MARYLAND DEPARTMENT OF HEALTH
Office of Health Care Quality

Maryland Hospital Patient Safety Program
Annual Report
Fiscal Year 2022

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Executive Summary

On behalf of the Office of Health Care Quality (OHCQ), we are pleased to present the Maryland Hospital Patient Safety Program's Annual Report for Fiscal Year 2022, the 18th year of the program. There was a significant increase in reported events in FY22 driven in part by the COVID-19 pandemic, which has posed additional complexities and challenges to healthcare through adverse events. Adverse events are often life-and function-threatening for patients. These events can also adversely impact a hospital's finances and the emotional and physical health of a hospital's workforce, leading to suboptimal performance or personnel loss.

Most hospital adverse events are the result of poorly designed processes, policies, and long-entrenched cultural and procedural factors. The underlying causes of individual variations in performance are usually multi-factorial and multi-disciplinary. Thus, hospital patient safety is not solely the responsibility of the patient safety officer; instead, it is the responsibility of everyone with a role in the hospital and requires a collaborative effort among all hospital leadership and staff. Optimizing the culture, hospital environment, and processes to reach the highest level of safe operation requires a hospital-wide concerted effort.

Key findings in this report include:

- There were 832 adverse events with 769 meeting Level 1 event criteria reported in FY22, an increase of 52 percent in the total number of events from FY21.
- Hospital-acquired pressure injuries (HAPI) reporting increased from 184 in FY21 to 375 in FY22.
- Falls reporting increased from 136 events in FY21 to 148 in FY22.
- Surgical event reporting increased from 31 events in FY21 to 64 in FY22, with 59 percent of the events due to RFOs.

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

1. Prioritize safety at every level of the organization, starting with the Board of Directors.
2. Provide sponsorship to optimize processes to prevent system failures and common causal factors due to workforce shortages and human factors.
3. Embed high reliability principles into day-to-day activities to create a just culture with a goal of zero harm.

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Optimizing Safety in a Challenged Health Care System

Much has changed since the Institute of Medicine (IOM) published the widely quoted report *To Err is Human*.[1] The report estimated that as many as 98,000 people die annually from medical errors in hospitals. The report challenged the health care industry to reduce the disparity between the number of errors occurring in hospitals and the perception that health care professionals do not cause harm.

The Miriam Webster dictionary defines "to err is human" as meaning that it is normal for people to make mistakes. The report highlighted that while people may make mistakes, the problem is not bad people in health care, but instead it is good people working in poorly designed systems that may increase risk for mistakes. Other publications have concluded medical errors may be the third leading cause of death behind heart disease and cancer,[2] with more than 250,000 people dying annually.

The COVID-19 pandemic has had a significant adverse impact on the health care system. Healthcare organizations have faced a myriad of challenges including changes in workflows, supply constraints, and a declining workforce.[3] To reduce medical errors across the health care continuum, safety must be optimized in a challenged healthcare system to create high reliability organizations.

High Reliability Organizations Facing Workforce Challenges

The Agency for Health Care Research and Quality (AHRQ) defines high reliability organizations as organizations that operate in complex high-risk conditions for extended periods without serious accidents or catastrophic failures.[4] By making safety a priority, these organizations are resilient and can recover with real-time adjustments. High reliability organizations have a leadership commitment to (1) zero harm, (2) process improvement, and (3) a just culture.

Organizations can also be characterized by their 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 thinking about the potential failures that can occur throughout the health system. No matter their role, everyone maintains a heightened sense of awareness. People within the organization consider

[1] 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.
[2] Makary M A, Daniel M. Medical error—the third leading cause of death in the US. BMJ 2016; 353 :i2139 doi:10.1136/bmj.i2139.
[3] https://psnet.ahrq.gov/perspective/ahrq-psnet-annual-perspective-impact-covid-19-pandemic-patient-safety#
[4] https://psnet.ahrq.gov/primer/high-reliability

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 improve before they significantly impact a person.

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

Organizations that are sensitive to operations, understand and appreciate the organization's complexity including formal and informal organizational communications structures. They are aware of the state of the systems and processes that impact patient care, enabling timely identification of errors and processes for improvement 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 can adapt and respond quickly to situations to minimize errors and harm.

High reliability is even more important given the challenges facing the healthcare industry. In August 2022, the Maryland Hospital Association released the State of Maryland's Healthcare Workforce report[5] detailing Maryland's future health workforce needs. The report indicated that one in every four hospital nursing positions is vacant and that an expected 13,800 additional nurses will be needed by 2035. The report indicated 62% of surveyed Maryland Board of Nursing license and certificate holders considered leaving the nursing profession. The reported reasons for leaving the field included feelings of being overworked, burned out, and unappreciated. The report provided practical recommendations for organizations to attract and maintain their workforce in order to better serve their local communities.

Classification of Adverse Events in Maryland

The Code of Maryland Regulations (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 10.07.06.02B(8) defines a "near miss" as a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

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5 www.mhaonline.org/docs/default-source/default-document-library/2022-state-of-maryland-s-health-care-workforce-report.pdf

In Maryland, the Hospital Patient Safety Program 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 National Quality Forum's (NQF) "Serious Reportable Events,"[6] also known as "never events" in the taxonomy of adverse events. Several states use this nationally recognized classification system, enabling OHCQ to compare its data with other state reporting systems. Because the Maryland Hospital Patient Safety Program 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 The Joint Commission's (TJC) definition of sentinel events. A sentinel event is a patient safety event that may result in death, permanent harm, severe temporary harm, and intervention required to sustain life.[7] There are 18 listed sentinel events.[8] Organizations accredited by TJC may voluntarily report sentinel events. However, organizational culture and leadership influence whether the organization voluntarily reports these events to TJC. Therefore, the Maryland Hospital Patient Safety Program's mandatory reporting plays an important regulatory role in ensuring the safety of patients.

A Just Culture

Fear of punishment may make health care organizations and professionals hesitant to report their errors. Unfortunately, failing to report adverse events may increase the likelihood of repeated occurrences of a serious adverse event. Health care organizations with punitive policies may

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

[7] https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

[8] https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

make staff hesitate to report errors, minimize the problem, or even fail to document the issue. Such actions or inaction can contribute to a culture of complacency and continuation of patient safety events.

To avoid this, organizations must create a just culture; that is, a system of shared accountability where organizations are accountable for the systems and working environment and the staff are accountable for their actions.[9] This model of accountability, developed by David Marx, focuses on three behaviors:

1. Human error: inadvertently completing the wrong action; a slip, a lapse, or a 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 behavior has a corresponding response. Under the just culture model, you console human error, but coach at-risk behavior and discipline reckless behavior.

A just culture emphasizes process improvement, which helps to identify the root cause of the problem and the best solution. Solutions focus on improving the system and not on 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. Hospitals have a regulatory and a moral obligation to hold staff accountable for following established, evidence-based processes and procedures. Without a just culture, staff may not report issues, resulting in lost opportunities for the organization to be made aware of system issues, to optimize those related systems, and to better protect staff and patients from uncorrected faulty systems.

Involvement of Hospital Leadership

The Maryland Hospital Patient Safety Program regulations require hospitals to designate an employee as the Patient Safety Coordinator. This requires a hospital-wide effort for patient safety starting with the Board of Directors. COMAR 10.07.06.03.B(3) requires a hospital governing body to develop a process to review the hospital's patient safety program and determine its effectiveness. Additionally, both the Centers for Medicare & Medicaid Services (CMS) and TJC require hospital-wide patient safety and quality activities that include the medical staff and governing body.

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

- Providing executive sponsorship to address adverse events.

[9] https://www.ahrq.gov/hai/cusp/modules/apply/ac-cusp.html

- 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.
- Supporting staff alignment with just culture principles.

Maryland Hospital Patient Safety Program

In response to the Institute of Medicine report, Maryland established the Maryland Hospital Patient Safety Program in March 2004, which is regulated under COMAR 10.07.06. The program focuses on creating a safe patient care environment. Hospitals must identify adverse events and are expected to report near misses. The hospital patient safety program additionally requires disclosure to patients and families.

The Maryland Hospital Patient Safety Program webpage is on OHCQ's website at https://health.maryland.gov/ohcq/Pages/Patient-Safety.aspx. The site includes links to the clinical alerts and annual reports as well as a section containing patient safety forms and tools for hospitals.

Hospital Reporting Requirements

The hospital's patient safety coordinator or members of the risk management team review and triage reported events to determine the level under the hospital patient safety program. COMAR 10.07.06.09A requires hospitals to self-report a Level 1 adverse event by submitting the initial notification to OHCQ within five days of the hospital's knowledge that the event occurred. The event is reported to OHCQ using the Initial Notification of an Adverse Event Form located on the OHCQ website via the dedicated mailbox hospital.selfreport@maryland.gov. OHCQ has received over 5,400 event reports since 2004.

The initial notification of an adverse event includes the date of report, date of event, event location, a brief description, age, initial diagnosis, prognosis, and outcome. The event will be classified as Level 1, Level 2, Level 3, near miss, or not reportable. It will be further categorized in the database consistent with the National Quality Forum (NQF) definitions of events.

Any event that is classified as a Level 1 event requires a root cause analysis (RCA). 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.[10]

Hospital's Submission of a Root Cause Analysis

To comply with COMAR 10.07.06, the hospital must submit an RCA within 60 days for reported Level 1 adverse events. If the patient is deceased at the time of report, the outcome will be noted as "death" and if the death is attributed to the event, unknown, or not attributed.

The RCA includes an in-depth review of the event by a multi-disciplinary team of individuals. COMAR 10.07.06.06C states:

> 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.

If an RCA fails to meet one or all of the requirements of COMAR 10.07.06, OHCQ may issue a deficiency statement or may send the hospital an extended review of the RCA that identifies specific areas of noncompliance with COMAR requirements and provides guidance for improving the quality of future RCAs.

The Institute for Healthcare Improvement (IHI) published RCA squared[11] (RCA2) to help hospitals systematically identify root causes and contributing factors and develop robust process improvement. Hospitals must additionally address the cultural components that strongly influence safety. This requires executive support and the resources necessary for a just culture. The Joint Commission also has an RCA framework for hospitals.

Hospitals may submit RCAs using their chosen framework, but the following information must be included:

- timeline;
- framework;
- cause-and-effect diagram (such as an Ishikawa or fishbone diagram);

[10] COMAR 10.07.06.02(B)(10).

[11] http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx

- process flow documents showing what happened, what should have happened, and the plan to fix it;
- clearly identified root cause(s) and contributing factors; and
- an action plan with measurable action items.

OHCQ provides RCA short forms for hospital-acquired pressure injuries (HAPI) and falls because these are high frequency events. The short forms can be used in lieu of a hospital's own framework. The forms allow teams to start by having front-line staff answering "yes" or "no" questions and identifying contributing factors and root causes through a streamlined process and tool.

Surveys and Enforcement Activities

When it is suspected that a hospital lacks a well-integrated patient safety program, or a complaint is verified regarding an event that should have been reported to OHCQ but was not, an on-site survey of the hospital's compliance with COMAR 10.07.06 may be performed. These enforcement actions do not focus on the adverse event itself; but instead focus on the hospital patient safety system to determine if the hospital is compliant with the program requirements. The regulations provide the option of assessing monetary penalties for noncompliant patient safety programs.

The Quality Assurance and Performance Improvement (QAPI) regulations of the CMS Conditions of Participation for Hospitals call for more attention to be paid to patient safety activities during complaint and validation surveys. Surveyors now review incident reports, the incident reporting process, and RCAs and failure mode and effects analyses (FMEAs). This process provides a double check of a hospital's patient safety program.

Analysis of Reported Events

Data is reviewed and compiled for this annual report, hospital report cards, and other purposes. Data from the OHCQ Annual Safety report is disseminated through the Maryland Patient Safety Center's[12] (MPSC) annual patient safety conference, other Maryland Hospital Association programs, and other events.

Figure 1 includes the number of adverse event reports submitted to the Maryland Hospital Patient Safety Program from Fiscal Year 2004 through 2022. Since the COVID-19 pandemic, there has been a significant increase in reported level 1 events compared to prior years. OHCQ saw a 52 percent increase in Level 1 reporting for FY22, compared to FY21. There were 832 events reported, with 769 of the events meeting the criteria for a Level 1 event.

[12] www.marylandpatientsafety.org

Figure 1

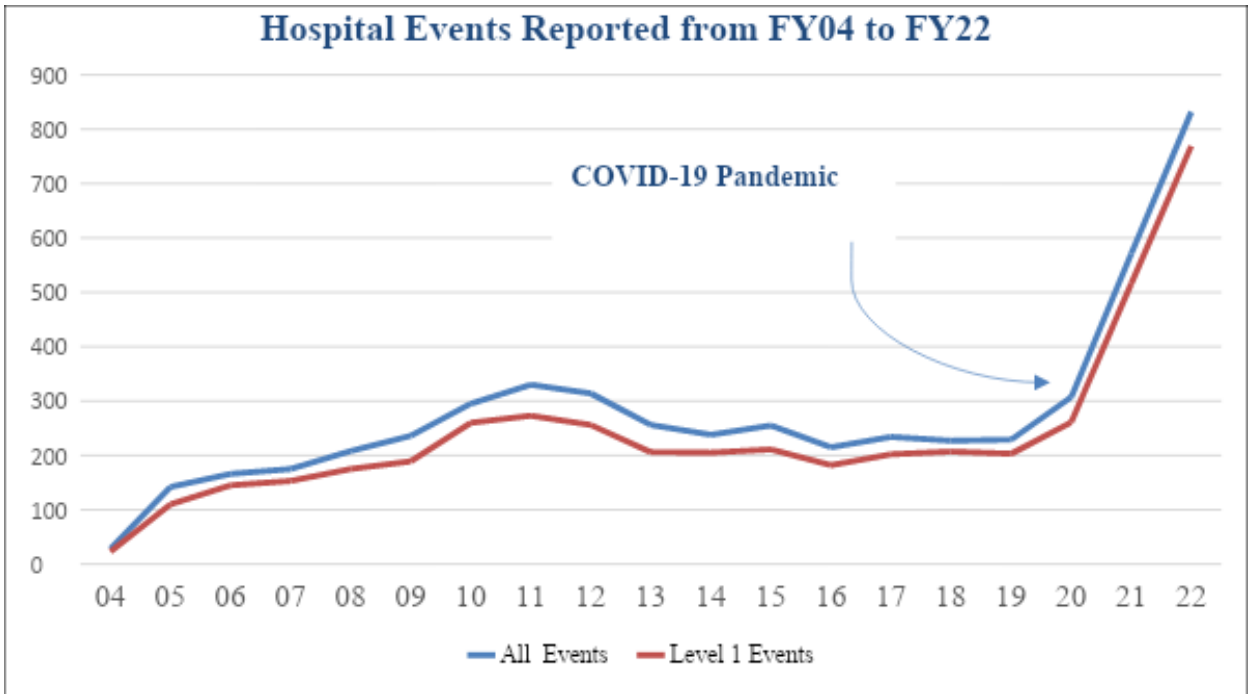


Figure 2 includes the number of events reported in certain categories in FY22. Pressure injuries, falls, delays in treatment, and surgical events account for 80 percent of the events reports in FY22.

Figure 2

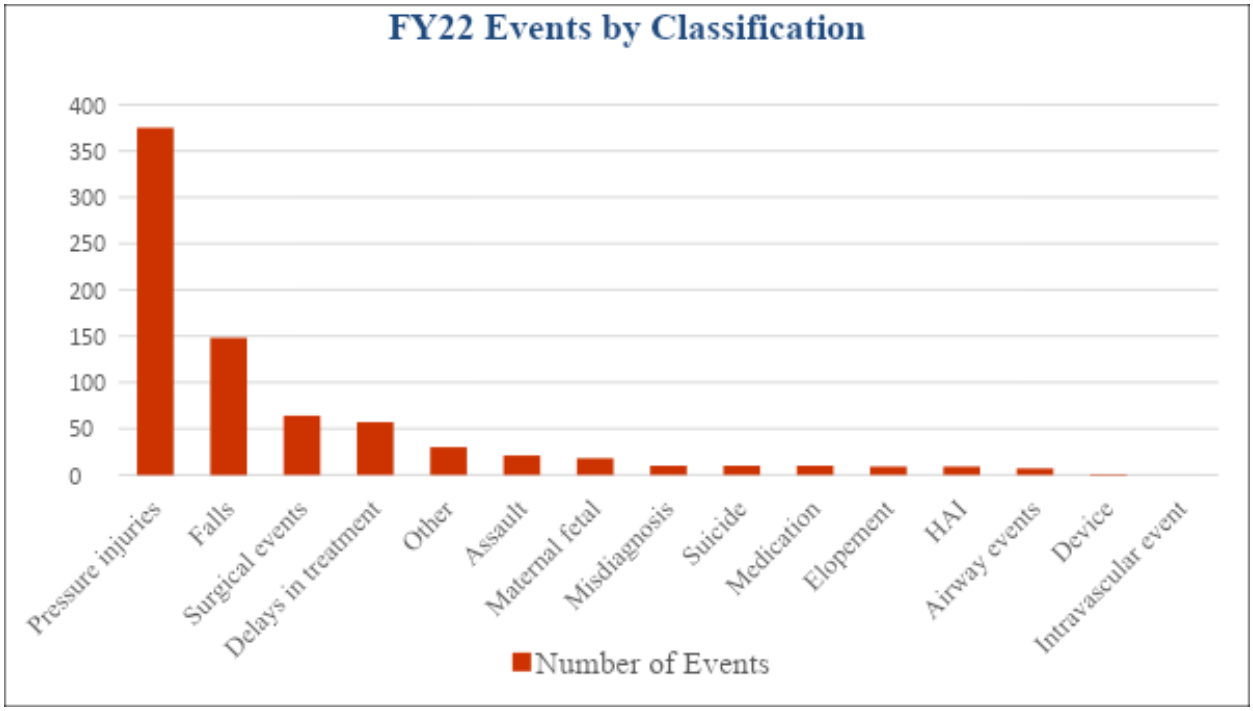
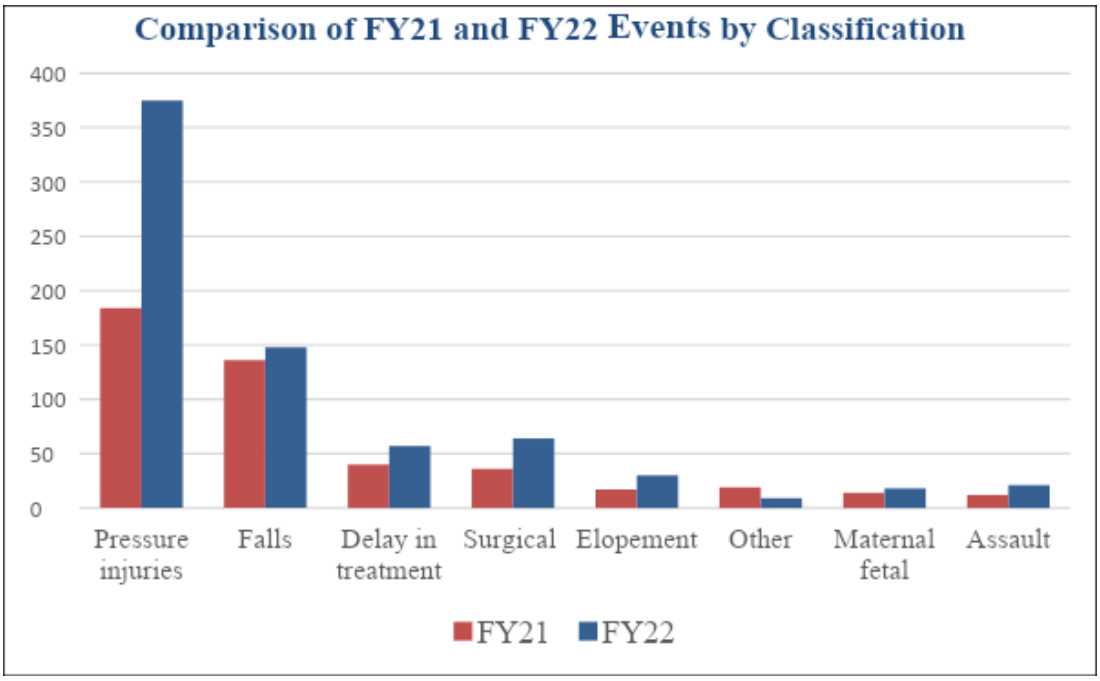


Figure 3 compares the number of events in certain classifications reported in FY21 and FY22. The most significant increase in reporting was in pressure ulcers from 184 in FY21 to 375 in FY22. Falls increased from 136 events in FY21 to 148 in FY22. Hospital-acquired pressure injuries increased from 184 events reported in FY21 to 375 in FY22.

Figure 3



Pressure Ulcers

A Hospital-Acquired Pressure Injury (HAPI) is defined as "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 Hospital Patient Safety Program are based on the National Quality Forum (NQF) definition above.[13] NQF considers these pressure ulcers a never event. Hospitals must report all HAPIs except:

> Those injuries that progress from wounds acquired pre-admission as long as they were recognized at admission. Exclude deep tissue injuries (DTIs) unless these evolve into or are debrided into Stage III or IV open wounds. Exclude Kennedy Ulcers that arise during the hypoperfusion state in the 24 to 48 hours prior to death.

The COVID-19 pandemic appears to have impacted pressure injury prevention in acute care hospitals. Turning and positioning has been a key strategy in pressure injury prevention. The

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

National Pressure Injury Advisory Panel (NPIAP)[14] published a position paper discussing unavoidable pressure injuries during COVID. Patients with COVID-19 experience hypercoagulopathy and corresponding skin changes. These skin changes appear discolored and can quickly become necrotic. They mimic the appearance of a deep tissue pressure injury (DTPI), especially when they occur over tissue exposed to pressure and/or shearing (e.g., sacrum, buttocks, heels) or under medical devices. In addition, NPIAP discusses true pressure injuries that rapidly deteriorate from microvascular thrombosis caused by the COVID-19 virus.

Medical devices were related to the development of 30 percent of HAPI. In one event, a patient was intubated for respiratory failure. The patient required proning therapy and an endotracheal tube (ETT) secured under the nose using tape. The patient received proning therapy for a total of ten days. A Wound Ostomy Care Nurse (WOCN) was consulted and identified a stage 3 pressure injury under the patient's nose from the ETT stabilizer.

The lessons learned from the reported HAPIs included:

- Skin assessment should be thorough and include staff checking under tubing and devices.
- Placing multi-layer foam dressings on bony prominences such as the forehead, chin, cheekbones, bridge of the nose, collarbones, hips, and knees prior to proning reduces risk of pressure injury.
- Adhesive and plastic commercial endotracheal tube securing devices may cause severe pressure injury while a patient is prone. Securing devices with adhesive and plastic anchors can be lifted and multilayer foam dressings be placed underneath to protect the skin.
- Medical tubes and devices cause 30 percent of in-hospital pressure injuries.[15] Properly securing medical tubes and devices is crucial to pressure injury prevention.

Falls

According to the Agency for Healthcare Research and Quality (AHRQ), more than one-third of hospital falls result in injury, including serious injuries such as fractures and head trauma. Fall prevention in hospitals requires a balance between managing a patient's underlying fall risk factors (e.g., problems with walking and transfers, medication side effects, confusion, and toileting needs) and enabling the patient to maintain autonomy in the unfamiliar hospital environment.

Falls often have multiple causes, including 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

[14] https://cdn.ymaws.com/npiap.com/resource/resmgr/white_papers/COVID_Skin_Manifestations_An.pdf
[15] 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).

the hospital environment. Fall event reporting increased from 136 events in FY21 to 148 in FY22.

In one event, a fall resulted in a patient requiring an emergency craniotomy for a large subdural hematoma. A patient fell in her room and hit her head. A CAT Scan (CT) of the brain was performed and was negative. Two days after the fall, the patient had a headache, was vomiting, and became hypertensive. A second CT identified a right subdural hemorrhage. The patient was transferred via flight to a tertiary facility for neurosurgical care. She had a rapid decline and underwent a craniotomy with evacuation of large subdural hematoma. The patient recovered and was discharged to an acute rehabilitation center.

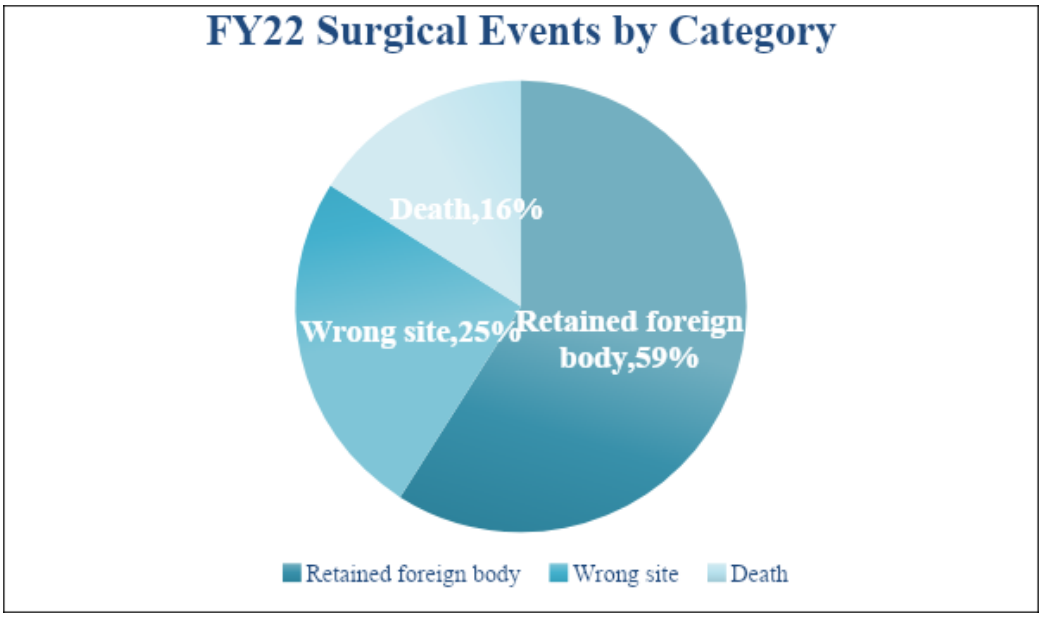
The lessons learned from the reported falls included:

- Engage the patient and family in the fall prevention process.
- Assess fall risk at the original point of encounter.
- Head injuries may require serial diagnostics as they may not be detected originally.
- Tailor the interventions to the patient. Staff should ensure that the right strategy is used for the right patient. This includes tele-sitter, which may not be appropriate for every patient.
- Consider strategies to be used with the tele-sitter if the patient needs to travel off the unit.
- Ensure beds, alarms, and other equipment are operational.

Surgical Events

The category of surgical events includes all patient and procedure events along with retained foreign objects (RFOs), intraoperative death in healthy individuals having low-risk procedures, and unanticipated intraoperative or immediately post-operative deaths. Historically, wrong-site events were in this category but were subsequently stratified separately as wrong-patient or other wrong event tracking in other areas such as radiology.

Figure 4



Surgical adverse events result in medical care, surgical intervention, or death, but surgical events typically have lower mortality compared to other event categories. Unexpected deaths may occur intraoperatively and postoperatively. Surgical event reporting increased from 31 events in FY21 to 64 in FY22. Figure 4 compares the proportion of surgical events by category, with 59 percent of reportable events due to RFOs.

In one event, a patient returned to the operating room for treatment of compartment syndrome in the non-operative leg after a lengthy operation. A patient had a planned surgical procedure that lasted 10 hours, which was five hours over schedule. The individual was receiving two allografts, which were prepared after anesthesia was induced. Preparation of the allografts, which normally takes 30-45 minutes, took approximately two hours. During this time the patient's non-operative leg stayed in the lithotomy position without any repositioning or peripheral vascular checks. The patient was taken to the Post Anesthesia Care Unit (PACU) for recovery, which averages 80 minutes. This patient stayed in PACU for 240 minutes due to the inability to safely stand or walk due to weakness of the non-operative leg and non-weight-bearing status of operative leg. The resident did not order typical post-op assessment orders, so nursing defaulted to every 4-hour documentation per policy. Overnight the patient experienced dark urine, continued pain and numbness in the non-operative leg, and the inability to ambulate. The surgeon was not made aware of overnight events until the morning rounds. The patient was taken back to the OR due to compartment syndrome and underwent a below-knee amputation of the non-operative leg. Additional assessments may have resulted in an earlier detection of compartment syndrome with a different outcome.

In another event, a Spanish-speaking patient was consented by both the surgical and the regional block teams for a right AV fistulogram with possible revision. An interpreter was used for

clinically significant communications. The vascular surgery physician assistant (PA) completed site marking. The patient also had a "red sleeve" on her right arm from the prior fistula, indicating that procedures should not be performed on that side. A block time out was conducted in the pre-op area, with the pre-op nurse, the block service attending, and the block service fellow participating. During the time out, the attending physician was on the patient's right side and the ultrasound machine was at the foot of the bed on the patient's right side. The time out possibly included correct laterality, but the surgical site marking placed by the PA was not visualized or examined as it was on her right shoulder and covered by her gown. Following the time out, the pre-op nurse left the area to care for another patient. Within a few minutes of the time out, the block team began initiating the block on the non-operative (left) side. Both team members were on the patient's left side and the ultrasound was on the patient's right side. The error was identified when the circulator entered the room to interview the patient and realized that the block team was beginning to block the incorrect side. The circulator pointed out the error and the block was immediately aborted. By this point, approximately 40% of the total amount of local anesthetic permitted for this patient had been administered.
Lessons learned from the reported surgical events included:

- Clearly mark site near the point of incision.
- Ensure staff are all in for the time out and are not distracted, multitasking, or inattentive.
- Clearly define roles and responsibilities including backup when needed.
- Empower staff to speak up and advocate for patients when procedures are prolonged.

Delays in Treatment

Missed and delayed diagnoses was identified as the number one patient safety concern by the ECRI Institute in 2020. AHRQ stated that diagnostic errors account for 17 percent of adverse events, and that a systematic review of 40 years of autopsy reports identified that 9 percent of patients died from an undiagnosed condition.

Diagnostic errors or omissions have various cognitive and systemic causes and are influenced by communication, access to pertinent information, and decision support systems. Much of the research is focused on errors made by individual clinicians. OHCQ has found that, like most adverse events, diagnostic errors are multidisciplinary and multifactorial. Diagnostic errors should generally be viewed as system or process defects, instead of or in addition to being the responsibility of individual providers.

In one event, a nurse entered a patient's room and found the patient off of telemetry. The monitor was placed back on the patient who was found to be in asystole. Resuscitative efforts were initiated immediately; but the patient could not be resuscitated. The primary nurse reported that during her shift, she was called at least six times to replace one or more leads that were removed because the patient was rolling around in the bed. The nurse stated that the patient was not purposely removing the leads, but they kept falling off because the gown pocket was not being

worn. At the time of the event, the charge nurse was performing the monitor technician function of telemetry monitoring while the monitor tech was on break. The charge nurse called the primary nurse about the patient's box being off, but also informed her about another patient's low oxygen saturation. The charge nurse reported that she could not leave the monitoring station long enough to respond and assess the patient who was at the end of the hall and in isolation The primary nurse was unable to timely assess the patient off of telemetry because she was responding to the other patient with low oxygen saturations. The patient had been off telemetry and without assessment for more than 30 minutes.

The lessons learned from events involving delays in treatment included:

- Assess alarms, monitoring functionality to avoid alarm fatigue.[16]
- Ensure that there is an escalation process in place for responding to alarms.
- Ensure that the staff know all functions of the monitoring equipment to prevent accidental silencing or canceling of critical alarms.
- Develop or optimize processes for interdepartmental communication.
- Implement rounding and bedside handoff for care team communication and collaboration.

Physical and Sexual Assaults

Reporting of physical or sexual assaults increased by 75 percent in FY22. These events commonly occur in the psychiatric care environment and in the Emergency Department (ED). These types of events frequently occur due to behavior associated with acute psychiatric illness. Patients may be acutely ill, and their behavior may be involuntary, which increases the risk for aggressive behavior and violence and the potential for patient or staff injury.

In one event, a patient was assaulted by another patient on the unit. The attack was unprovoked. The patient who was assaulted was due to be discharged the next day and was sitting in a common area with peers playing a game. The offending patient attacked from behind and choked the patient, who lost consciousness and then was dropped face-first to the floor by the offending patient. The attacked patient had swelling and bruising of the right eye, blood pooling in the mouth, and decreased range of motion of the right jaw. CT of the head and face revealed multiple facial bone fractures, including the jaw. The attacked patient was transferred to trauma service and underwent surgery to repair jaw and facial fractures. The offending patient was asked why he assaulted another patient and gave no response. It was later revealed that the offending patient had a history of assaulting strangers on the street as well as staff at other medical facilities, but this had not been documented in the medical record.

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16 https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_50_alarms_4_26_16.pdf

In a second patient-to-patient event, a patient on the Behavioral Health Unit (BHU) was becoming increasingly loud and aggressive with staff. He was also pulling on the plexiglass at the nurse's station. Security came into the BHU and attempted to stop the patient. He made it into another patient's room and punched the patient in the abdomen. When security entered the room, the aggressive patient swung his fists at the officers. Altogether, six security officers and three techs responded. The patient was restrained and given medications. During the event, the patient had grabbed the right arm of a security officer. The security officer reported right shoulder pain and imaging revealed a torn rotator cuff.

The lessons learned from the reported physical and sexual assaults included:

- Assaults may be random and unprovoked.
- Provide physical and emotional support to staff in areas with an increased risk of assaults.
- Ensure staff are trained and competent in de-escalation tactics.

Other Events

One event involved an infant receiving the wrong dose of a medication. An extremely low birth weight premature infant received four times the maximum daily dose of a steroid based on an order omitting the direction to divide the dose every six hours. The frequency error, failing to order the total daily dose to be split in four doses administered every six hours, continued for 13 days. Multiple new "weaning" orders lowered the total dose but again failed to include the instruction to divide the dose. At one point, a question was raised about the dosing. The RN, pharmacist and provider reviewed the dosing, but did not detect the frequency error and approved continuing to administer the medication as ordered. A duplication warning due to having two active orders for this medication was overridden by a pharmacist. The hospital identified that the electronic health record presented ten different options for ordering.

Another event involved a death related to a platelet shortage. A patient required pre- and intra-op anticoagulation therapy for vascular surgery because prior vascular surgeries had resulted in thrombosis. The patient had extensive history of restenosis, ongoing severe claudication, and rest pain with severe risk of limb loss without the surgical procedure. During the procedure, the patient had bleeding complications and required platelets. Only then did the surgery team become aware that there were no platelets available in the hospital. In fact, there was a nationwide blood and platelet shortage. Acquisition of platelets from another medical facility or from the American Red Cross would not arrive in time. The patient ultimately died due to bleeding complications. While the nationwide shortage was known to the clinical staff, there was no communication to the surgery team that there were no platelets available in-house. This communication would have prompted the team to delay and ensure platelets onsite due to the high risk for bleeding complications. The American Red Cross has released guidance for

hospitals to communicate availability of blood products to clinical staff and prioritize high-risk cases and ensure availability due to the critical shortage.

A third event involved an elopement. A patient with a past history of bipolar disorder presented under an emergency petition after a motor vehicle crash. On the scene, she was reported as being paranoid, locking herself in her car, and needing to be coaxed out of her vehicle. The patient stated that she was running away from her husband, who had abused her in the past. She thought that she was being boxed in by a tractor-trailer and by other cars, and she was worried that she was being chased and therefore she decided to make a rapid U-turn. She was treated medically and evaluated by behavioral health. The patient signed for voluntary admission to the BHU but was still in the ED. ED staff reported her missing and the elopement procedure was implemented, including a search and notification of Maryland State Police. The patient was found on a local bridge where she subsequently jumped into the river below.

A Culture of Patient Safety

Creating a culture of safety with a high reliability mindset is essential in consistently providing safe care every day. Many more examples from FY22 could be shared, but only a few are included in this report. Staffing challenges and disrupters like the COVID-19 pandemic must be overcome by the resilience that can be achieved when safety is truly the priority. The Maryland Hospital Patient Safety Program is essential in protecting the health and safety of hospital patients and in ensuring there is public confidence in the health care and community delivery systems.

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 or 4 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. It is the OHCQ categories of reports.

Appendix B: Adverse Reporting and Decision Tree

A Level 1 adverse event is defined in COMAR 10.07.06.02B(4) 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 "Serious Reportable Events"[17] taxonomy. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. The nationally recognized National Quality Forum (NQF) system enables the OHCQ 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 systems 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?

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

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

Hospital acquired pressure injuries (HAPI) are reportable if they are Stage III, IV, or unstageable pressure ulcers that are acquired after admission. This excludes progression from wounds acquired pre-admission as long as they were recognized at admission. It excludes DTIs unless these evolve into or are debrided into St. III or IV. It excludes so-called Kennedy Ulcers arising in the 24–48-hour period prior to death. It also 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, if a patient who goes into DIC and dies has an underlying coagulopathy or sepsis, or any other condition that caused the DIC, this would not be considered a reportable event. However, it is a reportable Level 1 event if the patient has a hemolytic transfusion reaction because of incorrect typing and goes into DIC and dies. Another example of a reportable Level 1 event is a patient who falls and develops a subdural hematoma and dies, even if the development of the SDH resulted from an underlying coagulopathy. The patient would not have developed the fatal SDH if 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 that is still present at the time of discharge.

Adverse Event Decision Tree