Patient Safety Reporting Program 2019 Annual Report

Building a Culture of Safer Care—Together

June 2020

The Oregon Patient Safety Commission, 2020

The Oregon Patient Safety Commission is a semi-independent state agency that operates multiple programs aimed at reducing the risk of serious adverse events occurring in Oregon's healthcare system and encouraging a culture of patient safety. The Oregon Patient Safety Commission's programs include the Patient Safety Reporting Program and Early Discussion and Resolution. To learn more about the Oregon Patient Safety Commission, visit oregonpatientsafety.org.

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Executive Summary

In our complex and constantly evolving healthcare system, unintended patient harm events can—and do—occur. To effectively manage the wide range of safety issues that arise in the process of delivering care, organizations must anticipate these risks, learn from events that occur, and continually adjust their systems to minimize risk. This ongoing diligence requires foundational systems that support an organizational culture of safety. These systems not only benefit patients, but they support the ability of care providers to do their jobs effectively and safely.

In 2019, Oregon healthcare organizations—ambulatory surgery centers (ASCs), hospitals, and nursing facilities—voluntarily contributed 312 adverse event reports to the Patient Safety Reporting Program (PSRP) for learning. Through both the information contributed to PSRP and research in the field of patient safety, we have highlighted three foundational patient safety lessons:

- **An organizational culture of safety is essential to make progress in patient safety.** Without a culture of safety, well-intentioned patient safety improvement efforts are less effective and unsustainable.
- **Changing systems—not individuals—is fundamental to changing culture.** Improving the safety of our healthcare system requires that organizations fix systems by addressing the core reasons why adverse events occur, rather than assigning blame to individuals.
- **Patient safety work requires ongoing problem solving.** Given the dynamic nature of healthcare, organizations must build and constantly refine their systems to address the wide range of safety issues that will arise.

Recommendations to Improve the Safety of Oregon's Healthcare System

We recommend that healthcare organizations take steps to strengthen how they respond to and learn from identified risk and adverse events, in two ways:

- Implement systems for responding to adverse events that support a culture of safety.
- Seek to understand the role of inequity in adverse events to inform concrete strategies for change.

Additionally, and perhaps more importantly, to truly make progress at the state level, patient safety challenges cannot be resolved in isolation by individual organizations. A coordinated and collaborative approach through PSRP can help ensure all of Oregon moves forward together.

At the Oregon Patient Safety Commission (OPSC), we are proud to serve Oregonians through PSRP by encouraging a culture of patient safety across Oregon's healthcare system, and by supporting healthcare organizations to learn about and improve systems of care for every patient they serve.

Introduction

Patient Safety in Oregon

Even though all of us in the healthcare field seek to keep patients safe, unintended harm sometimes occurs. The Oregon Patient Safety Commission (OPSC) promotes candid dialogue about patient harm events—not as a way to assign blame, but rather to understand what happened and learn from it—as a crucial step toward improving healthcare.

The Oregon Legislature created OPSC in 2003 as an independent voice for patient safety. At that time, many people in our state and around the world saw an urgent need for greater collaboration and systemwide insights to address underlying challenges in healthcare that increase the risk of patient harm. OPSC grew out of recommendations from a workgroup representing medical providers, insurers, purchasers, and consumers. They believed that the work of improving patient safety never ends and should not have to be done in isolation.

A Vision of Collaboration

"As I sought remedies that would support healthcare system improvements [and] result in quality outcomes for patients, I discovered that I was not alone. All the members of the group were part of this quest for a process and a culture of patient safety that would work for patients and the institutions charged with serving them."

— Workgroup Member Ellen C. Lowe, public testimony in support of House Bill 2349

Building a Culture of Safer Care—Together

OPSC supports all representatives and users of Oregon's healthcare system in working on shared goals that advance our mission—to reduce the risk of patient harm and encourage a culture of patient safety (ORS 442.820 (2)). Today, OPSC is a multi-faceted, semi-independent state agency operating two mission-driven programs, the Patient Safety Reporting Program and Early Discussion and Resolution. OPSC's body of work is independent of any regulatory functions and seeks to advance, support, and encourage patient safety in Oregon.

OPSC's Founding Principles

- Create a safe, non-punitive, and confidential haven for the collection and use of patient safety information for learning.
- Change the climate of patient safety in Oregon, while acknowledging that such change will require a long-term, sustained effort.
- Identify and share best practices.
- Fully represent patients and their experiences in patient safety efforts.
- Encourage a "just culture" framework that balances individual accountability with a non-punitive, learning approach to achieve system improvements.

The Patient Safety Reporting Program

Oregon's Patient Safety Reporting Program (PSRP) is designed to make care safer by sharing knowledge across the state about adverse events and strategies for prevention. It is a non-punitive system to cultivate trust, inspire information sharing, and motivate quality improvement among healthcare organizations.

Healthcare organizations—ambulatory surgical centers (ASCs), hospitals, nursing facilities, and pharmacies—voluntarily contribute information to PSRP about when, how, and why patient harm occurs, as well as their strategies for preventing it in the future. (See Appendix I. PSRP Eligibility and Participation for more information.) This information gives us insight into an organization's processes and systems for responding to and learning from patient harm events to make care safer for all patients. We analyze that information and share what we learn statewide so that broader system improvements can be put into place throughout Oregon. All contributions to PSRP are protected under state law, creating a safe and confidential environment where patient safety innovation can thrive.

Because healthcare is constantly changing and evolving, PSRP focuses on understanding and building Oregon's capacity for learning from adverse events, which has the potential to serve all Oregonians. When organizations use adverse events as an opportunity to learn and improve their systems of care, they are also building the skills necessary to address the wide range of safety issues that will inevitably arise.

It's About Learning and Minimizing Risk

"The number of events reported to patient safety reporting systems will not provide the answer [to the question 'how do we know that the reporting system actually improved patient safety?']. One measure of safety could be whether we learned from the mistake, intervened, and reduced the probability that another patient would be harmed from a similar event."

—Pronovost et al. 2008[2]

2019 PSRP data provides a window into how reporting organizations respond to adverse events. This information can help us understand how these organizations are learning from adverse events to minimize risk and where support is needed to strengthen the culture of safety in Oregon's healthcare system.

What We've Learned About Patient Safety

An adverse event is defined as any aspect of a patient's care, and not the patient's underlying disease or condition, that results in unintended harm or creates the potential for harm. Adverse events may or may not be preventable. The causes of adverse events remain much the same today as they were when the Institute of Medicine published its seminal work, *To Err is Human*, 20 years ago. They stem from problems in the process of providing healthcare in a complex delivery system.

So, how can healthcare organizations effectively manage the wide range of safety issues that will arise while working within a constantly-evolving healthcare delivery system? Research in the field of patient safety and information contributed to PSRP both highlight several fundamental patient safety principles that organizations should use to guide their work:

- An organizational culture of safety is essential to make progress in patient safety.
- Changing systems—not individuals—is fundamental to changing culture.
- Patient safety work requires ongoing problem solving.

An Organizational Culture of Safety Is Essential to Make Progress in Patient Safety

In its report *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years After To Err is Human*[3]*,* the National Patient Safety Foundation identified leadership support for a culture of safety as the most important of their recommendations for achieving patient safety. Without a culture of safety, well-intentioned patient safety improvement efforts are ineffective and unsustainable.

A recent study published in the *Journal of Patient Safety* found that a facility's organizational culture impacts the efficacy of Just Culture training—a specific methodology intended to end the "shame and blame" response to adverse events.[4] The relationship between a culture of safety and effective patient safety programs was also noted by Armstrong et al., who found that the use of a quality measurement tool expressly designed to avoid blame in an organization lacking a culture of safety was, in practice, experienced as a "blame allocation device."[5(p163)] Without a culture of safety, the tool undermined patient safety work, despite its intent and careful design. To build an effective patient safety program, an organization must first have a culture of safety.

Culture of Safety: How We Do Things Here is in Pursuit of Safety

Culture of safety is an organization's shared perceptions, beliefs, values, and attitudes that combine to create a commitment to safety and an effort to minimize harm.[6] The Joint Commission identifies the following key features of a culture of safety:

- "Staff and leaders that value transparency, accountability, and mutual respect.
- "Safety is everyone's first priority.
- "Behaviors that undermine a culture of safety are not acceptable, and thus should be reported to organizational leadership by staff, patients, and families for the purpose of fostering risk reduction.
- "Collective mindfulness is present, wherein staff realize that systems always have the potential to fail and staff are focused on finding hazardous conditions or close calls at early stages before a patient may be harmed.
- "Staff who do not deny or cover up errors but rather want to report errors to learn from mistakes and improve the system flaws that contribute to or enable patient safety events.
- "By reporting and learning from patient safety events, staff create a learning organization."[7(p6)]

Changing Systems—Not Individuals—is Fundamental to Changing Culture

Adverse events stem from problems in the process of providing healthcare in a complex delivery system. However, our natural reaction when things don't go as planned is often to focus on individuals, and more specifically on assigning blame. This can be counterproductive to patient safety improvement. In his 1997 testimony to the U.S. Congress, Dr. Lucian Leape, a professor at Harvard School of Public Health and patient safety expert, stated that, "[T]he single greatest impediment to error prevention is that we punish people for making errors."[8] Dr. Leape has argued that we need to dispel two myths that perpetuate blame:

1. **The perfection myth:** "If people try hard enough, they will not make any error."[9(p140)]
2. **The punishment myth:** "If we punish those who do make errors, they will make fewer of them."[9(p140)]

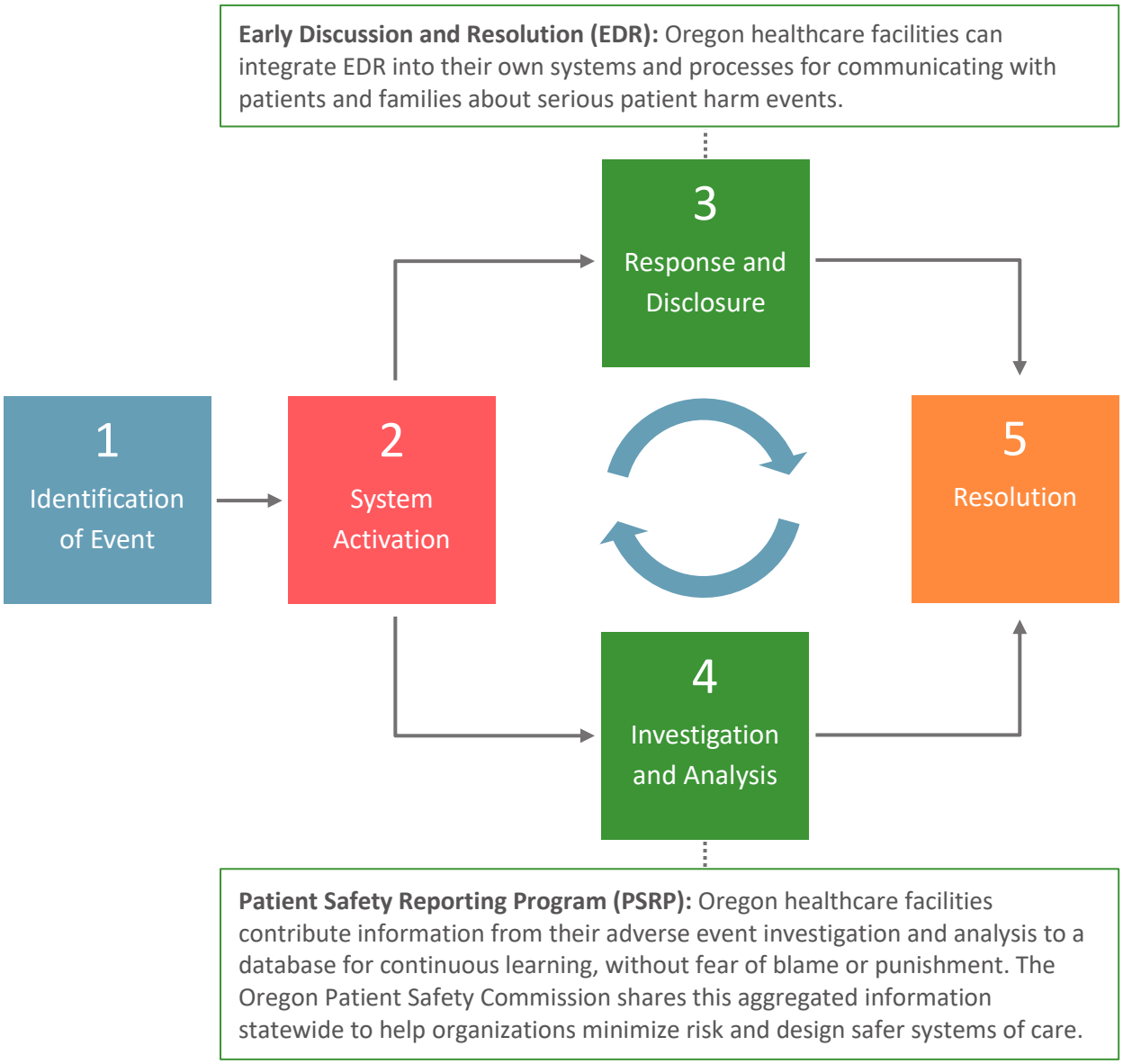
Improving the safety of our healthcare system requires a shift in focus from assigning blame to fixing systems by addressing the core reasons why mistakes occur. This system-based approach is essential to building a culture of safety.

In 2016, the Agency for Healthcare Research and Quality (AHRQ) published its toolkit for responding to patient harm that incorporates a comprehensive, system-based approach called Communication and Optimal Resolution (CANDOR). The CANDOR Toolkit provides a structured process for ongoing communication with and care for the affected patient and family, support for healthcare providers involved in the event, and a focus on system-based learning to prevent recurrence.

CANDOR provides organizations with a roadmap to build and sustain a culture of safety. And here in Oregon, OPSC's programs align with organizations' efforts to implement CANDOR by supporting two core elements of the model (Figure 1):

- **Investigation and Analysis:** PSRP collects and analyzes information from healthcare facilities about their investigation and analysis of serious patient harm or near misses, as well as their strategies for prevention. OPSC shares the broader lessons learned to support facilities in refining their best practices and preventing future harm.
- **Response and Disclosure:** The voluntary Early Discussion and Resolution (EDR) process helps connect patients who experience harm (or a family member) and their healthcare provider so that they can speak candidly about the harm that occurred, work toward reconciliation, and contribute to safeguarding others from similar harm.

Figure 1. The CANDOR[10] Process and Alignment with OPSC's Programs: A Model for Building and Sustaining a Culture of Safety



Patient Safety Work Requires Ongoing Problem Solving

In the complex and rapidly changing healthcare delivery system, patient safety is not a box that can be checked or task that can be completed. Patient safety work is ongoing. With the introduction of new processes, systems, and technologies in healthcare, new and often unanticipated risks are also introduced. To effectively manage the wide range of safety issues that will arise, healthcare organizations must be able to both anticipate these risks and continually adjust their systems.[1]

Patient Safety is a Moving Target

"Safety in healthcare is a constantly moving target. As standards improve and concern for safety grows, we come to regard an increasing number of events as patient safety issues. In this respect, healthcare differs from almost all other safety-critical industries. What we regard as harm in, for instance, civil aviation remains the same whatever advances may occur in aviation technology or practice. In contrast, innovation and improving standards in healthcare alter our conceptions of both harm and preventability."

—Vincent and Amalberti 2015[11]

As we work to make healthcare safer, we also expand our concept of what is in our control, and things that seem unpreventable today will seem preventable tomorrow. For example, today, healthcare organizations recognize that most healthcare-associated infections (HAIs) are preventable. But that wasn't always the case.[11] "[HAIs] were long accepted by clinicians as an inevitable hazard of hospitalization."[12] It has taken a coordinated effort between healthcare organizations, regulators, and support agencies for more than a decade to improve the infection rate. Even so, a meta-analysis of 144 HAI prevention studies found that 30-50% of currently-occurring HAIs could be prevented.[13]

The COVID-19 Pandemic Highlights the Need for a Culture of Safety

The ongoing identification and management of risk in healthcare requires a culture that supports learning and improvement, in times of stability and during periods of intense stress on the healthcare system, like the COVID-19 pandemic.

Risks that already exist can be exacerbated by things like fatigue, burnout, illness, poor psychological safety, and lack of team trust. This increased risk can contribute to adverse events and inhibit the ability of care providers to safely deliver care.[14] Whether the risk is related to the safe administration of medication or having adequate personal protective equipment for staff, an organization with a culture of safety will be better equipped to navigate these situations.

Building organizational capacity to manage risk and address safety issues on an ongoing basis is more important than ever as organizations face the COVID-19 pandemic, and a culture of safety is foundational to these efforts. Leadership must continue to prioritize and resource programs that support culture development to keep their patients and providers safe.

Adverse Events in Oregon

In 2019, Oregon healthcare organizations voluntarily contributed 312 adverse event reports to PSRP for learning: 78 reports were from ASCs, 231 were from hospitals, and three were from nursing facilities. Pharmacies did not report in 2019. Table 1 provides a list of the types of adverse events that Oregon healthcare facilities contributed to PSRP.

Table 1. Adverse Event Type by Segment, 2019

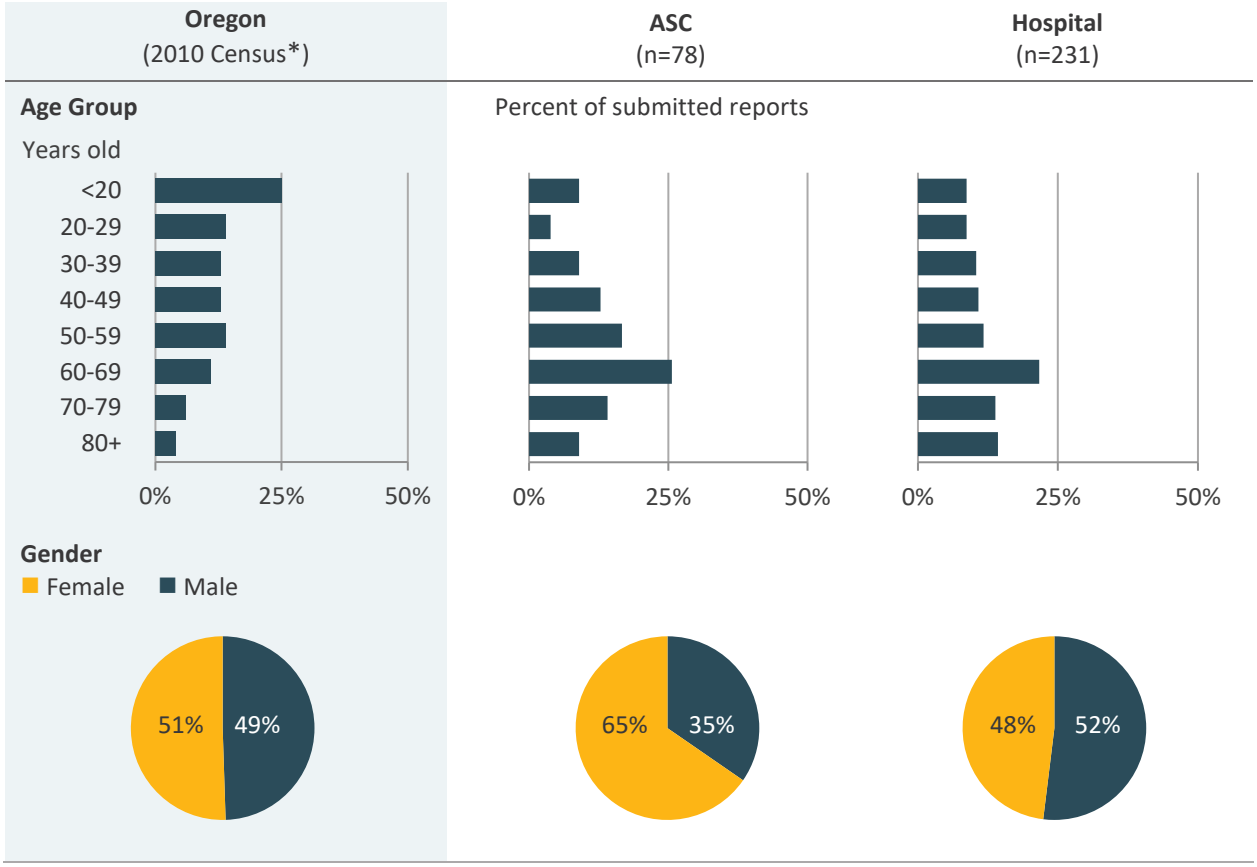
Event Type	ASC	Hospital	Nursing Facility	Total
Surgical or other invasive procedure	46 (59%)	12 (5%)		58 (19%)
Fall	5 (6%)	39 (17%)		44 (14%)
Care delay		33 (14%)		33 (11%)
Device or supply	6 (8%)	25 (11%)	2 (67%)	33 (11%)
Medication or other substance	6 (8%)	24 (10%)		30 (10%)
Healthcare-associated infection (HAI)	7 (9%)	19 (8%)		26 (8%)
Suicide or attempted suicide		19 (8%)		19 (6%)
Pressure injury		12 (5%)		12 (4%)
Retained object	1 (1%)	9 (4%)		10 (3%)
Perinatal		9 (4%)		9 (3%)
Maternal		8 (3%)		8 (3%)
Other		7 (3%)	1 (33%)	8 (3%)
Anesthesia	5 (6%)	2 (1%)		7 (2%)
Failure to follow up test results		6 (3%)		6 (2%)
Elopement		4 (2%)		4 (1%)
Irretrievable loss of irreplaceable specimen	1 (1%)	2 (1%)		3 (1%)
Blood or blood product		3 (1%)		3 (1%)
Burn		3 (1%)		3 (1%)
Contaminated drugs, devices, or biologics	1 (1%)	1 (0.4%)		2 (1%)
Radiologic		2 (1%)		2 (1%)
Aspiration	2 (3%)			2 (1%)
Deep vein thrombosis (DVT)	1 (1%)			1 (0.3%)
Restraint or bedrail related		1 (0.4%)		1 (0.3%)
Total Events	**81**	**240**	**3**	**324**
Total Reports	**78**	**231**	**3**	**312**

Reporters may select multiple event types in a single report. Percentage is of total reports rather than total events, so percentages may add to more than 100.

Adverse Events Can Happen to Anyone

Adverse events are the result of system-level factors and they can—and do—happen to anyone. Because PSRP reporting is voluntary, the demographics of patients involved in reported events may not be representative of all patients that experience adverse events in Oregon (Figure 2). The patients affected by adverse events reported in 2019 ranged in age from newborn to 96. Patients aged 60 and older accounted for almost half (49%) of reported events. National data on healthcare use[15] indicates that utilization goes up as we age, and more contact with the healthcare system presents more opportunity to experience an adverse event.

Figure 2. Patient Age Group and Gender by Segment, 2019



* U.S. Census Bureau, 2010 Census of Population and Housing, Population and Housing Unit Counts, CPH-2-39, Oregon, U.S. Government Printing Office, Washington, DC, 2012.

Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

Healthcare Inequity Increases the Risk of an Adverse Event for Some Groups

Research indicates that there is inequity—a lack of fairness or justice—in healthcare that plays a role in patient safety.[16,17] One study[17] identified race differences for serious harm events by both type of event and hospital setting for events reported in a voluntary reporting system. There is, however, little

information about why these differences exist. More than 40% of reports submitted to PSRP in 2019 indicated that race or ethnicity was *unknown* (Tables 2 and 3).

Table 2. Patient Ethnicity by Segment, 2019

Ethnicity	ASC (n=77)	Hospital (n=231)	Nursing Facility (n=3)	All Segments (n=312)
Hispanic	11 (14%)	11 (5%)	1 (33%)	23 (7%)
Non-Hispanic	37 (47%)	113 (49%)	2 (67%)	152 (49%)
Unknown	30 (38%)	107 (46%)	0 (0%)	137 (44%)

Pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

Table 3. Patient Race by Segment, 2019

Race	ASC (n=77)	Hospital (n=231)	Nursing Facility (n=3)	All Segments (n=312)
American Indian or Alaskan Native	1 (1%)	1 (0.4%)	0 (0%)	2 (1%)
Asian	2 (3%)	3 (1%)	0 (0%)	5 (2%)
Black or African American	1 (1%)	3 (1%)	0 (0%)	4 (1%)
Native Hawaiian or Pacific Islander	0 (0%)	2 (1%)	0 (0%)	2 (1%)
Other	4 (5%)	7 (3%)	0 (0%)	11 (4%)
White	47 (60%)	105 (45%)	2 (67%)	154 (49%)
Unknown	23 (29%)	110 (48%)	1 (33%)	134 (43%)

Healthcare facilites can select more than one race, but only one ethnicity, on an adverse event report.

Pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

Without Adequate Data, Oregon Healthcare Organizations Cannot Understand and Address the Role Inequity Plays in Patient Safety

To better understand how inequity impacts patient safety in Oregon and address it, facilities must submit more complete demographic information to PSRP. Oregon healthcare organizations must seek to understand the role of race and ethnicity in identified safety risks and adverse events that occur, by integrating this information into their existing event investigation and analysis processes. Not until we all take steps to understand the root causes of inequity in patient safety, can we implement targeted strategies and make progress.

Patient Harm from Adverse Events

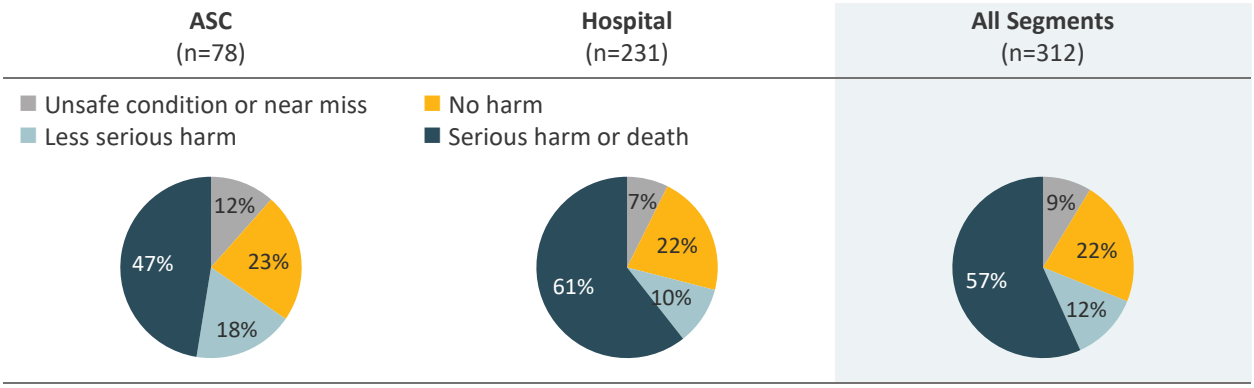
All Events, Regardless of Harm, Are Opportunities to Learn

"There is much to learn from the ability of the system to detect and recover from failures and close calls."

—Vincent et al. 2017[18]

Healthcare organizations that participate in PSRP are required to report serious adverse events. Participants are also encouraged to report less serious harm events, no harm events, and near misses or close calls, because all events, regardless of harm, are prime opportunities to learn about and improve systems of care.[18] As expected from the program's emphasis on serious adverse events, more than half of the reports submitted to PSRP in 2019 (57%) resulted in serious harm or death (harm categories F, G, H, or I) (Figure 3, See Appendix III for more information on harm categories).

Figure 3. Harm Category of Events Reported by Segment, 2019



Note: Surgical and other invasive procedures are more likely to cause serious harm; therefore, OPSC expects more serious harm events from ASCs and hospitals, as they provide higher-risk services to patients.

Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

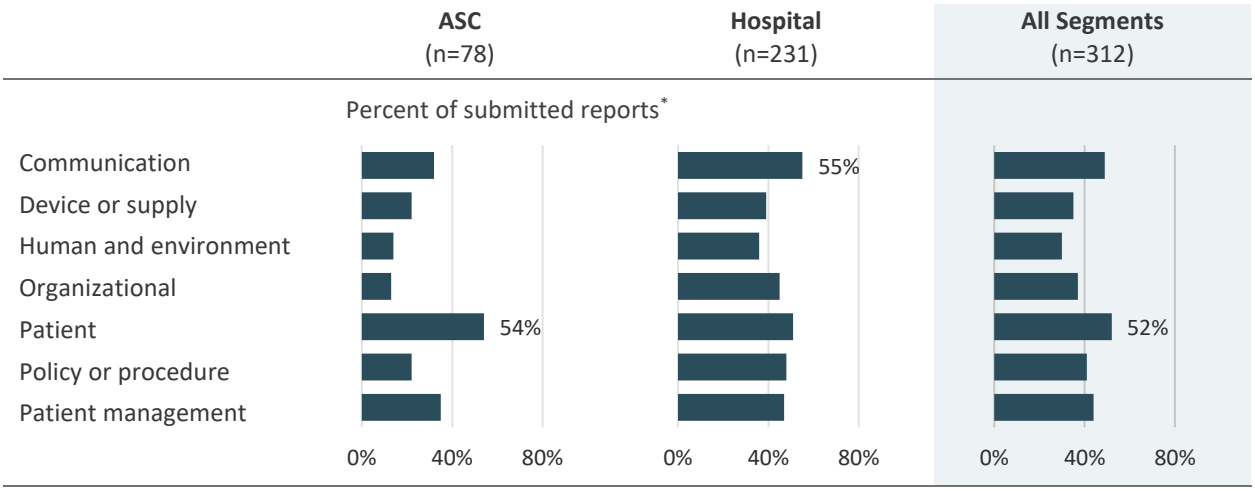
The harm category proportions found in PSRP are not representative of all adverse events.[19] Research estimates that 14% of adverse events result in permanent disability or death, 20% result in temporary disability and 56% of adverse events result in "no or minor disability." Experts believe that near misses occur much more frequently than adverse events, with likely "dozens of near misses" for each serious adverse event that occurs.[20] Variations in the severity of harm by reporting segment may be due to the patient populations served and the types of services provided.

Adverse Events Have Common Causes

The causes, or contributing factors, of adverse events are the situations, circumstances, or conditions that increase the likelihood of an event. By identifying system-level factors, such as *communication* and *patient management* factors, organizations have a solid starting point to uncover deeper system-level causes (or root causes) that can be addressed to prevent the event from recurring.

PSRP organizes contributing factors into seven categories. The most frequently selected category of contributing factors in 2019 was *patient* factors (52%), followed by *communication* factors (49%), and *patient management* factors (44%) (Figure 4). The 312 events submitted in 2019 identified 60 unique contributing factors across the seven categories.

Figure 4. Contributing Factor Categories by Segment, 2019



* Percents total more than 100 as reports may indicate contributing factors in multiple categories.
Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

In 2019, 79% of submitted PSRP reports identified at least one system-level contributing factor. (See "Relevant system-level contributing factors" on page 14 for more information.) Four of the five most frequently selected individual contributing factors in 2019 were system-level factors (*patient factors* are inherently not system-level).

Table 4. Top Five Most Frequently Selected Contributing Factors, 2019

Category	Factor	All Segments (n=312)
Patient	Fragile health status	84 (27%)
Communication	Among interdisciplinary teams	71 (23%)
Communication	Between providers and staff	68 (22%)
Device or supply	Use or selection by healthcare provider or staff	65 (21%)
Patient management	Treatment or care plan	65 (21%)

Adverse Events are Opportunities to Learn

When organizations use adverse events as an opportunity to learn about and improve their systems of care, they are also building the skills necessary to address any number of safety events that they are likely to encounter. Event reports submitted to PSRP provide a window into an organization's event review and analysis process. OPSC reviews reports based on a set of quality components, which serve as indicators of a strong event review and analysis process that can prevent future events. Those quality components are:

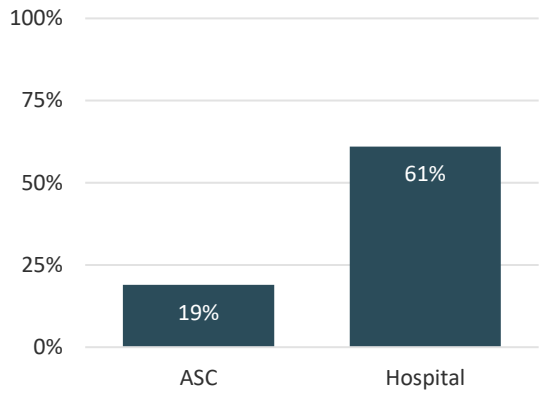
- Pertinent information to fully understand what happened
- Consistent information
- Leadership participation in the event analysis (only required for serious harm events)
- Relevant system-level contributing factors

- One or more root causes
- One or more system-level action plans designed to minimize risk

In 2019, 61% of all reports submitted by all segments contained all six quality components (Figure 5). Of the 155 reports that did not contain all quality components, 58 (37%) were only missing a single component. The two most frequently missing quality components were:

1. One or more system-level action plans designed to minimize risk
2. One or more root causes

Figure 5. Percent of Reports that Included All Six Components by Segment, 2019



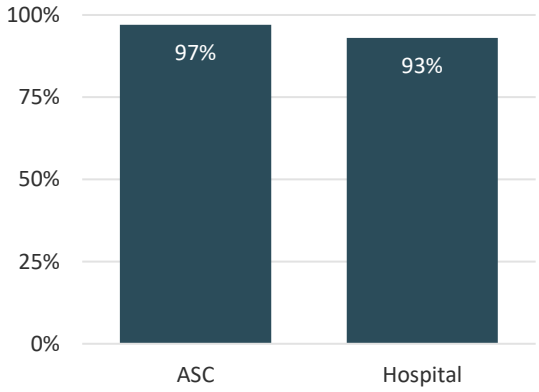
Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

Individual Quality Components

I. Pertinent information to fully understand what happened

The majority of reports received by OPSC include enough information for us to understand what happened (Figure 6).

Figure 6. Percent of Reports that Included Pertinent Information to Fully Understand What Happened by Segment, 2019

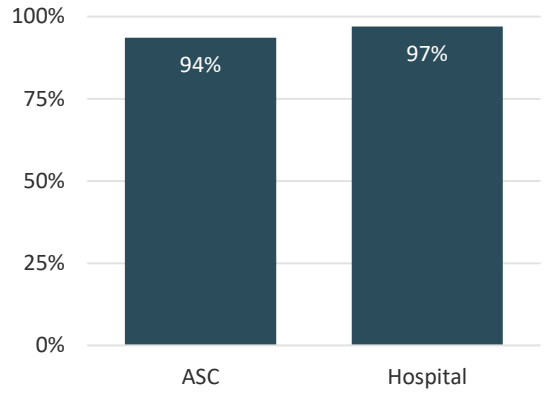


Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

II. Consistent information

Because organizations submit information to us after their review and analysis process is complete, they generally have a clear understanding of what happened and why they believe it happened. It is rare for a report to have four or more inconsistencies (Figure 7).

Figure 7. Percent of Reports that Included Consistent Information by Segment, 2019

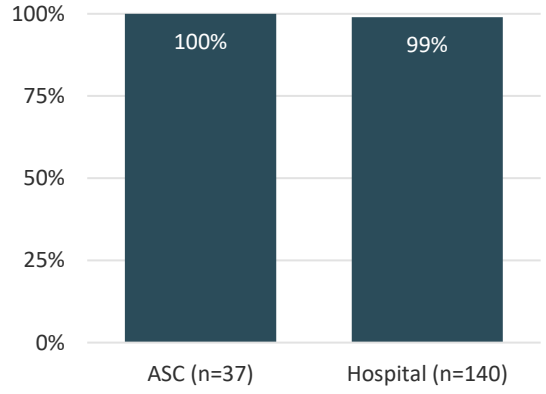


Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

III. Leadership participation in the event analysis

Leadership involvement is essential, not only to resource and implement strong solutions, but also to demonstrate to staff that safety is a priority, and that staff reports of safety issues and adverse events are taken seriously. Lack of leadership support and closed-loop communication regarding a reported safety issue or adverse event are two of the main reasons that healthcare staff don't report these types of events internally. In 2019, nearly all reports from healthcare organizations indicate leadership involvement in the adverse event review and analysis process for serious adverse events (Figure 8).

Figure 8. Percent of Reports that Included Leadership Participation in the Event Analysis* by Segment, 2019



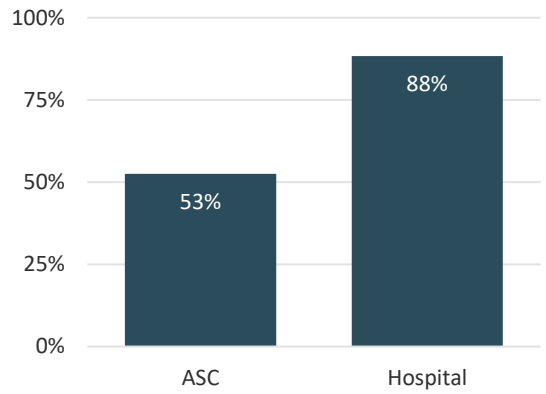
* Only required for serious harm events

Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

IV. Relevant system-level contributing factors

Contributing factors are the situations, circumstances, or conditions that increase the likelihood of an event. By identifying system-level factors, such as *communication* and *patient management* factors, organizations have a solid starting point to uncover deeper system-level causes, or root causes, that can be addressed to prevent the event from recurring. Seventy-nine percent of submitted reports identified at least one system-level contributing factor in 2019 (Figure 9).

Figure 9. Percent of Reports that Included Relevant System-Level Contributing Factors by Segment, 2015-2019

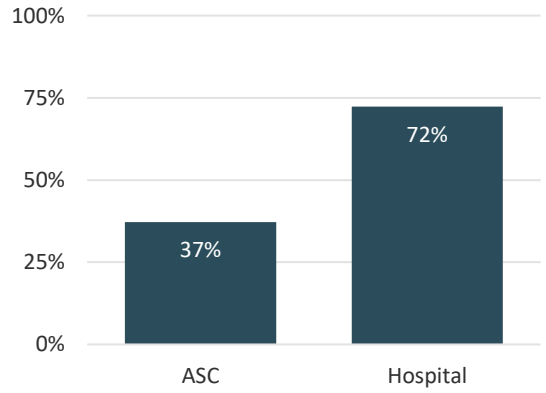


Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

V. One or more root causes

Identification of contributing factors is the first step to uncovering the deeper system-level causes, sometimes called root causes, of an event. By truly understanding the reasons why an event occurred, organizations are better equipped to develop solutions to prevent the event from recurring. There are typically multiple system-level causes, not just one single root cause (Figure 10).

Figure 10. Percent of Reports that Included One or More Root Cause by Segment, 2019



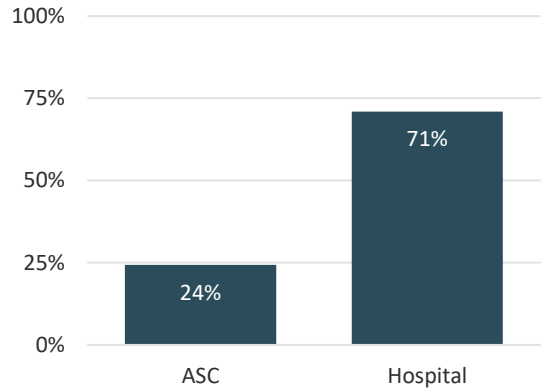
Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

VI. One or more system-level action plans designed to minimize risk

System-level action plans outline the steps an organization will take to prevent similar events from occurring. To be effective, action plans should address the root cause(s) of an adverse event and focus on minimizing risk and making systems of care stronger for all patients, not just one patient. Action plans that have the greatest chance of success (i.e., strong actions; see callout box on page 16) do not depend on staff to remember to do the right thing. Although system-level actions may not completely eliminate the vulnerability, they provide strong controls.

Overall, 60% of reports submitted in 2019 contained at least one system-level action plan.

Figure 11. Percent of Reports that Included One or More System-Level Action Plans Designed to Minimize Risk by Segment, 2019



Nursing facility and pharmacy data is not included due to low reporting volume (i.e., less than 10 reports).

Finding an Action Plan that Will Minimize Risk

Action plans can be categorized as weak, intermediate, or strong based on the likelihood that they will prevent similar occurrences in the future.

Strong Actions

Best at removing the dependence on the human to get it right because they are physical and permanent, rather than procedural and temporary

Examples

- Architectural/physical plant changes
- Forcing/constraining functions (engineering controls)
- New devices with usability testing before purchasing
- Simplifying processes and removing unnecessary steps
- Standardizing equipment or processes
- Tangible involvement and action by leadership in support of patient safety

Intermediate Actions

Reduce the reliance on the human to get it right, but do not fully control for human error

Examples

- Checklist/cognitive aid
- Eliminating look-alikes and sound-alikes
- Eliminating/reducing distractions
- Increase in staffing/decrease in workload
- Independent verification
- Read back/hear back
- Redundancy
- Software enhancements/modifications

Weak Actions

Support or clarify the process but rely solely on the human; these actions do not necessarily prevent the event/cause from occurring

Examples

- Additional study/analysis
- Double checks
- New policy/memorandum
- Training/education
- Warnings and labels

Adapted from the VA National Center for Patient Safety's Root Cause Analysis Tools.

Event Review and Analysis Timing

A quick response following an adverse event ensures that an organization is able to collect complete and reliable information about what happened. Timely review and analysis are necessary to design safer systems of care for future patients, both within an organization and by OPSC. In 2019, more than half of reports (57%) were considered timely (submitted within 45 days of event discovery), which is an improvement over 2018 (52%) (Table 5).

Table 5. Timeliness of Reports by Segment, 2019

	ASC (n=77)	Hospital (n=214)	Nursing Facility (n=3)	All Segments (n=294)
Number of reports that were timely	66	100	2	168
Percent of reports that were timely	86%	47%	67%	57%

Events that do not meet the definition of adverse event, or that are discovered during chart review or while analyzing another event, are excluded. Reports may also be excluded at OPSC's discretion.

Written Notification

Following an adverse event, written notification communicates to a patient that the healthcare organization is accountable for the care it provides and is committed to maintaining the patient's trust. Per Oregon Administrative Rule (OAR 325-010-0045), PSRP participants must provide written notification of reportable serious adverse events to the patient or patient's personal representative. In 2019 written notification was provided in 32% of the reported serious events for which it was required. Healthcare organizations also provided written notification in 9% of the cases where it was not required.

Conclusion and Recommendations

In our complex and constantly-evolving healthcare delivery system, adverse events and other safety issues will continue to occur, both in times of stability and in times of uncertainty. To effectively manage risk in healthcare, these fundamental patient safety principles can guide individual healthcare organizations as well as efforts at the state-level as we work together on the shared goal of improving the safety of our healthcare system:

- An organizational culture of safety is essential to make progress in patient safety.
- Changing systems—not individuals—is fundamental to changing culture.
- Patient safety work requires ongoing problem solving.

To improve the safety of Oregon's healthcare system, we recommend that healthcare organizations take steps to strengthen how they respond to, and learn from, adverse events in two ways:

- **Implement systems for responding to adverse events that support a culture of safety**. Organizational leadership must prioritize building systems that allow for a quick response to identified risks and adverse events that occur, regardless of what additional stressors the organization may be facing, such as COVID-19. These systems must cultivate a culture of safety by focusing on learning, ongoing problem solving to strengthen systems of care, and supporting the people working within those systems. Evidence-based tools like CANDOR can serve as a roadmap for organizations committed to building and sustaining systems that both drive a culture of safety and improve the safety of care delivery. Organizations should also use PSRP to support their internal system for adverse event investigation and analysis and contribute to building Oregon's capacity for learning from adverse events, to the benefit of all Oregonians.
- **Seek to understand the role of inequity in adverse events to inform concrete strategies for change.** There is limited information about the role inequity plays in patient safety. Healthcare organizations must collect and analyze data on race and ethnicity related to adverse events and share what they learn, through PSRP. Not until we all take steps to understand the root causes of inequity in patient safety, can we implement targeted strategies and make progress.

Patient safety work is never complete, and it will take a coordinated and collaborative approach to make progress as a state. At OPSC, we are proud to serve Oregonians through PSRP by encouraging a culture of patient safety across Oregon's healthcare system, and by supporting healthcare organizations' efforts to learn from events, continuously address risks, and adjust their systems of care.

The Ongoing Legacy of One of Oregon's Patient Safety Leaders

As we reflect on the passing of Representative Mitch Greenlick in May of 2020, we are thankful for the many contributions he made to healthcare and patient safety in Oregon that continue today. As one of the sponsors of OPSC's founding legislation in 2003, he played an instrumental role in making our work possible. We are grateful for the example he has set for all of us working to make healthcare safer for Oregonians.

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Appendix I. PSRP Eligibility and Participation

Four healthcare segments—ASCs, hospitals, nursing facilities, and pharmacies—are eligible to participate in the Patient Safety Reporting Program (PSRP). PSRP has been operating since 2006, starting with hospitals and then gradually adding other healthcare organizations to the program. Among ASCs, hospitals, and nursing facilities, 83% of eligible facilities have enrolled in the program (Table 6).

Table 6. Facility Participation in Reporting Program by Segment, 2019

	ASC	Hospital	Nursing Facility	Pharmacy	All Segments
Number of facilities enrolled	65	59	108	116	348
Total eligible facilities	89	59	130	701	979
Percentage of participating facilities	73%	100%	83%	17%	36%

Not all facilities that are enrolled in the reporting program report each year. Twenty-one facilities have consistently reported every year since they began reporting. More than half of enrolled facilities (57%) have submitted at least one report since the beginning of the program. In 2019, 53 (15%) of the enrolled facilities submitted one or more reports (Table 7).

Table 7. Number of Reporting* Facilities by Segment, 2019

	ASC	Hospital	Nursing Facility	Pharmacy	All Segments
Number of reporting facilities	18	33	2	0	53
Number of enrolled facilities	65	59	108	116	348
Percentage of enrolled facilities that reported	28%	56%	2%	0%	15%

* A facility that submitted at least one report in 2019.

Oregon facilities submitted 312 adverse event reports in 2019 (Table 8). The median number of reports per reporting facility was four, with a range of one to 33.

Table 8. Total Submissions by Segment, 2019

	ASC	Hospital	Nursing Facility	All Segments
Total reports submitted*	78	231	3	312
Number of reporting facilities	18	33	2	53
Median reports per facility	2.5	4	1.5	4
Range of reports per facility	1-33	1-26	1-2	1-33

* Includes event reports that did not meet the definition of adverse event

Appendix II. Event Types

• Indicates event type is reportable

Event type	ASC	Hospital	Nursing Facility	Pharmacy
Air embolism	•	•		
Anesthesia	•	•		
Aspiration	•	•	•	
Blood or blood product (including hemolytic reactions)	•	•		
Burn (unrelated to the use or misuse of a device or medical/surgical supply)	•	•	•	
Care delay (including delay in treatment, diagnosis)	•	•	•	
Choking			•	
Contractures			•	
Dehydration			•	
Contaminated drugs, devices, or biologics	•	•		
Contaminated, wrong or no gas given to a patient	•	•		
Deep vein thrombosis with or without pulmonary embolism	•			
Device or medical/surgical supply (including use error)	•	•	•	
Diabetic coma			•	
Discharge or release of a patient of any age, who is unable to make decisions, to an unauthorized person		•	•	
Electric shock	•	•		
Elopement		•	•	
Failure to follow up or communicate lab, pathology, or radiology test results		•		
Fall	•	•	•	
Fecal impaction			•	
Healthcare-associated infection (HAI)	•	•	•	
Intravascular embolisms related to IV therapy			•	
Irretrievable loss of irreplaceable biological specimen	•	•		
Maternal		•		
Medication or other substance	•	•	•	•
Perinatal		•		
Pressure ulcer		•	•	
Radiologic		•		
Resident transfer related			•	
Restraint or bedrail related	•	•	•	
Strangulation			•	
Suicide or attempted suicide		•	•	
Surgical or other invasive procedure	•	•		
Unintended retained foreign object (includes retained surgical items)	•	•		
Other event (please describe)	•	•	•	

Appendix III. Harm

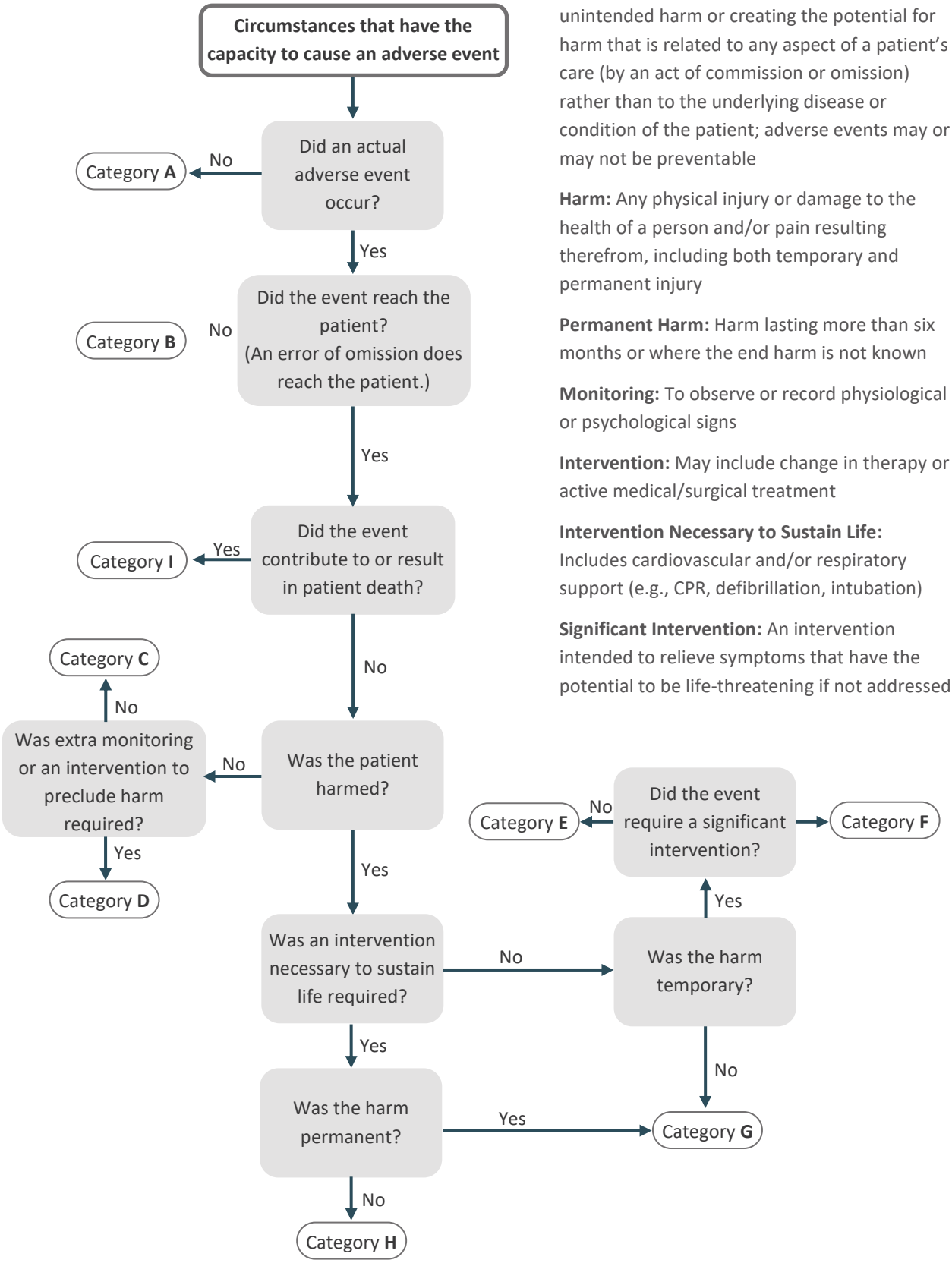
The Patient Safety Reporting Program (PSRP) has adapted the National Coordinating Council for Medication Error Reporting and Prevention's (NCC MERP) Medication Error Index (2001) to classify adverse events[1] according to the severity of the outcome. PSRP participants are required to report serious adverse events. Participants are also encouraged to report less serious harm events, no harm events, and near misses, because all events, regardless of harm, are prime opportunities to learn and improve systems of care.

Harm Categories

Category A	Circumstances that have the capacity to cause an adverse event	**Unsafe condition or near miss**
Category B	An event occurred that did not reach the patient (an "error of omission" does reach the patient)	
Category C	An event occurred that reached the patient but did not cause patient harm *Harm is defined as "any physical injury or damage to the health of a person requiring additional medical care, including both temporary and permanent injury"*	**Adverse event, no harm**
Category D	An event occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm *Monitoring is defined as "to observe or record physiological or psychological signs"* *Intervention is defined as including "change in therapy or active medical/surgical treatment"*	
Category E	An event occurred that may have contributed to or resulted in temporary harm to the patient but did not require a significant intervention *Significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	**Adverse event, less serious harm**
Category F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required a significant intervention *Significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	**Adverse event, serious harm or death**
Category G	An event occurred that may have contributed to or resulted in permanent patient harm *Permanent harm is defined as "harm lasting more than 6 months, or where end harm is not known ('watchful waiting')"*	
Category H	An event occurred that required intervention necessary to sustain life *Intervention necessary to sustain life is defined as including "cardiovascular and/or respiratory support (e.g., CPR, defibrillation, intubation)"*	
Category I	An event occurred that may have contributed to or resulted in patient's death	

[1] An adverse event is an event resulting in unintended harm or creating the potential for harm that is related to any aspect of a patient's care (by an act of commission or omission) rather than to the underlying disease or condition of the patient; adverse events may or may not be preventable.

Harm Algorithm



Definitions

Adverse Event: An event resulting in unintended harm or creating the potential for harm that is related to any aspect of a patient's care (by an act of commission or omission) rather than to the underlying disease or condition of the patient; adverse events may or may not be preventable

Harm: Any physical injury or damage to the health of a person and/or pain resulting therefrom, including both temporary and permanent injury

Permanent Harm: Harm lasting more than six months or where the end harm is not known

Monitoring: To observe or record physiological or psychological signs

Intervention: May include change in therapy or active medical/surgical treatment

Intervention Necessary to Sustain Life: Includes cardiovascular and/or respiratory support (e.g., CPR, defibrillation, intubation)

Significant Intervention: An intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed