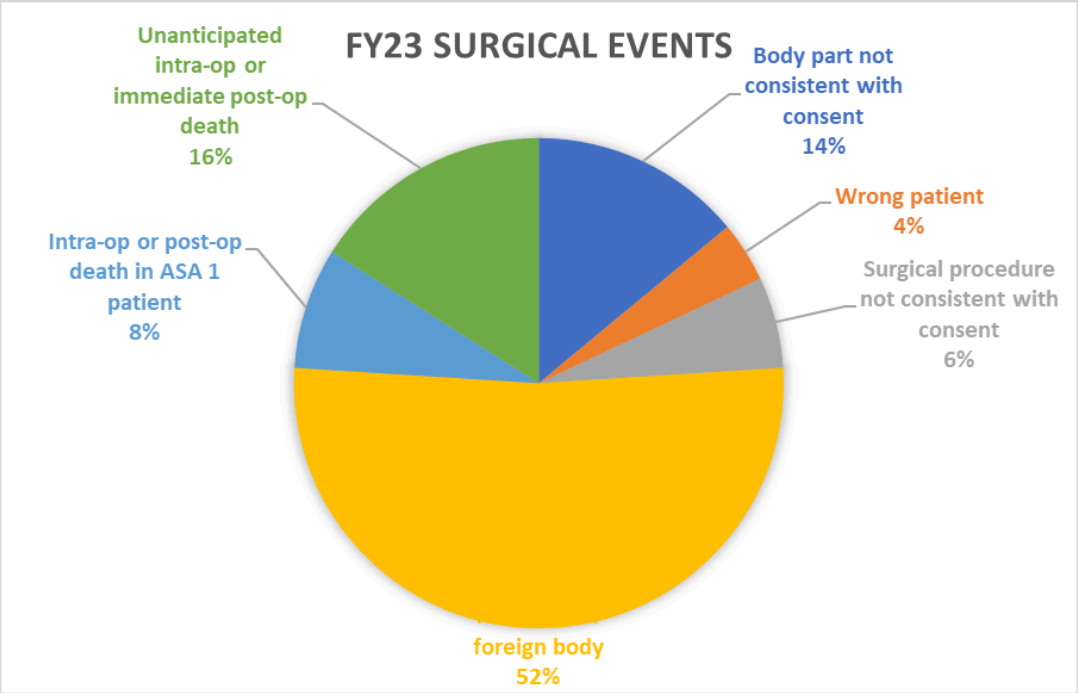
The most frequent surgical event reported to the MHPSP is unintended retained foreign objects (RFO). These events can cause death, prevent wound healing, and cause physical and emotional

harm. TJC released Sentinel Event Alert 51 in October 2013 focused on RFO.[19] Sentinel event alerts are significant in that they make accredited organizations aware of sentinel events that are frequently reported to TJC and include specific considerations for redesigning processes and implementing reasonable alternatives to prevent such events from occurring.

Like TJC, the MHPSP has also received reports of RFOs. These objects include sponges, towels, unretrieved devices, stapler components, guidewires, catheters, needles, and other sharps. In FY23, 52 percent of the Level 1 surgical events involved retained foreign objects.

Intraoperative (intra-op) or immediate post-operative (post-op) deaths are the next highest reported events in the surgical events category. The American Society of Anesthesiologists defines the classification of ASA 1 as normal healthy patients. NQF considers post-op deaths of ASA 1 patients as a never event. The MHPSP requires the report of intra-op and immediate post-op deaths.

Figure 3: FY23 Surgical Events by Category



Retained Clamp

A patient underwent a procedure for part one of arteriovenous fistula formation. The procedure was completed without any known complications. In less than 60 days, the patient returned for the second part of the procedure. A pre-procedure ultrasound noted a foreign object. The original incision was opened and revealed a retained bulldog clamp. The clamp was removed and sent to pathology. An additional incision was made, and part two of the fistula formation

[19] https://www.jointcommission.org/resources/sentinel-event/sentinel-event-alert-newsletters/sentinel-event-alert-issue-51-preventing-unintended-retained-foreign-objects

was successfully completed. The RCA revealed that while the sponges and cloths were counted at the end of the procedure, the pieces of equipment, including clamps, were not counted.

Lessons learned and considerations for hospitals include:

- Count every item that goes into the body that should come out.
- Clearly define roles and responsibilities, including backup when needed.
- Empower staff to speak up and advocate for accurate counts of equipment and parts.

Medication Errors

According to the World Health Organization (WHO), medication errors are the leading cause of avoidable harm in healthcare.[20] Medication errors account for an estimated $42 billion annually in added health care costs. The analysis of medication errors focuses on the five rights of administration- right patient, right drug, right dose, right route, and right time. In 2023, ECRI listed the risk of not looking beyond the five rights to achieve medication safety as the number 7 patient safety concern.[21] One of the common causal factors identified in the review of medication errors is the failure to follow the five rights. Additionally, system and process failures must be considered and addressed as common contributing factors to medication errors. Often, medication errors occur as a result of not having an accurate medication list. ECRI listed medication errors resulting from inaccurate patient medication lists as the number 8 patient safety concern for 2023. Medication reconciliation errors occur in 36 percent of patients when initially obtaining the patient's medication list. Unfortunately, discrepancies and inaccuracies can persist all the way to discharge, with 91 percent of the errors being clinically significant.

Medication Omission Due to Interhospital Transfer for Procedure

A patient was admitted for a myocardial infarction and management of malignant hypertension. Subsequently, the patient was transferred from hospital #1 to hospital #2 to undergo cardiac catheterization. The patient had a successful procedure and was ordered dual antiplatelet therapy with Plavix and aspirin. The provider at hospital #2 electronically prescribed Plavix prior to the patient being transferred back to hospital #1. When the patient was stable, they were discharged home.

Five days later, the patient returned to hospital #1's Emergency Department with complaints of the sudden onset of chest pressure with shortness of breath. When questioned about home medications, the family reported the patient was taking baby aspirin. An EKG revealed the patient was having an ST-elevation myocardial infarction. The patient was emergently taken to the cardiac catheterization lab. The procedure showed the occlusion of the main blood vessel that was previously treated five days prior. This occlusion was likely due to the absence of dual antiplatelet therapy. While in the Cath Lab, the patient went into cardiac arrest. Resuscitation was initiated, and the patient was transferred to hospital #2 for a higher level of care.

[20] https://www.who.int/initiatives/medication-without-harm
[21] https://www.ecri.org/top-10-patient-safety-concerns-2023-special-report

The RCA identified that the original Plavix order was entered electronically at hospital #2 and subsequently appeared as a home medication in the electronic record when the patient was transferred back to hospital #1. Although the medication was started at hospital #1, after returning from the procedure, it was not prescribed at discharge.

Lessons learned and considerations for hospitals include:

- Address organizational and system factors that contribute to medication errors.
- Standardize the medication reconciliation process.
- Identify and address gaps within the system that may exist due to inter-hospital transfers for procedures and testing.
- Engage the patient and family, as appropriate, when prescribing new medications and prior to prescribing discharge medications.
- Ensure the patient understands the reasons for the medications on the home medication list.

Other Significant Events

Oxygen Management

A patient was transferred from another facility with a small bowel obstruction complicated by a cardiac arrhythmia. The patient had a tracheostomy that was to remain in place until thyroid surgery. The patient had been previously on a ventilator but was able to transition to oxygen using a tracheostomy collar. The patient was ordered for diagnostic testing, and transport was requested by the technician after a call with the primary nurse. The patient arrived for testing with the tracheostomy collar attached to a 15-liter venturi oxygen setup.

Once the testing was completed, the patient was transported back to the unit. The primary nurse noted the patient was slouched in bed with a thready pulse. A rapid response was called, which progressed to full resuscitation efforts. The patient could not be resuscitated, and time of death was called.

The RCA noted that staff were not readily aware of the oxygen management policy that was in place. Additionally, the oxygen cylinder supply time guide was attached to the oxygen cylinder, but the staff was not aware of the supply time guide. There was a lack of transport coordination and communication for proper management of the venturi setup for the oxygen dependent patient. Additionally, the technician failed to transfer the oxygen from the tank to the wall in the diagnostic area. This resulted in the oxygen cylinder running out during the duration of testing and transport back to the unit.

Lessons learned and considerations for hospitals include:

- Ensure oxygen management policies are clear, accessible, and consistently reinforced through training.
- Require staff to verify oxygen levels and equipment functionality before patient transport.

- Use handoff tools to communicate critical information about patient needs during transport and diagnostic procedures.
- Provide regular education on oxygen management, tracheostomy care, and transport safety protocols.
- Consider portable oxygen monitors or alarms to prevent oxygen depletion during transport.

Summary

A need to advance patient safety post pandemic must continue to be a priority. Leadership commitment to safety through the enrichment of patient safety culture requires a total systems approach. Workforce challenges must be addressed as a factor impacting care delivery in operational excellence. Processes must be evaluated to eliminate gaps that allow opportunity for error. The various and lingering challenges from the pandemic continue and must be considered in ongoing patient safety efforts.

Together, providers, MHPSP, and other stakeholders must continue to strive toward improving systems, processes, and organizational culture to ensure higher reliability and safety for patients receiving hospital care throughout Maryland.

Appendix A: Classification of Events*

1A. Body part not consistent with consent
1B. Wrong patient
1C. Surgical procedure not consistent with consent
1D. Post-surgical retention of foreign body
1E. Intra-op or post-op death in ASA 1 patient
1F. Unanticipated intra-op or immediate post-op death
2A. Contaminated drug, device, or biologic
2B. Malfunctioning device
2C. Intravascular air embolism
2D. Infrastructure failure
2E. Death or serious disability associated with the use of a vascular access device
3A. Infant discharged to wrong person
3B. Patient elopement
3C. Suicide or attempted suicide resulting in serious disability
4A. Death or serious disability associated with medication error
4B. Hemolytic blood reaction due to administering ABO-incompatible blood or blood products
4C. Maternal death or serious injury associated with labor or delivery
4D. Death or serious disability associated with hypoglycemia
4E. Death or serious disability associated with failure to diagnose or treat hyperbilirubinemia in neonate
4F. Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission
4G. Death or serious disability associated with spinal manipulative treatment
4H. Death or serious disability associated with a staff member's failure to act
4I. Death or serious disability associated with the use of anticoagulants
4J. Misdiagnosis
4K. Death or serious disability associated with a delay in treatment
4L. Death or serious disability associated with airway management
4M. Unanticipated fetal death or injury
4N. Unanticipated complication of treatment
4O. Death or serious disability associated with hospital-acquired infection
5A. Death or serious disability associated with electric shock
5B. Delivery of wrong or contaminated inhaled gas to patient
5C. Death or serious disability associated with a burn that occurred in a health care facility
5D. Death or serious disability associated with a fall
5E. Death or serious disability associated with the use of restraints, seclusion, or side rails
6A. Care ordered or provided by someone impersonating a physician, nurse or other licensed provider
6B. Patient abduction
6C. Sexual assault of a patient within or on the grounds of a facility
6D. Death or serious injury of patient or staff due to physical assault within or on facility grounds
6E. Intentionally unsafe care
6F. Abuse or neglect
6G. Other

* This list does not limit the types of reports but is how MHPSP categorizes reports.

Appendix B: Adverse Reporting and Decision Tree

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability. Serious disability is defined in COMAR 10.07.06.02B(11) as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or is present at the time of discharge.

OHCQ's Patient Safety Program continues to classify the types of Level 1 adverse events in our database using the National Quality Forum's (NQF) "Serious Reportable Events"[22] Taxonomy. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the NQF system is nationally recognized, it enables the MHPSP to compare its data with other state reporting systems. Because the Maryland Patient Safety Program is focused on patient outcomes and does not define or limit the types of events reported by hospitals, we have supplemented the NQF list with other types of frequently reported events.

These additional classifications include:

- Death or serious disability related to the use of anticoagulants;
- Death or serious disability resulting from an unanticipated complication;
- Death or serious disability related to a delay in treatment;
- Death or serious disability associated with airway management;
- Death or serious disability related to a health care-associated infection;
- Unanticipated fetal or neonatal death or injury; and
- Misdiagnosis causing death or serious disability.

A hospital shall report any Level 1 adverse event to the Department within 5 days of the hospital's knowledge that the event occurred (Date of discovery). When in doubt about whether to do an RCA for Level 3 and near misses, remember that a lot of valuable information can be gained in the process. Asking these questions may help you decide if an RCA is needed:

1. Does this event or hazard represent a substantial risk to patient safety?
2. Is the event due to faulty processes or system failures that are likely to cause a similar, perhaps more harmful event if not corrected?
3. If the hazardous condition is not corrected, is there a high probability that a sentinel or adverse event will occur?
4. Will the organization receive significant negative publicity if the cause of the event is not corrected?
5. Will failure to conduct an RCA result in deterioration of staff or physician morale and/or trust in the leadership's commitment to patient safety?

If an event is a criminal or deliberate unsafe act, consider other reporting requirements and risk management review.

[22] http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre4

Hospital acquired pressure injuries (HAPI) are reportable if Stage III, IV, or unstageable pressure ulcers are acquired after admission.

- Excludes progression from wounds acquired pre-admission as long as they were recognized at admission.
- Excludes DTIs unless these evolve into or are debrided into Stage III or IV.
- Excludes Kennedy ulcers arising in the 24-48 hour period prior to death.
- Excludes dry necrotic areas on feet from arterial insufficiency.

Within the Adverse Event Decision Tree, an event would be considered to be part of a patient's normal disease course if the untoward event arose from the patient's intrinsic condition rather than from the exogenous medical treatment. For instance, a patient goes into DIC and dies. If the patient has an underlying coagulopathy or sepsis or any other condition that caused the DIC, this would not be considered a reportable event. However, if the patient has a hemolytic transfusion reaction because of incorrect typing, goes into DIC, and dies, it is a reportable Level 1 event.

Another example is if a patient falls and develops a subdural hematoma and dies, this is a reportable Level 1 event, even if the development of the SDH was the result of an underlying coagulopathy. The patient would not have developed the SDH that killed him had he not fallen. The event is the fall, not the development of the SDH. Serious disability is defined in COMAR 10.07.06 as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or still present at the time of discharge.

Adverse Event Decision Tree