



MARYLAND DEPARTMENT OF HEALTH
Office of Health Care Quality

Maryland Hospital Patient Safety Program
Annual Report Fiscal Year 2021

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Table of Contents

Executive Summary	3
Purpose of the Maryland Hospital Patient Safety Program	4
Do No Harm	4
High Reliability Health Care.....	5
Defining Adverse Events.....	6
Maryland Classification of Adverse Events	6
A Just Culture.....	7
Hospital Leadership Involvement	8
Ensuring Quality.....	9
The Hospital Patient Safety Program Process	9
FY21 Hospital Demographics and Reporting.....	10
RCA Process.....	11
RCA Submission and Corrective Action Review	12
Enforcement Activities.....	13
Data Collection, Review, Analysis, and Dissemination.....	13
FY21 Adverse Event Reporting Data	14
FY21 Summary Data.....	14
Pressure Injuries	18
Falls.....	22
Surgical Events	27
Delays in Treatment.....	30
Physical and Sexual Assaults.....	33
Other Significant Events	35
Summary	37
Appendices.....	38
Appendix A: Classification of Events	38
Appendix B- Adverse Event Reporting and Decision Tree	39

Executive Summary

On behalf of the Office of Health Care Quality, we are pleased to present the Maryland Hospital Patient Safety Program's Annual Report for Fiscal Year 2021, the 17th year of the program. There was a significant increase in reported events in FY21 that in part was due to COVID-19. The pandemic posed additional complexities and challenges to healthcare through adverse events. 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.

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. Patient safety 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. Both the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC) require hospital-inclusive patient safety activities and integration of patient safety into medical staff and governing body functions.

Key findings in this report include:

- 570 events reported involving 590 patients, with 517 Level 1 events. This number is substantially higher than the previous year.
- Eighty-six patients died in FY21 from preventable medical errors— 40 more than in FY20.
- Pressure injuries, representing 36 percent of events, are the most reported event for FY21.
- Hospital-acquired pressure injuries (HAPI) increased from 63 in FY20 to 184 in FY21.
- Falls are the second most reported event, representing 27 percent of FY21 events.
- Delays in treatment are the third most reported events, representing 8 percent of FY21 events.
- Surgery-related events increased from 18 reported events reported in FY20 to 31 in FY21.

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 and resources for process improvement to optimize processes to prevent system failures and common causal 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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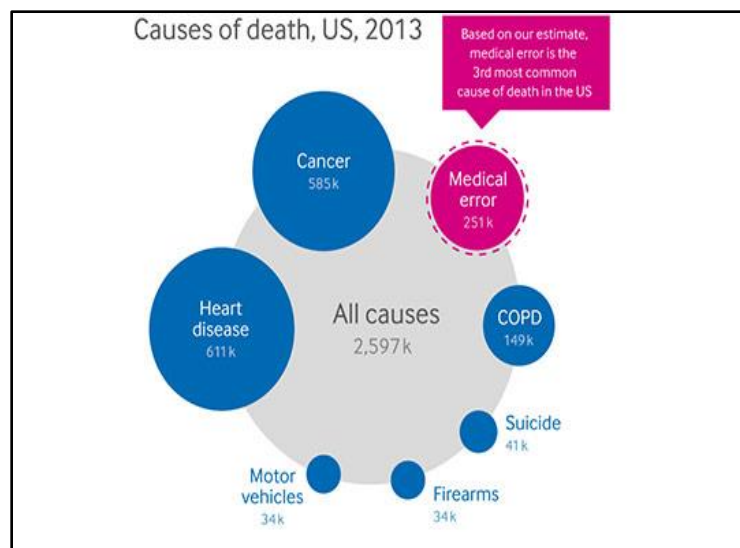
Purpose of the Maryland Hospital Patient Safety Program

Do No Harm

In 1999, 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. That is more deaths than those caused by auto accidents or cancer. The report challenged the health care industry to decrease 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 make them prone to mistakes.

In 2016, the British Medical Journal (BMJ) published an article titled *Medical Error - the 3rd Leading Cause of Death in the US*.² In this article, Martin Makary and Michael Daniel identified the failure of death certificates and International Classification of Disease (ICD) coding to identify deaths due to medical errors and identified the need for better systems to do so. This results in inaccurate counts of deaths related to medical error.

Figure 1: Medical Error - Third Leading Cause of Death in the United States



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.

Data from the IOM report and other literature was extrapolated to estimate that more than 250,000 people die annually from medical errors, making it the third leading cause of death behind heart disease and cancer. The article called for greater recognition of patient safety science. Optimizing the science of safety is critical to creating high reliability organizations to reduce medical errors across the health care continuum.

High Reliability of Care

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.³ 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 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 improve before they significantly impact a person.

Reluctance to simplify refers to the willingness to collect, analyze, and act on all warning signs that something may be wrong and 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, 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.

³ <https://psnet.ahrq.gov/primer/high-reliability>

Defining Adverse Events

In general, an error does not always result in harm. An error or mistake is an unintentional act where the desired outcome is not achieved. Harm is any temporary or permanent physical injury, pain, or damage to someone as a result of an event. The patient safety industry generally is reluctant to use the term "error," as it has a negative connotation. Instead the term adverse event is commonly used.

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 additionally 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

Maryland's Office of Health Care Quality's (OHCQ) 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,"⁴ also known as "never events" in the taxonomy of adverse events. This nationally recognized classification system, which several states use, enables 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 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

⁴ http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre4

required to sustain life.⁵ There are 18 listed sentinel events.⁶ Organizations accredited by The Joint Commission may voluntarily report sentinel events. Organizational culture and leadership influence whether the organization reports these events to The Joint Commission.

A Just Culture

It is important to report adverse events. Fear of punishment may make health care organizations and professionals hesitant to report their errors. Although they may be concerned for patient safety, they also fear disciplinary action, including losing their jobs, if they report an adverse event.

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 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.⁷ 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 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, coach at risk behavior and discipline reckless behavior.

A just culture emphasizes process improvement. Process improvement helps you identify the root of the problem and discover the best solution. Solutions focus on improving the system and not just about the person who made the error.

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. Staff who willfully deviate from standards, for example, by diverting narcotics, require disciplinary action.

⁵ https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

⁶ https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/camh_24_se_all_current.pdf

⁷ <https://www.ahrq.gov/hai/cusp/modules/apply/ac-cusp.html>

The intent of the staff member who makes an error must be considered. Was the error the result of reckless behavior or an intentional deviation from policy or procedure, or did it result from at-risk behavior, where an individual was impaired or otherwise incapable of complying with policy and procedure? If neither is true, then the underlying human factors must be investigated and process improvement initiated.

In addition to individual accountability, process improvement recognizes that a similar person of equal experience and training in the same circumstance could make the same mistake. Very few of the adverse events reported to OHCQ since 2004 have been due to the actions of just one person. Patients trust organizations to heal them and not hurt them. A just culture is essential to patient safety. Without it, staff do not report issues, organizations are not aware of system issues, the system isn't optimized, and patients get hurt in the course of care.

Hospital Leadership Involvement

The Maryland Hospital Patient Safety Program regulations require hospitals to designate someone to function as the Patient Safety Coordinator. A change in this crucial position may affect organizational interest and engagement in the patient safety process.

However, patient safety is not just the responsibility of one individual. It requires a hospital-wide effort 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 CMS and TJC) require hospital-wide patient safety and quality activities that include the medical staff and governing body.

For all these reasons, a hospital's leadership must be committed and involved in patient safety, as follows:

- Providing executive sponsorship and resources for process improvement to address adverse events;
- Providing regular reports regarding adverse events to the Board and other executive level committees, including 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;
- Establishing and participating in administrative rounds focusing on patient safety;
- Educating staff and leaders at all levels about the hospital's patient safety program, emphasizing the importance of reporting;
- Establishing patient safety goals and monitoring the hospital's performance towards those goals; and
- Supporting staff alignment with just culture principles.

Ensuring Quality

OHCQ's mission is to protect the health and safety of Marylanders and to ensure public confidence in the health care and community delivery systems. The agency's vision is that all care recipients in Maryland can trust that their health care facility or program is licensed and has met the regulatory requirements for the services they offer.

In response to the aforementioned Institute of Medicine report, Maryland established the Maryland Hospital Patient Safety Program in March 2004 under COMAR 10.07.06, focusing on creating 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.

The Hospital Patient Safety Program Process

Staff should report adverse events in a timely fashion. This may be done via an adverse event reporting system, a reporting hotline, or other methods. The patient safety coordinator or members of the risk management team will review and triage the event to determine the level under the hospital patient safety program. If the event has been determined to meet the definition of a Level 1 event or is of concern, the hospital will submit the initial notification to OHCQ. The event is reported to OHCQ using the Initial Notification of an Adverse Event Form located on the OHCQ website via the dedicated mail box hospital.selfreport@maryland.gov.

COMAR 10.07.06.09A requires hospitals to self-report any Level 1 adverse event to OHCQ within five days of the hospital's knowledge that the event occurred. OHCQ has received over 4,600 event reports since 2004.

Although accredited by TJC, hospitals may be less likely to voluntarily report Level 1 events to TJC. Since the Maryland Hospital Patient Safety Program started, hospitals have only indicated notifying TJC for 47 Level 1 events. Because of reporting trends, the Maryland Hospital Patient Safety Program has the most complete record of patient safety issues across the state.

Hospitals may not have internal mechanisms for capturing all adverse events. OHCQ assumes that hospitals with robust reporting systems are safer than hospitals that under-report. For example, OHCQ has not yet identified the reason why two hospitals with similar catchment areas and population densities and with nearly identical bed capacity have adverse event reporting rates that

differ by 50 to 75 percent. It may be that the differences in hospital cultures account for the variation in reporting.

Upon initial notification of an adverse event, the information is entered into OHCQ’s Hospital Patient Safety Database. The information includes 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.⁸

The patient safety database automatically generates an event number that will then be used to reference the specific event. The event number and RCA due date in 60 days will be emailed back to the staff reporting on behalf of the hospital from the hospital.selfreport@maryland.gov mailbox.

If the patient is deceased at the time of report, the outcome will be noted as death. The database will further indicate if the death is attributed to the event, unknown, or not attributed.

FY21 Hospital Demographics and Reporting

Maryland hospitals are classified into five categories: acute general, psychiatric, chronic, children’s, and rehabilitation. Acute general hospitals continue to account for 73 percent of all licensed Maryland hospitals and reported 97 percent of the Level 1 adverse events in FY21. Psychiatric and rehabilitation hospitals accounted for 4 percent of reports. Thirteen hospitals did not report any adverse events in FY21. Forty-six percent of non-reporters are psychiatric hospitals.

Table 1: Events per Hospital Based on Hospital Size

Hospital Size	Number of Hospitals	Total Events Reported FY21	Reported Events per Hospital FY21	Reported Events per Hospital FY20	Percent Change
300 or more beds	11	225	20	9	125%
200 – 299 beds	15	215	14	6	128%
100 – 199 beds	14	110	8	6	40%
<100 beds	22	37	2	2	12%

⁸ COMAR 10.07.06.02(B)(10).

RCA Process

The Institute for Healthcare Improvement (IHI) published RCA squared⁹ (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 resources necessary for a just culture.

In order to comply with COMAR 10.07.06, the hospital must submit a root cause analysis for reported Level 1 adverse events. The RCA includes an in-depth review of the event by a multi-disciplinary team of individuals to determine, through a series of “why” questions, the actual root causes of the event. Though an RCA can be done for any event, it is a resource-intensive process, and there are other ways to analyze processes. Root causes are generic; that is, the causes of a given adverse event may occur almost anywhere in patient care areas and may lead to identical or similar outcomes if not fixed.

Root cause analyses should focus primarily on systems and processes. The hospital staff must also identify risks and contributing factors for recurrence and determine what improvements in systems or processes are needed to prevent recurrence. The causal and contributing factors of events are often complex and multifactorial. 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.

If an RCA fails to meet one or all of the requirements of 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.

As part of its key role in patient safety, hospital leadership can aid the RCA process by:

- Setting expectations for a timely response while providing accountability for the analysis and response;
- Providing oversight authority for timely and effective completion of RCAs;
- Managing any external risks or liabilities;
- Actively participating in an RCA.

⁹ <http://www.ihl.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx>

Participation by leadership can provide valuable insight into the challenges faced by patients and by front line staff; Leadership participation also lets the staff know that administration supports the RCA process.

RCA Submission and Corrective Action Review

In FY21, OHCQ reviewed 488 RCAs. Hospitals may submit RCAs using their chosen framework. This may be a framework such as The Joint Commission RCA framework or one that the organization has developed internally. The submitted RCA should include:

- 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.

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 RCA. 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.

Strong, sustainable solutions are needed to keep patients safe. Hospitals continue to struggle with implementing enduring corrective actions that eliminate or control hazardous conditions. Policy changes and training remain perennial favorites for corrective actions. Although each is considered a weak intervention individually, both are likely to be part of the typical hospital corrective action plan. Even weak interventions like education and policy changes can be strengthened with frequent, random observations of staff performance. Staff may be less likely to continue shortcuts or policy deviations if they are observed and corrected in real time.

More hospitals are improving problematic processes using Lean Six Sigma or process engineering to streamline and standardize processes. This approach to process improvement can make processes more fault-tolerant by building safeguards into day-to-day workflows and care.

OHCQ documents the hospital corrective actions as the following:

- Environmental changes refer to structural changes;
- Discipline refers to individual counseling or performance improvement plans;
- Changes in workload generally refers to changes in staff tasks, responsibilities, or deployment;

- Equipment modification refers to changing the function or configuration of equipment; for instance, eliminating the ability to lower the volume on monitor alarms;
- Data tracking and trending refers to either mid-term or long-term tracking of performance improvement measures;
- Other corrective actions for those situations that don't fit into a defined corrective action category.

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; instead, as hospitals are expected to do in their RCAs, the survey focuses on the systems, culture, reporting and analysis, and policies and procedures needed for a robust patient safety program. The regulations provide the option of assessing monetary penalties for not reporting events.

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

Data Collection, Review, Analysis, and Dissemination

All adverse event data is entered into the OHCQ Hospital Patient Safety Database. The database contains data on all events reported since 2004. Data is reviewed and compiled for this annual report, hospital report cards, and other reports as needed.

Since 2011, OHCQ has issued annual report cards to hospital patient safety officers. The report cards provide a way to double check the events reported, reconcile the hospital's files with OHCQ's information, and ensure there are no outstanding RCAs. The report cards also provide a way for OHCQ to monitor longitudinal reporting rates of individual hospitals. Feedback received from several hospitals indicates that the patient safety officers and quality personnel use the report cards to ensure they are not missing any opportunities to review adverse events.

Data from the OHCQ Annual Safety report is disseminated through the OHCQ update at the Maryland Patient Safety Center¹⁰ (MPSC) annual patient safety conference, other Maryland Hospital Association programs, and other events.

¹⁰ www.marylandpatientsafety.org

FY21 Adverse Event Reporting Data

FY21 Summary Data

OHCQ saw a 91 percent increase in Level 1 reporting for FY21, compared to FY20. There were 570 events reported involving 590 patients, with 517 of the 570 events meeting the criteria for a Level 1 event. After a peak period between 2009 and 2013, reporting to OHCQ was relatively stable for the five years prior to FY21.

Figure 1: Adverse Event Reporting Over Time

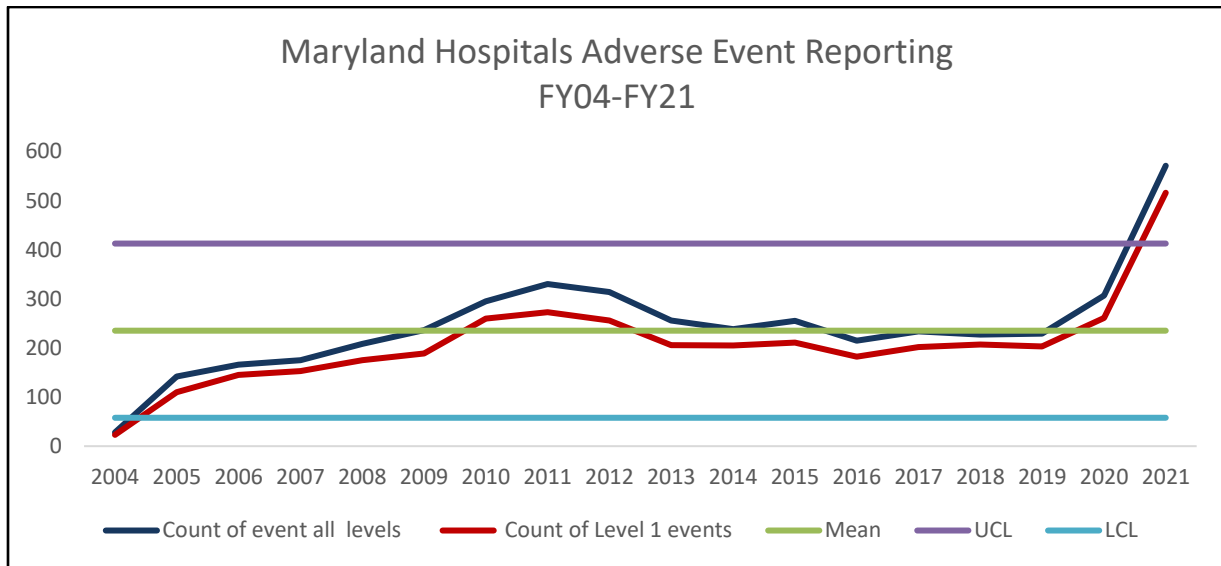
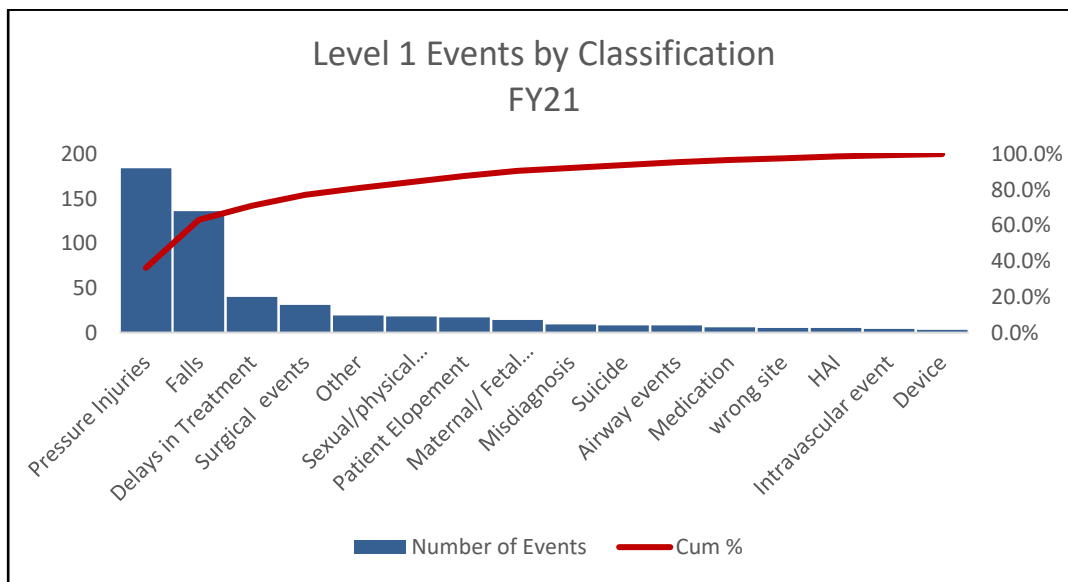
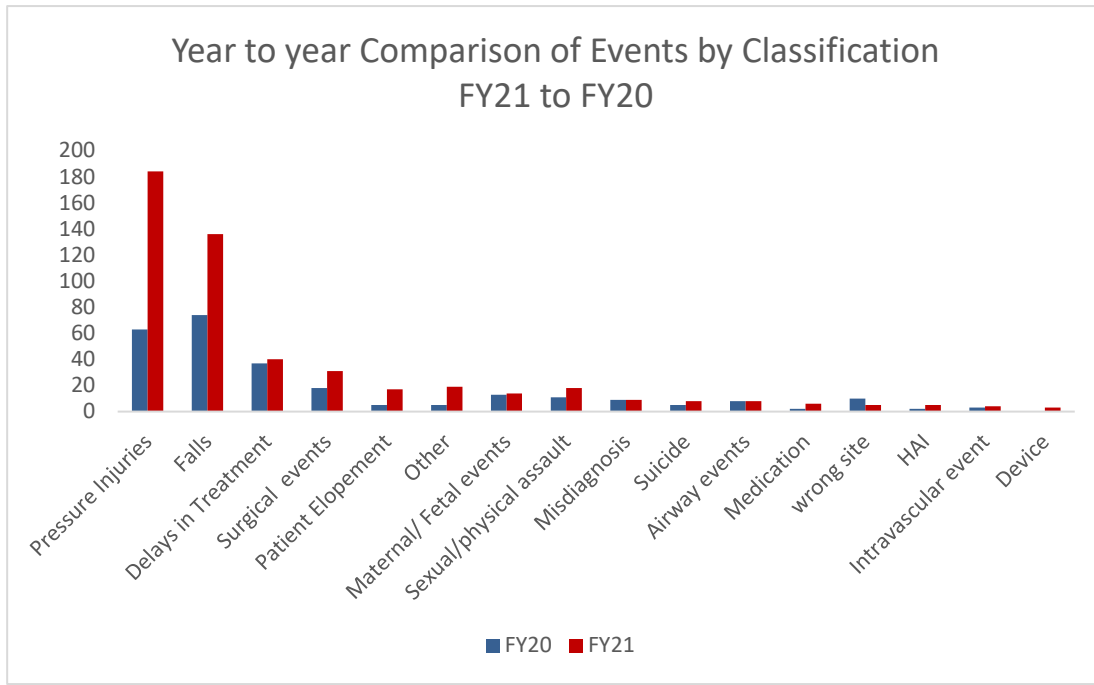


Figure 2: Events by Classification



The categories contributing to 80 percent of the events received in FY21 include pressure injuries, falls, delays in treatment, surgical events, sexual and physical assaults and other events.

Figure 3: Year-to-year Comparison By Classification

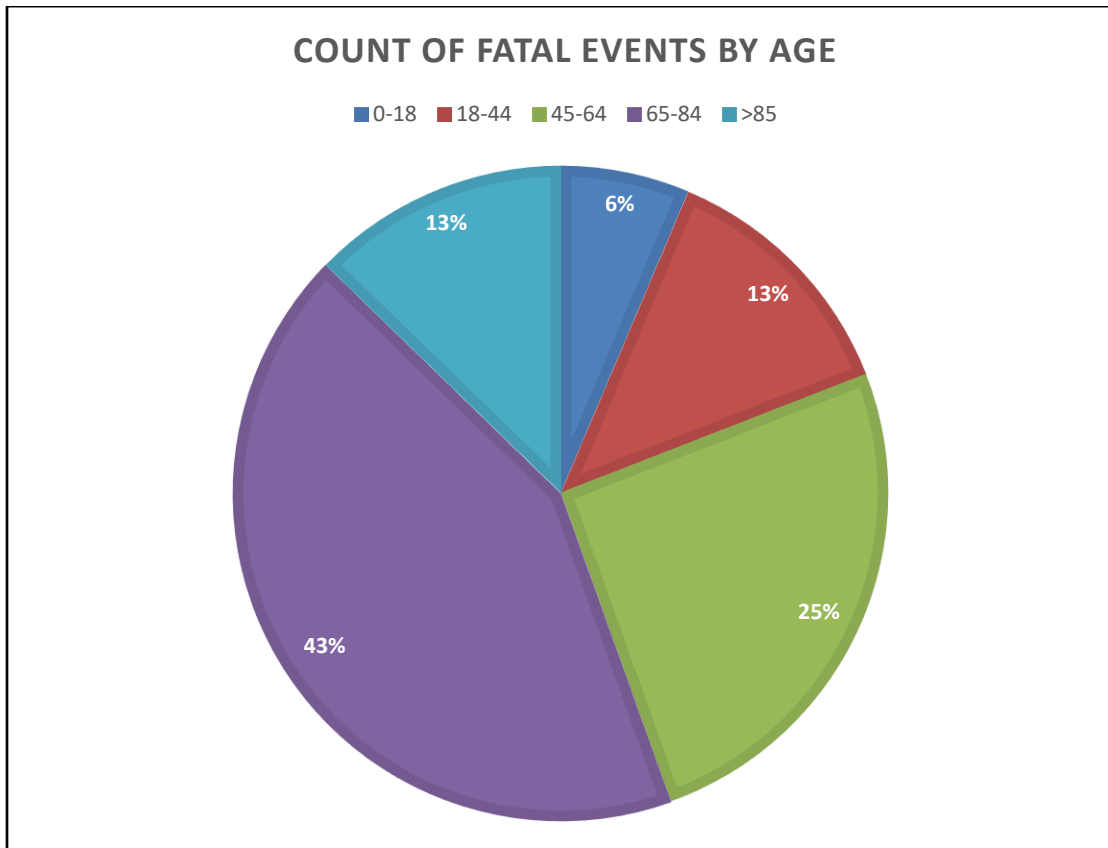


Much of the significant increase in reporting comes from more reports for pressure injuries and falls. However, more reports related to surgical events, elopements, and other events also contributed to the steep increase in events reported in FY21.

Falls increased from 74 events in FY20 to 136 in FY21 and hospital acquired pressure injuries went from 63 events reported in FY20 to 184. The categories and cases section of this report will consider possible reasons for this increase. Reports of hospital acquired infections and medication events, traditionally not as frequently reported, also increased substantially compared to the previous year.

Level 1 adverse events affect patients in a wide variety of age groups. Through the data tracked in the patient safety database, OHCQ identified the largest population experiencing a fatal event as being between the ages of 65-84. This increased from 39 percent in FY20 to 43 percent in FY21. Fatal events in the second largest group, between the ages of 45-64, decreased from 31 percent in FY20 to 25 percent in FY21. All other age groups remained proportionately the same from the previous year.

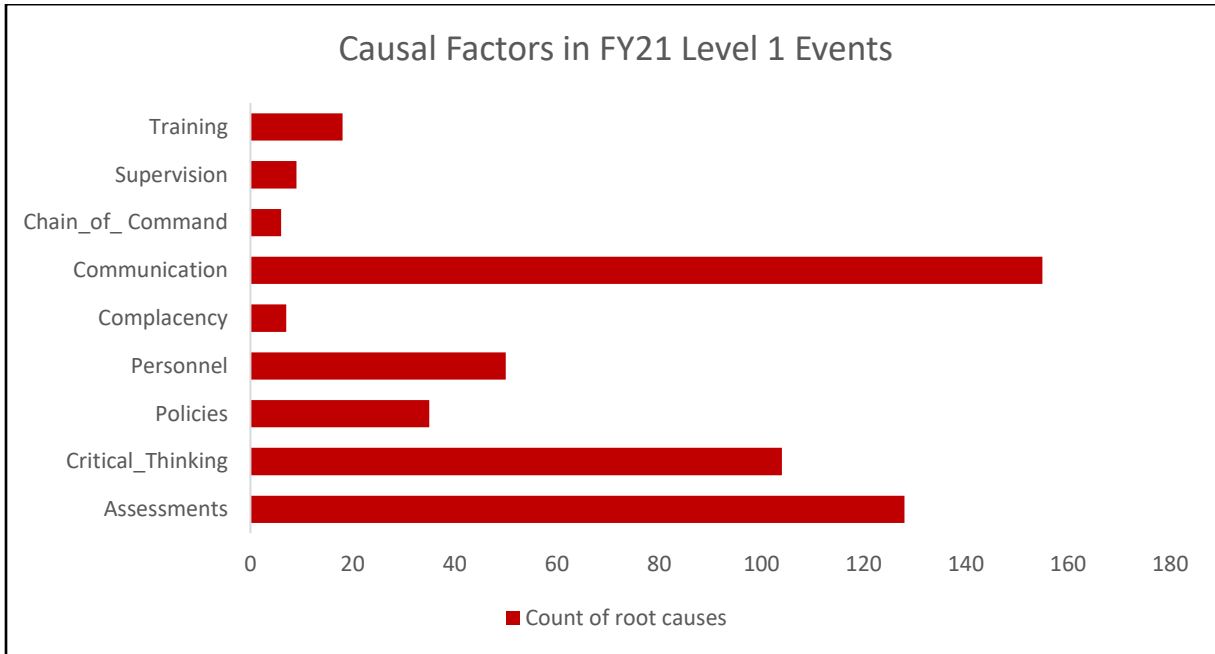
Figure 4: Proportion of Events by Age Range



While causes vary across events, they are often similar. Common causal factors tracked in the patient safety database include:

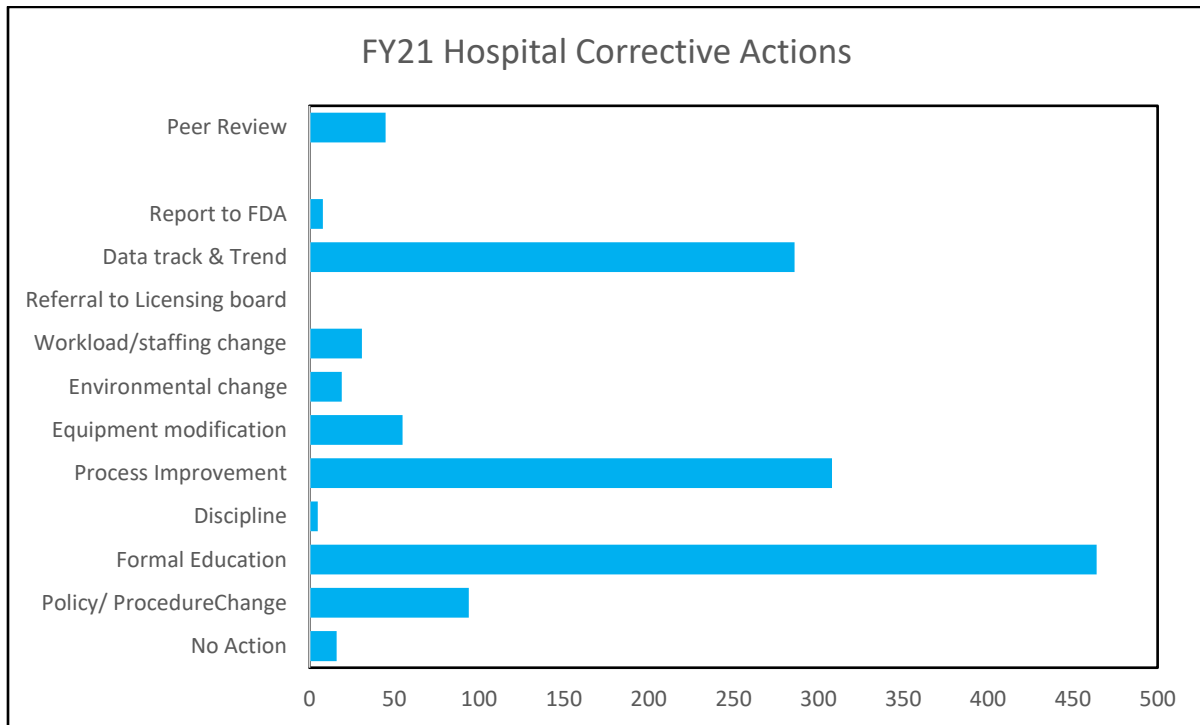
- Inadequate training
- Lack of supervision
- Failure to follow chain of command
- Lapses in communication
- Complacency
- Personnel issues
- Lack of policy/procedure
- Lack of critical thinking
- Missing assessment
- Inadequate assessment

Figure 5: Common Causal Factors in FY 21 Level 1 Events



The top three causes identified in Level 1 RCAs for FY21 include lack of communication, lack of assessment, and lack of critical thinking.

Figure 6: RCA Corrective Actions



Hospitals develop corrective actions based on identified causes from their RCAs. COMAR 10.07.06.03B requires hospitals to monitor the results and effectiveness of all action plans derived from the RCAs.

Hospitals continue to struggle with differentiating between process steps (process measures) and evaluating how effective a corrective action has been in remediating the circumstances that led to the adverse event (outcome measures). While hospitals should track implementation of actions, this alone is not a measure of effectiveness. Hospitals need to determine the goals of the corrective action and how to measure goal attainment. Each corrective action, where applicable, should be patient-focused.

Pressure Injuries

A Hospital Acquired Pressure Injury, considered by the National Quality Forum (NQF) to be a never event, 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 NQF definition. 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 hypo-perfusion state in the 24 to 48 hours prior to death.

The COVID-19 pandemic appears to have changed significant aspects of pressure injury prevention in acute care hospitals. Turning and positioning has been a key strategy in pressure injury prevention. The National Pressure Injury Advisory Panel (NPIAP)¹¹ 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 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. If blood vessels are already severely or fully occluded, then adequate reperfusion may not be achievable even with reasonable repositioning and turning of the patient and the use of appropriate support surfaces. In addition, NPIAP discusses true pressure injuries that rapidly deteriorate from microvascular thrombosis caused by the COVID-19 virus.

With this in mind, OHCQ reviews event details and RCA findings to appropriately classify HAPI events involving COVID-19 patients. Based on the RCA findings, this may result in an event

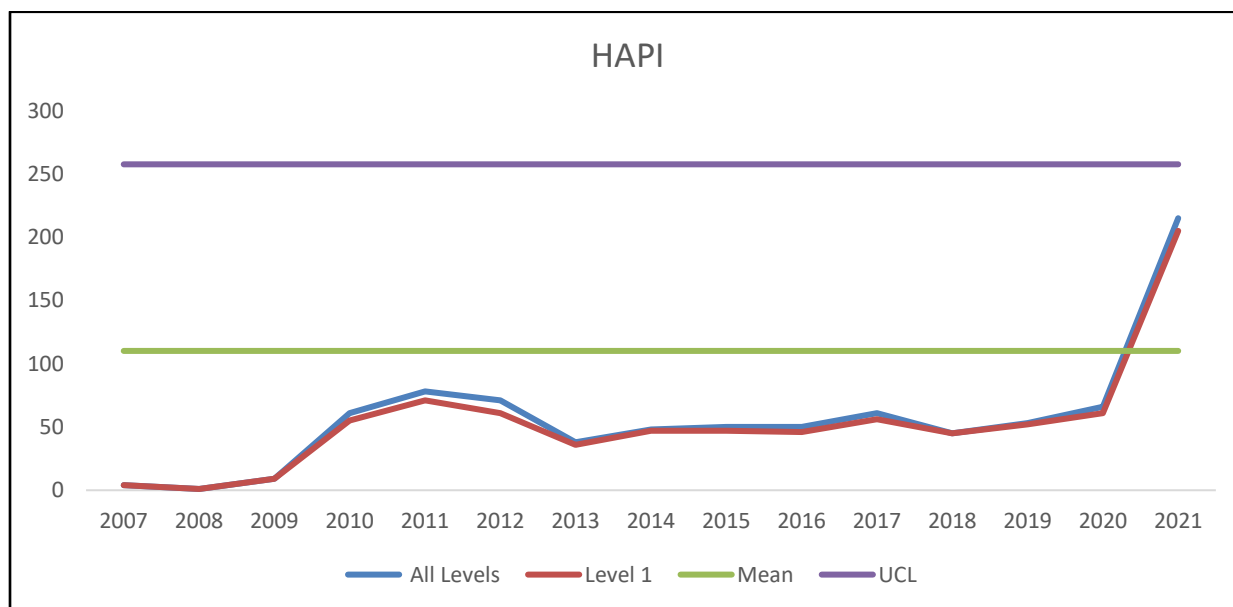
¹¹ https://cdn.ymaws.com/npiap.com/resource/resmgr/white_papers/COVID_Skin_Manifestations_An.pdf

classification change to "not reportable" or remain a Level 1 event on a case-by-case basis. However, COVID-19 disease diagnosis does not necessarily preclude a reportable HAPI event. With the number of questions related to COVID-19 and hospital acquired pressure injuries, OHCQ was able to clarify and reinforce with many organizations the criteria for HAPI events.

Over the course of the patient safety program, the criteria for reporting have changed to align with changing national standards. For example, deep tissue injuries previously were included, but now only those that debride to a Stage 3 or 4 wound are included. The hospital program'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. Unstageable pressure injuries are serious reportable events because they are Stage 3 or Stage 4 pressure injuries obscured by slough or eschar.¹² This was further reinforced during the OHCQ update at the Maryland Patient Safety Conference OHCQ update April 29, 2021.

All of this has prompted organizations to report their unstageable hospital-acquired pressure injuries, just as they had previously reported the Stage 3 and Stage 4 ones. With the increased reporting, organizations have been able to recognize the significance of multiple pressure injuries on a given hospital unit identified in the same time frame during prevalence studies. This has allowed the organization to review opportunities presented by several events, instead of in isolation, to support more robust process improvement.

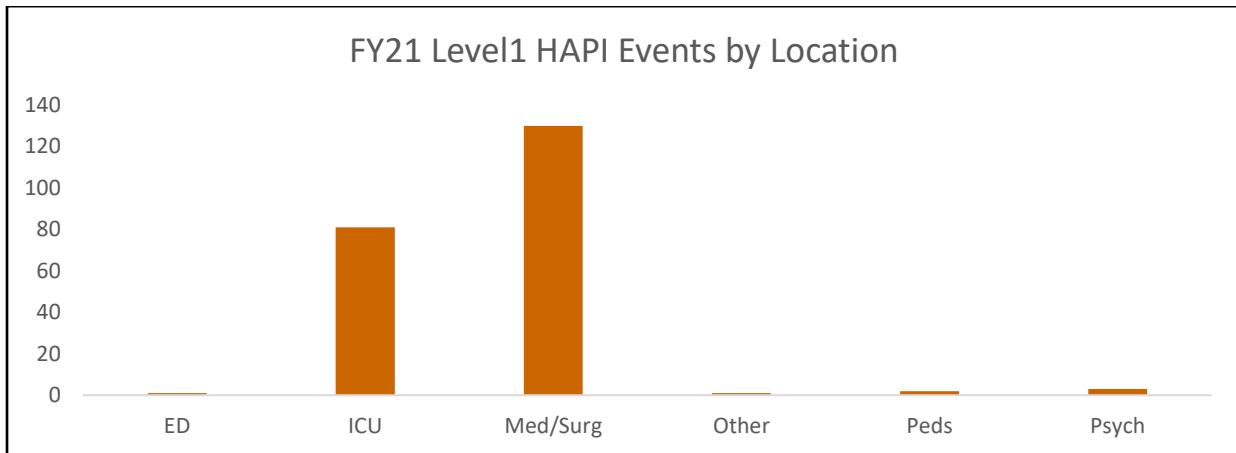
Figure 7: Pressure Injuries Over Time



Hospital-acquired pressure injuries went from 63 events reported in FY20 to 184 in FY21.

¹² https://cdn.ymaws.com/npiap.com/resource/resmgr/online_store/npiap_pressure_injury_stages.pdf

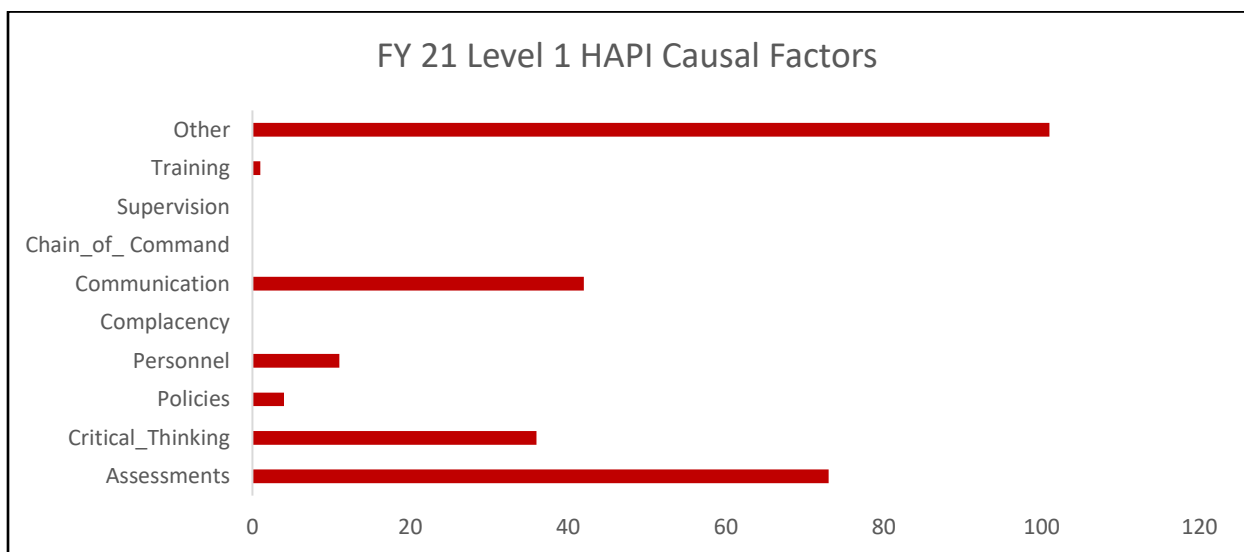
Figure 8: Pressure Injury Locations



Most of the reported pressure injuries occurred in medical/surgical areas or the ICU. The leading cause of pressure injuries reported in FY21 was "other," largely due to Coronavirus disease (COVID-19). COVID-19 was listed as a major cause in many cases. For the first time, OHCQ saw multiple events related to proning COVID-19 patients for acute respiratory distress. This included many patients who developed unstageable wounds on the cheeks of the face from proning.

The second most common factor for pressure injuries is assessment. There was increased use of devices such as Bi-level Positive Airway Pressure (BiPAP) and high flow nasal cannula for oxygen delivery. These require a tighter fit and staff may fail to consistently assess the areas around the ear and nose. The third major cause related to communication; i.e., the primary care team failed to communicate or engage wound and ostomy care nursing (WOCN) team in a timely fashion.

Figure 9: Pressure Injury Causal Factor



Stage 3 HAPI

A 63-year-old patient was diagnosed as an outpatient with COVID-19 infection. The patient was brought to the hospital by family after experiencing extreme fatigue, loss of appetite, and inability to get out of bed. The patient arrived at the Emergency Department (ED) with extreme hypoxia with oxygen saturations in the 70s on room air and tachycardia with a heart rate in the 150s.

The patient was immediately placed on non-rebreather oxygen and then on BiPAP. While in the ED, the patient became increasingly delirious and was transferred to the ICU and remained on BiPAP. After 9 days on BiPAP, the patient was intubated. The patient was on numerous medications, including vasopressors for hypotension. The patient remained intubated and on a ventilator for 39 days but could not tolerate proning. The patient also received enteral nutrition. The patient was ordered for WOCN consult but the initial assessment did not include the sacral area because the patient was too unstable at the time of assessment. WOCN ordered an air mattress, which the patient was placed on. However, the mattress was not plugged into the air pump. The patient developed a Stage 3 pressure injury to the sacrum.

Stage 4 HAPI

A 75-year-old patient who was diagnosed as an outpatient with COVID-19 infection presented to the ED after 4 to 5 days of shortness of breath and poor appetite. The patient complained of having some watery diarrhea and a productive cough with yellowish sputum. Initially the patient was admitted to the medical/surgical floor. After 4 days the patient's oxygen status wasn't improving, and the patient was transferred to the ICU on BiPAP. The patient was placed on an air mattress and plugged into the air pump. Eventually, the patient required intubation and proning with enteral feeding for nutrition. The patient subsequently required a tracheostomy and percutaneous endoscopic gastrostomy (PEG) tube placement. The patient had persistent diarrhea requiring a rectal tube. WOCN assessment revealed an area of eschar on the sacrum that was debrided to a Stage 4 wound.

Lessons Learned and Considerations for Hospitals

- Thorough skin assessment should always be done. Staff should be sure to check under tubing and devices.
- 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.
- 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.¹³ Proper security of medical tubes and devices is crucial to pressure injury prevention.
- Proper body positioning, support, and offloading are crucial to pressure injury prevention. Standard pillows, as well as donut-shaped pillows, should not be used to support the head while proning, as they place too much pressure on the cheeks, forehead, ears and chin.
- Specialized foam head cushions are preferred because they have tunneled spaces that allow for passage of the endotracheal tube to prevent it from being pressed directly against the patient's face.
- Swimmer's position is the preferred method of patient body positioning when proning. Extremities can be supported with pillows with rotation of head, neck and extremities done every 2 hours.¹⁴

Falls

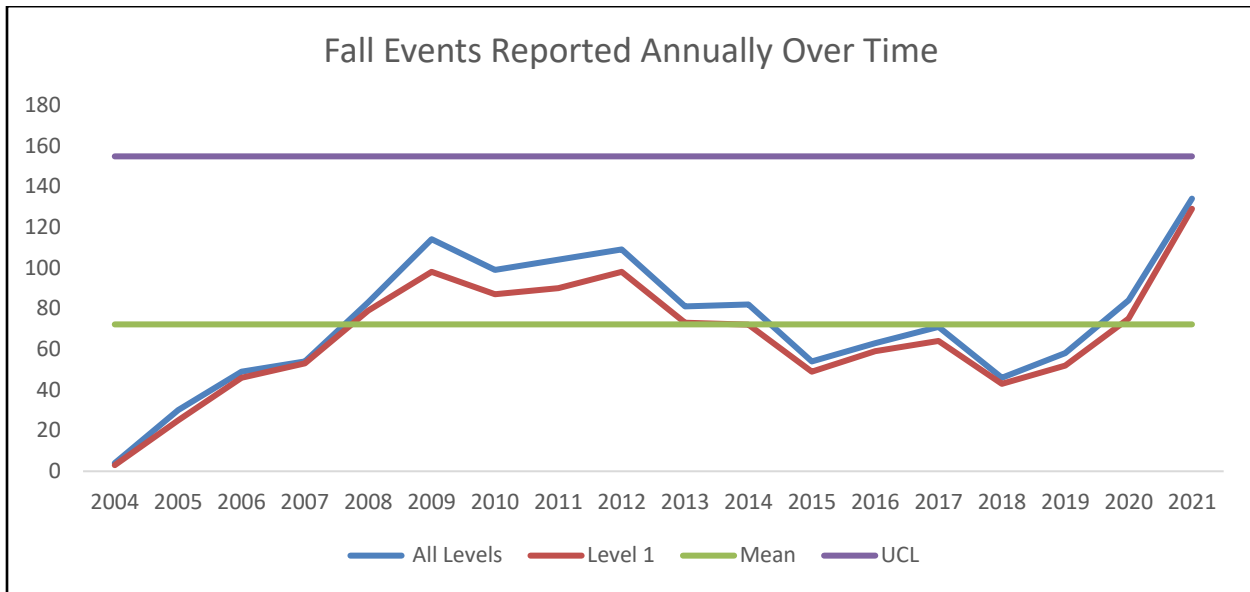
According to the Agency for Healthcare Research and Quality (AHRQ), more than one-third of hospital falls result in injury, including serious injuries such as fractures and head trauma. Death or serious injury from a fall in a health care facility is considered a never event, and CMS does not reimburse hospitals for the associated additional costs. 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, frequent toileting needs) and enabling the patient to maintain autonomy while adapting to the unfamiliar hospital environment.

Falls have been reported and tracked since the beginning of the Hospital Patient Safety Program. The number of fall events reported varies from year to year. Falls occur due to a variety of physical, cognitive and systemic factors. OHCQ has found that falls are multifactorial, but often result from 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.

¹³ Bakarar-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).

¹⁴ Lucchini, A., Bambi, S., Mattiussi, E., Elli, S., Villa, L., Bondi, H., Rona, R., Fumagalli, R., Foti, G. (2019). Prone position in acute respiratory distress syndrome patients. *Dimensions of Critical Care Nursing*. Vol. 39(1).

Figure 10: Falls Over Time



FY21 saw the largest number of fall reports since the 2009-2012 time frame. Fall event reporting increased from 74 events in FY20 to 136 in FY21. Most falls occurred in the medical/surgical areas of the hospital and ED. The majority of falls resulted in a medical intervention. Forty-three percent of the falls resulted in surgical intervention. Death occurred in 8 percent of the reported events.

Figure 11: Fall Event Outcomes

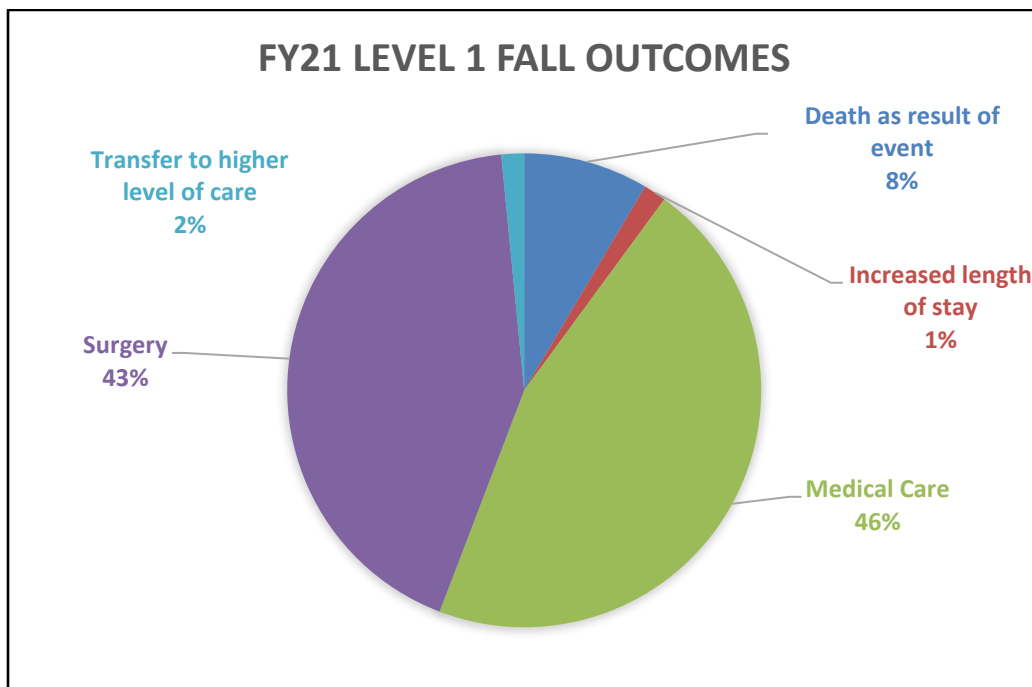
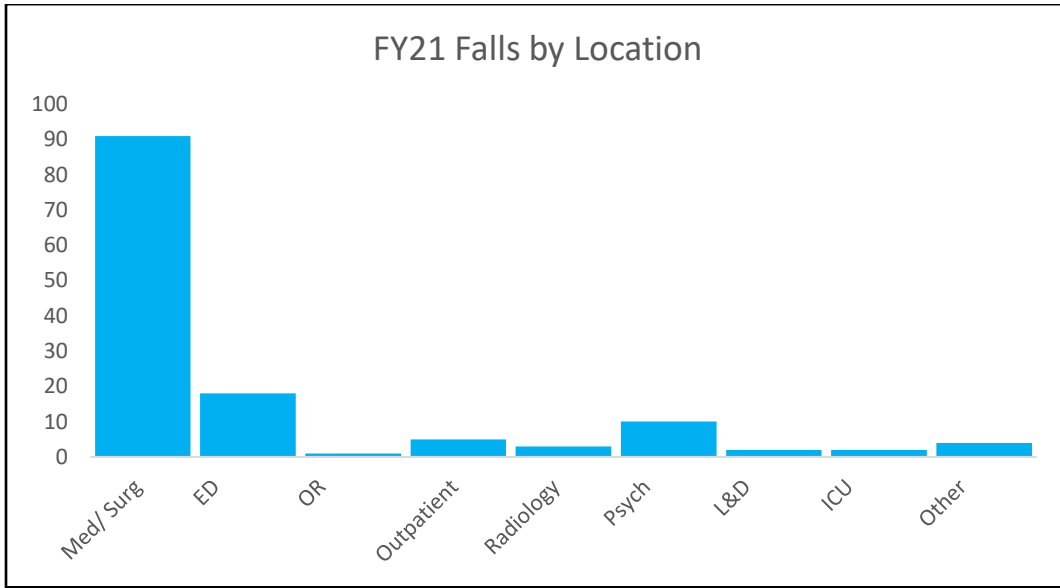
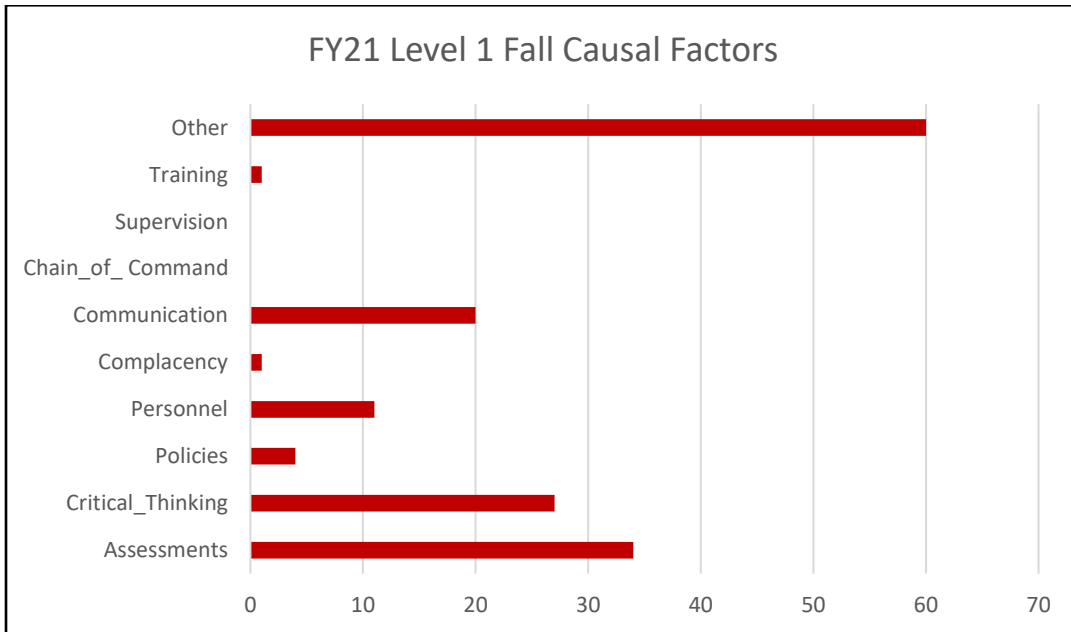


Figure 12: Falls By Location



The top three causes of fall events were assessments, critical thinking, and other factors. "Other" was the most common, as falls are often due to an underlying medical condition. Prior to FY21, assessments had been the chief cause of falls. OHCQ often sees discrepancies in assessing fall risk or identifies that staff failed to assess the risk. This remains a top cause of falls. Communication breakdowns also occur between the staff and patients or among staff regarding fall prevention strategies.

Figure 13: Fall Causal Factors



Fatal Fall with Delay in Diagnosis Case

A patient presented to the ED with generalized weakness and shortness of breath and was admitted with a diagnosis of sepsis, anemia, and a suspected pancreatic mass. Two days after admission the patient sustained an unwitnessed fall but denied hitting their head. The primary nurse documented notifying a physician about the fall but did not document the name of the provider called. There was no post-fall patient assessment by a provider. Four hours after the fall, the patient began having anxiety and difficulty concentrating. Two days later, the patient became hostile and was alert only to self. After two more days, a rapid response was called when the patient became unresponsive to painful stimuli. A CT scan revealed an acute hemorrhage, and the patient was taken to the OR for right craniotomy and hematoma evacuation. A brain flow study revealed no cerebral perfusion consistent with brain death, and the patient was pronounced dead.

It was noted that there was no discussion after the fall between nursing and medical providers regarding the patient's fall or change in mental status. Additionally, there was inconsistent documentation of the patient's mental status by nursing staff and providers. The provider's notes post-fall stated that the patient was alert and oriented with no deficits while nursing daily notes described the patient's mental status as deteriorating. There was no known communication to advocate for the patient's deteriorating mental status.

Fall with Delayed Response

A 73-year-old patient presented to the ED with weakness, cough, and intermittent pain. The patient tested positive for COVID-19 and required admission to the ICU. The patient required intubation but was eventually able to wean from the vent and be transferred to the medical/surgical COVID-19 unit. The patient had been assessed as a high fall risk and the bed exit alarm had been engaged for fall prevention. The bed exit alarm had been set to a zone level two setting and began alerting staff when 50 percent of the patient's weight shifted from the center of the bed.

Staff members were alerted to an activated bed exit alarm via an audible alarm from the bed, a blinking light outside the patient's room, and an emergency alarm text message, indicating the activated bed exit alarm. The alarm was delivered to the individual phone of every nursing staff member on the unit. The message indicated the exact room and bed of the activated bed exit alarm. When the primary nurse responded, the patient was found face down on the floor.

Upon assessment, the patient was alert to person only and had repetitive speech. The patient was quickly sent for a CT of the head due to being anticoagulated and having a visible facial injury. The left eye was blackened and swollen with bruising of the left temple and cheek. A CT of the head and face confirmed a fracture of the left zygomatic arch and floor of the orbit, requiring no intervention.

When the bed alarm sounded, the primary nurse was in with another patient and a Code Green (escalating patient requiring additional staff support) was also in progress for another patient on the unit. The nurse shared that the patient's room door was closed due to COVID-19 precautions, and that numerous staff were attending the Code Green in the next room. The staff in the other patient's room did not hear the audible bed exit alarm due to both patient room doors being closed. They did receive the messaging on the phone but were unavailable to respond to the bed exit alarm. Each of the patients that unit staff were attending to were COVID-19 positive, requiring full personal protective equipment (PPE). The nurse described having to doff and don from patient to patient, prior to entering the patient room, to respond to the activated bed exit alarm.

The unit staff escalated the unit's acuity to the house supervisor, but no additional staff members could be freed to offer additional support. The house supervisor was on the unit assisting elsewhere during the patient fall. It was also noted that the unit charge nurse had her own patient assignment.

Fall with Transfer to Higher Level of Care

A remote safety observation monitoring (telesitter) was implemented for a redirectable patient with a chronic neurological condition and periods of confusion. Despite implementation of telesitter, the patient fell. A head CT scan was read initially as not showing any abnormality. The patient's spouse contacted the medical provider via phone with a concern that the patient was more lethargic and not responsive to the spouse's voice. Two days after the fall, the patient was noted to be increasingly lethargic and then obtunded. A rapid response was called. The patient was intubated and then began having seizures. A repeat CT showed a left parietal subdural hematoma. The patient was flown to shock trauma where two craniotomies were completed for evacuation of an intracranial bleed. The event review revealed lack of communication between the telesitter and nursing. There were challenges of the telesitter monitoring ten screens with multiple challenging patients. When the fall occurred, the telesitter was distracted as she was attending to another patient who had a fall. The telesitter did not see events prior to the patient fall and there were no backups to assist with monitoring the other patients. The telesitter did not inform the primary nurse that the patient was becoming increasingly restless. When the telesitter called the unit, the nurse in charge of the patient was not available. Additionally, telesitter hand-off did not occur that day and the charge nurse was not even aware the patient had remote monitoring engaged.

Lessons Learned and Considerations for Hospitals

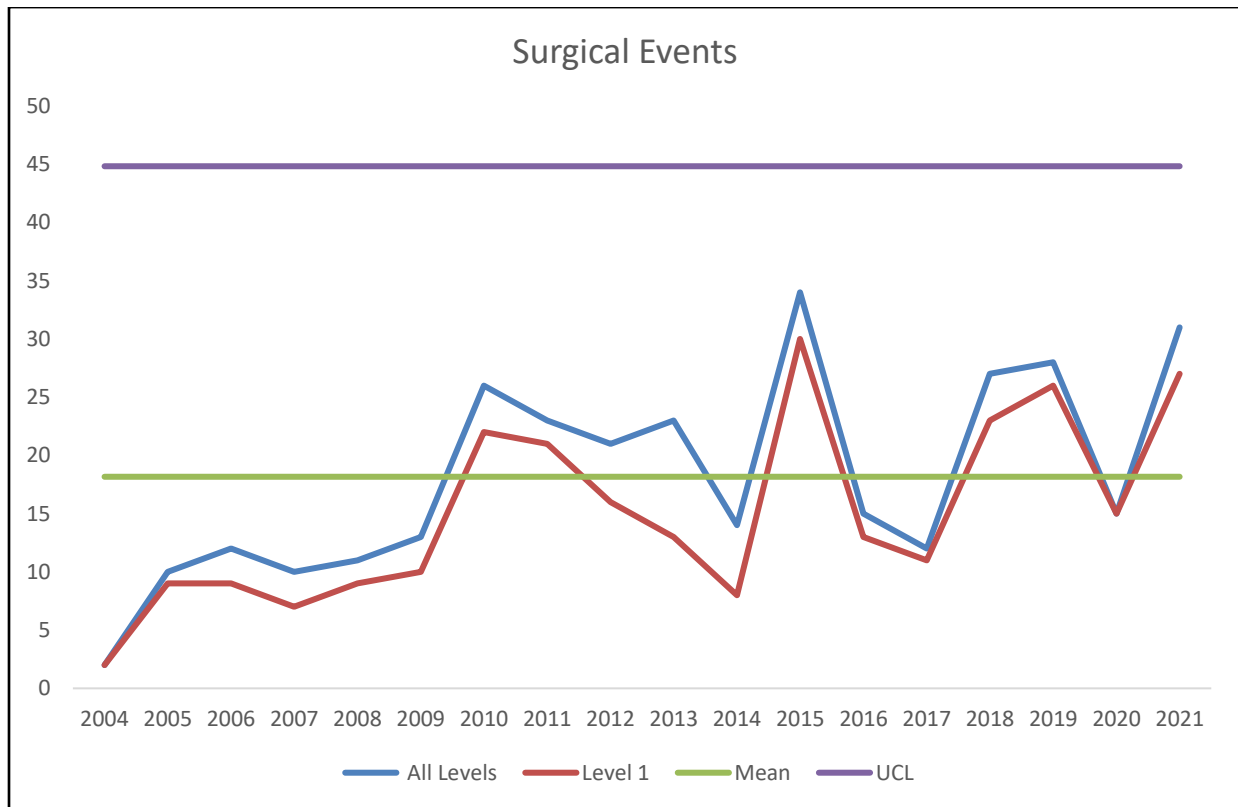
- Engage the patient and family in the fall prevention process.
- Assess fall risk at the original point of encounter. OHCQ often reviewed events occurring in EDs where a validated tool was not used, and preventive strategies were not initiated before arrival to the care floor.

- Tailor the interventions to the patient. Staff should ensure that the right strategy is used for the right patient. This includes telesitter, which may not be appropriate for every patient.
- When using telesitter, consider which strategies will be used should the patient need to travel off unit.
- Ensure beds and other equipment are operational.

Surgical Events

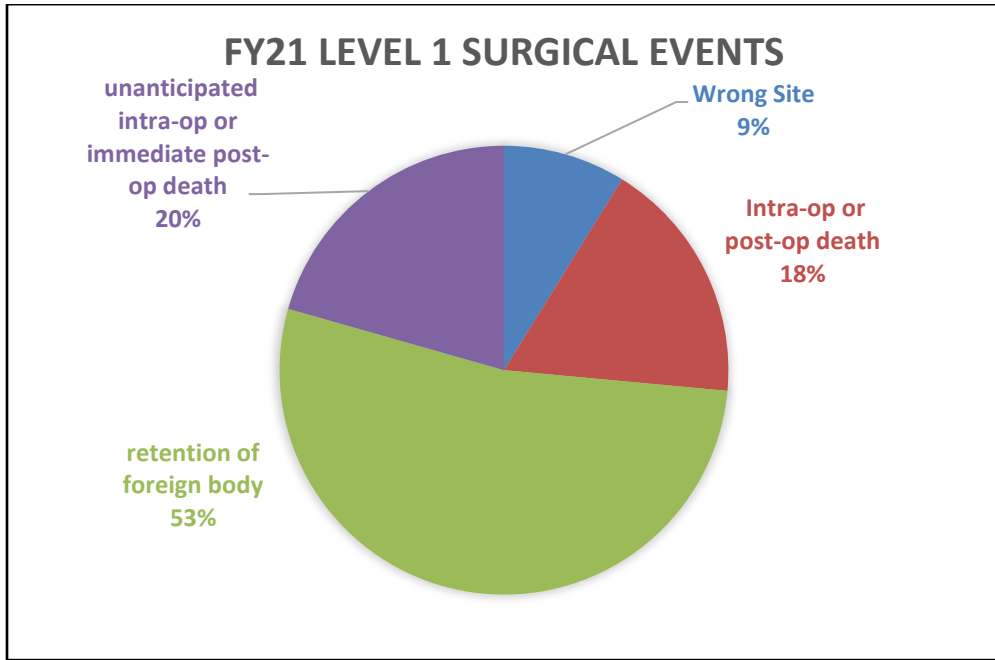
The category of surgical events includes all patient/procedure events along with retained foreign objects (RFOs), intraoperative death in healthy individuals having low-risk procedures, and unanticipated intraoperative or immediately post-operative deaths. Historically, wrong site events were captured in this category but were stratified separately as wrong patient or other wrong event tracking in other areas such as radiology. Surgical events typically have low mortality compared to other event categories, but unexpected deaths do occur intraoperatively and postoperatively.

Figure 14: Surgical Events Over Time



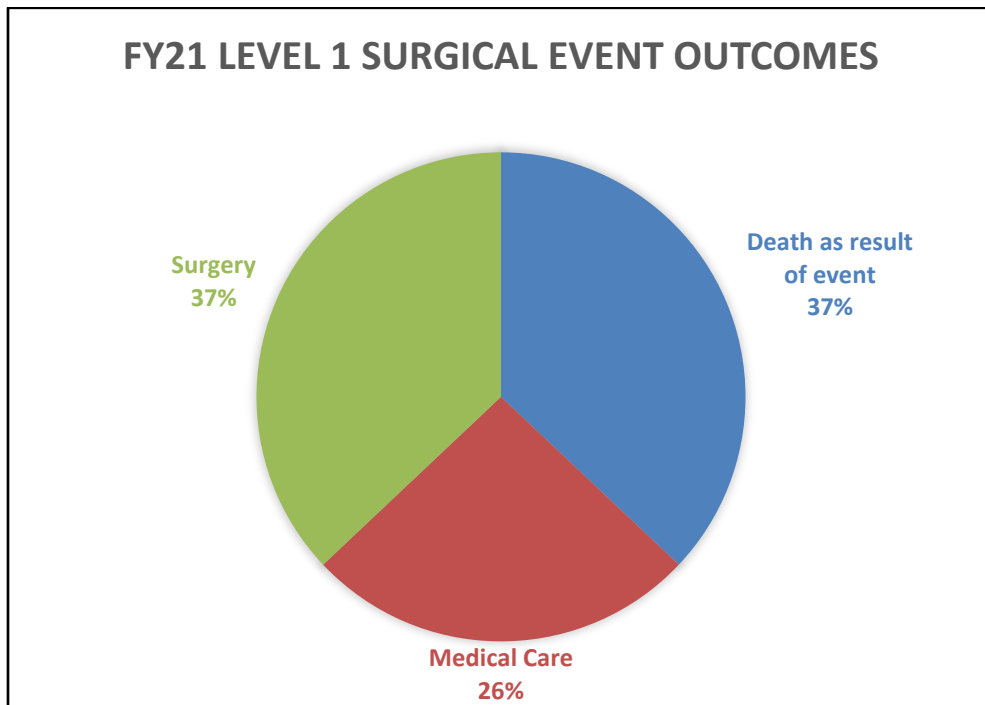
Surgical events vary from year to year. Surgical event reporting increased from 18 in FY20 to 31 events in FY21. More than half of the events reported to OHCQ are retained foreign bodies.

Figure 15: Proportion of Surgical Events by Category



Surgical adverse events result in medical care, surgical intervention, or death as a result of the event. Surgical intervention occurred in 37% of cases reviewed and deaths occurred in 37% of cases.

Figure 16: Surgical Event Outcomes



Retained Sponge

A patient presented for a laparoscopic appendectomy which was converted to an open procedure due to inadequate visualization. The surgeon asked the scrub technician to assist him during the conversion. It was unclear if sponge counts were done during the conversion. The surgeon left the operating room (OR) during skin closure during the closing count. During count reconciliation, the circulating nurse noted an incorrect sponge count and called the surgeon back to the OR. No x-ray was done because the surgeon immediately reopened the surgical site. The event review revealed the count policy was not followed. The surgeon did not participate in count reconciliation activities, continued to close, and failed to give the staff time to complete the count prior to closing. The scrub technician acted as a second assistant to the surgeon, delaying the double verification of the count. This resulted in an unintentionally retained sponge in a layer of the abdominal cavity. The surgeon did not document the reopening the surgical wound to retrieve the sponge. Roles and responsibilities were unclear regarding a surgeon's request for assistance for a conversion from a closed to open procedure, including a contingency plan for the circulating nurse to request the charge nurse to assist with the count when the scrub technician converts to assisting the surgeon.

Wrong Site Procedure

A wrong-site procedure occurred on a patient who underwent surgical procedure for a right long finger trigger release. The patient arrived for pre-op and the nurse entered the patient in the system. The surgeon arrived and verified the history and physical and the operative site with patient. The nurse obtained consent and marked the site at bedside. Report was given to the OR team with consent, history and physical, and site marking verified. The patient was transported to the OR suite and prepped and draped. The OR team called a time-out prior to the start of the procedure. The surgeon did not mark the site where the incision was to be made, but instead marked the dorsal side of the right hand. The surgeon stated he did not mark the lateral side of the right hand because marking would be in the way of his incision. The surgeon started the incision on the lateral part of the right hand which was visibly unmarked. At the postoperative evaluation in the surgeon's office two weeks later, the surgeon identified that the wrong finger (the right ring finger, not the long finger) had been operated on. The patient was rescheduled for a procedure on the correct finger.

Lessons Learned and Considerations for Hospitals

- OR Staff should count in and count out (sponges, tools and equipment).
- Use evidence-based tools like sponge counters.
- Don't close the patient until all items going in have been counted out.
- Clearly mark site near the point of incision.
- Ensure staff are all in for the time out (not distracted, not multitasking, and attentive).
- Clearly define roles and responsibilities including backup when needed.

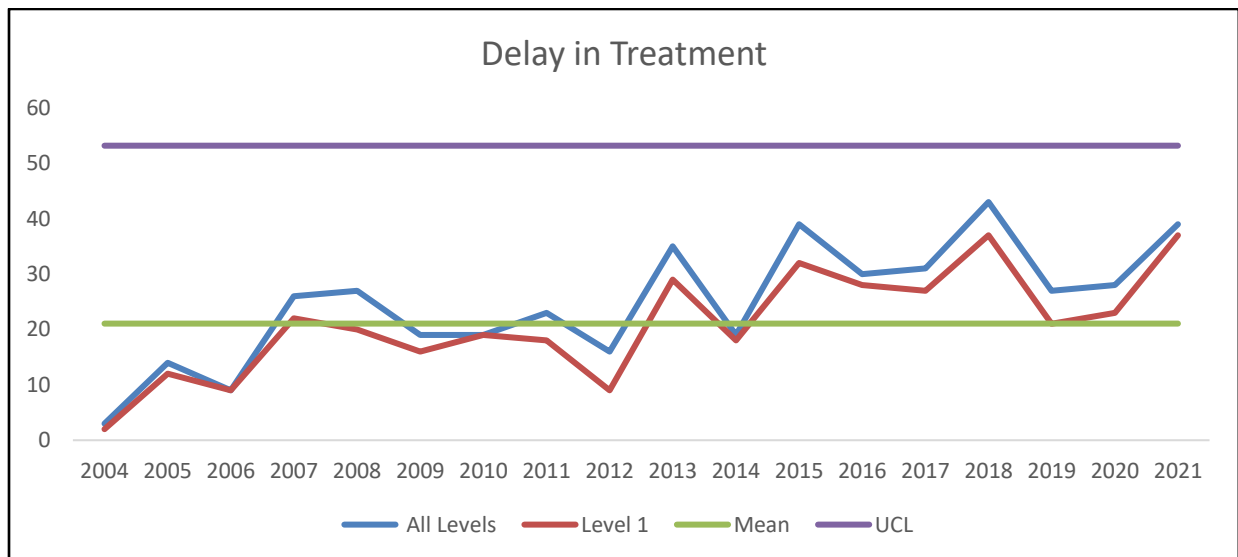
Delays in Treatment

Missed and delayed diagnoses was identified as the number one patient safety concern by the ECRI Institute for 2020. The Agency for Healthcare Research and Quality (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. A 2019 Society for Diagnosis in Medicine (SIDM) study, also published by AHRQ, estimates that one in three malpractice cases involving serious harm related to diagnostic error. According to Sarah Creswell, MSN, RN, CPHQ, patient safety analyst, ECRI, “When a diagnosis is missed or delayed, the patient might not get the treatment they need when they need it.” When this happens, “we’ve missed a critical window.”

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. An individual provider rarely arrives at a diagnosis without some input from the electronic medical record, consultants, nursing, laboratory personnel, or radiology. Therefore, diagnostic errors should generally be viewed as system or process defects, instead of or in addition to being the responsibility of individual providers. By assessing the contributing factors leading to the actions of physicians and licensed independent practitioners (LIPs), valuable information and opportunities for improvement can be gained.

In the Maryland Patient Safety Program, diagnostic errors and delays in treatments are captured in our categories of misdiagnosis, delays in treatment and a staff member’s failure to act.

Figure 17: Delay Event Over Time



Fatal Delay in Treatment - Alarm Fatigue

An acute myocardial infarction patient underwent cardiac catheterization with stenting. After the procedure, the patient was admitted to the telemetry unit on continuous cardiac monitoring. Bilateral restraints for safety had been ordered for the patient. The patient was found several hours later in her room in cardiac arrest. A retrospective review of telemetry data indicated the patient had an episode of tachycardia, then continuous “leads fail” alerts, for approximately 2 hours prior to being found in cardiac arrest. Review of monitor data found that these alerts had been repeatedly silenced. Multiple system failures were identified. The manufacturer of the telemetry monitoring system had released a national alert to change advisory alarms to crisis alarm settings in October 2020 in order to complete a software upgrade. In January 2021 at the height of the COVID-19 pandemic, the manufacturer had emailed a national notice to return alarms to advisory alert. The email notification was missed during that time. The investigation noted that there was only one team member assigned to review software updates. The update schedule was in one of 42 tabs in a spreadsheet that was only accessible to that one team member. The return to advisory alarm from crisis alarms was not discovered until after the investigation of the patient’s death. The monitor system had a built-in hot button to silence alarms. When this button was clicked, it silenced all 16 patients hooked up to telemetry routed to that particular monitor. Staff did not know about the consequences of clicking this built-in button. It is theorized that someone clicked on that hot button to silence another patient’s alarms, consequently silencing the patient’s tachycardia alarm. As a result, the primary nurse did not see the first indications of tachycardia through the phone.

The telemetry monitor manufacturer recommends routing all cardiac alerts to their central monitors. The organization’s historical decision for the alerts to be routed to the nurse’s phones contributed to alarm fatigue. Five other alarms (call bell, code button, bathroom cord alarm, shower cord alarm, bed alarm) were also routed to the phones. The failure to return to advisory alerts due to the missed national notice, led to an increase in telemetry alarms (1,077 per hour for almost 1 year) in addition to 5 other alarms routed to the phones. The alarm fatigue combined with the hot button silence of the telemetry system resulted in failure to recognize the patient’s deteriorating cardiac condition and a consequent treatment delay.

Delay in Treatment - Alarm Fatigue

A patient was admitted to the ICU with COVID-19 pneumonia and diabetic ketoacidosis. The patient had a complicated course but was able to be extubated and placed on high-flow nasal cannula. Over six minutes, the patient had a drop in oxygen saturation from the low 80s down to the 30s. The oxygen saturation increased to 51 and at that point the provider saw the patient’s monitor and noticed agonal breathing while standing outside of the patient’s room. The team rushed to the room and started bagging the patient. The patient became pulseless, and resuscitation was initiated. Return of spontaneous circulation was attained after 22 minutes of resuscitative

efforts. The patient was re-intubated and stabilized. A head CT completed a few days later identified anoxic brain injury. The patient was terminally extubated. It was noted in the investigation that the current oxygen saturation monitoring system alarms sound the same regardless of the level of the low measurement. The monitoring system was outdated and could not be configured to differentiate between a crisis alarm and non-crisis alarm for oxygen saturation. The monitor for the patient had sounded as a warning, not as a crisis. Staff believed that an extremely low oxygen saturation would sound as a crisis alarm and would allow them to respond urgently. There were multiple alarm alerts on the unit, which led to increased alarm fatigue and a greater likelihood that significant warnings would be missed.

Delay in Treatment

A 93-year-old patient on telemetry monitoring was transferred from her inpatient room on the fourth floor to the first floor for scheduled imaging studies. While the patient was having the imaging studies completed, the monitor tech notified the patient's nurse that the patient's heart rate was bradycardic. Staff did not know the patient's location in the Imaging Department and had difficulty finding her. Eventually, the vascular lab tech confirmed that the patient was in the Vascular Lab and awaiting transport back to her room. When the Vascular Lab tech checked on the patient, she was unresponsive, and a Code Blue was called. The patient was resuscitated and transferred to the ICU. Per family decision, all heroic measures were discontinued, and the patient expired. During the RCA, the primary nurse explained that she scheduled transport for the patient to Nuclear Medicine for a lung scan and she had left the floor for her scan. In an effort to cluster care and prevent multiple trips from the floor, the techs at Nuclear Medicine saw the order for CT chest and transported the patient to CT, which was very close to Nuclear Medicine. Following the CT scan, the CT tech then transferred the patient to the nearby Vascular Lab for the venous duplex study. Both the nuclear medicine tech and CT tech stated the patient was alert and awake. As a result of the event, the "Ticket to Ride" tool, which communicates key information to other department staff when the patient has to travel off the floor, was updated. This now requires the full name and phone number of the patient's primary RN. When patients leave the unit for more than one test, the department sending the patient to their next destination will use the information on the "Ticket to Ride" to notify the primary RN via phone for each department transfer.

Lessons Learned and Considerations for Hospitals

- Assess alarms, monitoring functionality to avoid alarm fatigue.¹⁵
- Ensure that there are redundancies and contingencies for responsibilities for critical alarm updates or configurations for safety.

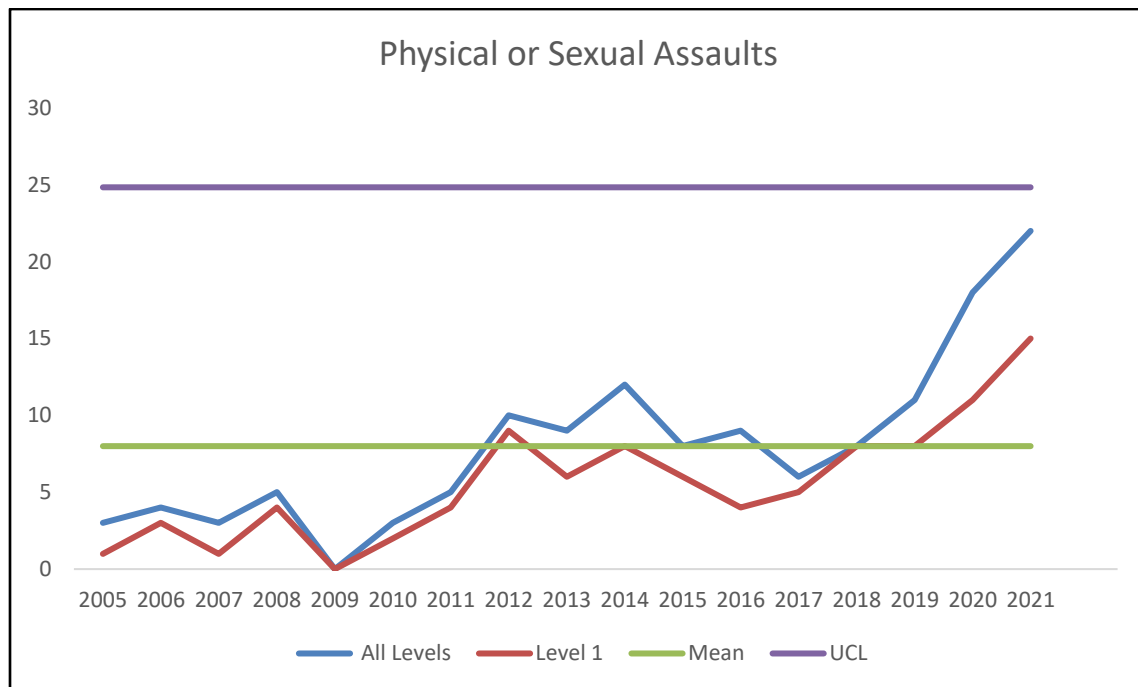
¹⁵ https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_50_alarms_4_26_16.pdf

- Ensure that the staff are knowledgeable in 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

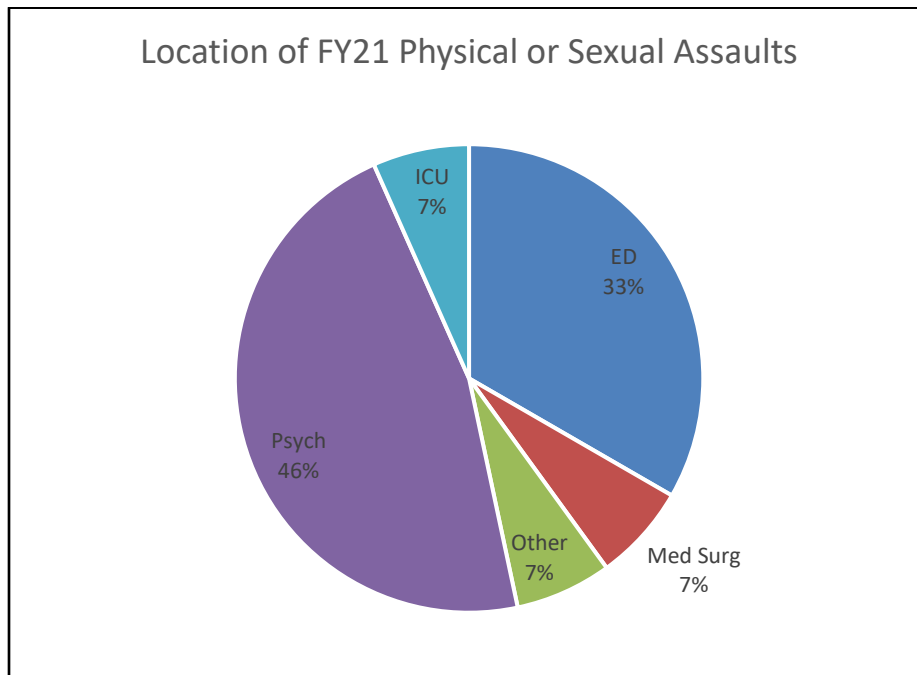
The National Quality Forum defines a physical assault within or on the grounds of a health care setting as a never event. Additionally, death or serious injury of a patient or staff member resulting from a sexual assault that occurs within or on the grounds of a health care setting is also a never event. Organizations have routinely reported patient assault but had not considered reporting the assault on staff as reportable events. This was reinforced and communicated with hospitals during the OHCQ presentation at the annual patient safety conference and the Maryland Hospital Association update.

Table 18: Physical or Sexual Assault Events Over Time



Reporting of physical or sexual assaults increased by 50 percent in FY21. These events commonly occur in the psychiatric care environment and in the 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.

Figure 19: Locations of Assaults



Sexual Assault of a Patient by Staff

Hospital security contacted local law enforcement to report a suspected staff theft of a hundred dollar bill and a check from a patient. While searching the staff member's personal effects and cell phone, local law enforcement located videos, photos, and written lists of what appeared to have been credit card information. The staff member was fired. During their investigation, local law enforcement located a video on the staff member's cell phone of a female patient wearing an adult diaper being sexually assaulted. Hospital security was made aware, and a subpoena was issued for the names of patients transported by the former staff member on the date of assault. According to the list of patients, only one female had been transported. The staff member suspected of the assault was arrested and charged and was awaiting trial. The patient was made aware of the assault.

Physical Assault of Staff by a Patient

A 20-year-old male patient came to the ED following a syncopal event with fall in the bathroom at home. As a result of the fall, he suffered a 2 cm laceration to the back of his head. This patient was not a behavioral health patient and staff did not identify the patient as a safety risk to the health care team. The patient had no prior documented visits, so there was no way to anticipate or predict sudden violent behavior. As the ED provider was placing staples in his occipital laceration, the patient suddenly jumped up and ran from the ED treatment room. A hospitalist physician was working at the computer terminal outside this room, with his back to the room. The patient grabbed

the provider from behind, threw the provider to the floor and began punching the provider. A male ED nurse attempted to intervene and was punched above the left eye, causing a laceration. The patient then encountered the ED physician and punched him in the face, breaking his nose. A Code Green was called for internal security response and 911 was called for police response. After assaulting three hospital staff members, the patient managed to leave the ED area and enter the back hallway and elevators to the main hospital. Security staff were able to stop him before he got on the elevator. He was placed on a stretcher and brought back to the ED, where he was medicated and placed in four-point restraints for the protection of the patient and staff. The patient's father was notified and given additional information relevant to the patient's behavior and care.

Lessons Learned and Considerations for Hospitals

- 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.
- Promote a just culture that includes zero tolerance for reckless behavior such as intentionally unsafe or criminal acts.

Other Significant Events

Fatal Medication Omission

A 34-year-old patient was a restrained driver involved in a front-end car collision with air bag deployment. He was brought to the ED via ambulance as a trauma Level 2 designation. Upon clinical assessment, the patient was diagnosed with right-sided T-type acetabular fracture and multiple closed rib fractures. The orthopedics team recommended surgical stabilization of the right acetabulum. During open reduction and internal fixation in the OR, the patient coded, and the procedure was aborted. CPR was performed and CT was completed showing bilateral pulmonary embolism. The patient was transferred to the ICU, where he coded again and ultimately expired. Subsequent review identified that orders for deep vein thrombosis (DVT) prophylaxis had been omitted for one-and-a-half days. The orthopedics team recommended DVT prophylaxis but did not verify whether it had been ordered. The trauma team's physician assistant documented in his progress notes that patient was on DVT prophylaxis, but there was no order placed in EMR. Prior to surgery, the trauma team did not fully review orders and evaluate the patient. The trauma provider failed to follow the protocol for placing medication orders in the EMR.

Fatal Medication Overdose

An Emergency Department (ED) physician consulted with a neurologist about initiating intravenous immune globulin (IVIG) medication regime for myasthenia gravis. The neurologist

recommended the patient receive IVIG 2 gm/kg over 5 days (that is, 0.4 gm/kg daily for 5 days). The ED provider ordered 2 gm/kg daily for five days. The patient received eight (8) grams total over four days before a pharmacist caught the error. The treatment team contacted Poison Control, which recommended treatment with plasmapheresis. The patient had a religious objection to transfusion and refused. The intensivist also contacted a specialty team to explore bloodless alternatives and use of erythropoietin and iron were recommended. The treatment team also ordered steroids, but interventions were not successful. The patient developed acute renal failure due to the medication error and became severely anemic. The patient expired as a result of the IVIG infusion overdose.

Among the challenges identified was that the conversation between the ED and neurology provider occurred over the phone. There was a misinterpretation of the information given. Additionally, the order set for ordering IVIG is very difficult to use for providers who are unfamiliar with how to order it. Although the EMR defaults dosing IVIG to 0.4 g/kg/dose and suggests 0.5 g/kg/dose and 1 g/kg/dose, it did not warn providers who entered a dose of 2 g/kg/dose, apparently because a one-time 2 g/kg dose is appropriate for some indications. Subsequently, ordering of IVIG was changed to be restricted to gastroenterology, hematology/oncology, obstetrics/gynecology, neonatology, neurology, and pediatrics practitioners who would be familiar with the dosing.

Fatal Accidental Oxygen Supply Shutoff

Maintenance staff inadvertently closed a valve on the medical oxygen supply line that feeds the ICUs, ED, and patient care areas. The staff member thought the valve was a medical air tie-in valve that was installed previously during facility construction. At the time of the incident, the ceiling tile frame beneath this valve was labeled “TIE-IN FOR CCU/HOSP MED AIR.” The loss of oxygen supply was evident immediately by all ventilators alarming, the call bell system alarms, and the ICU medical gas zone alarm panels also alarming. The ICU director communicated this to the maintenance staff, who then re-opened the oxygen valve. Shortly after re-opening this valve, the maintenance staff zip tied the oxygen valve open and labeled it “Oxygen.” While the oxygen valve was closed, resuscitation was initiated on three patients. Two patients died and a third died within a day. While the oxygen valve was closed, multiple patients declined, resulting in three code blues. Three patients ultimately died. The third patient death occurred 13 hours later but the death was not directly attributed to the event.

Findings from the investigation included:

- Medical gas labeling inaccuracies,
- Ceiling valves not locked,
- Alarm panels outdated or missing,
- Communication breakdowns between maintenance staff and contractors,

- Lack of communication between maintenance staff and clinical leaders regarding medical gas, and
- General medical gas knowledge deficit.

Summary

Creating a culture of safety with a high reliability mindset is essential in providing safe care consistently every day. Many more examples from FY21 could be shared, but only a few are included in this report. Production pressures, staffing challenges, and disruptors like the COVID-19 pandemic must be overcome by the resilience that can be achieved when safety is truly the priority.

The hospital industry has made continuous strides in innovations to cure and heal patients every day. Yet, we still have harm. Patients expect safe and effective care, which is why the hospital patient safety program is essential. OHCQ has a uniquely broad perspective of hospital patient safety in Maryland, despite the likelihood of under-reporting. The Hospital Patient Safety Program is essential to OHCQ's mission to protect the health and safety of Marylanders and to ensure 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 but is how OHCQ 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 "Serious Reportable Events"¹⁶ taxonomy. This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the National Quality Forum (NQF) system is nationally recognized, it 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 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?

¹⁶ 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 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 St. III or IV. Excludes so-called 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 and goes into DIC and dies- that 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 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

