Patient Safety Reporting Program 2018 Annual Report

Share. Learn. Improve **Patient Safety**.

OREGON
PATIENT SAFETY
COMMISSION

June 2019

The Oregon Patient Safety Commission, 2019

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, adverse events can—and do—occur. These events are prime opportunities to learn and to design safer systems of care for the next patient. Healthcare organizations must continue to develop their skills to learn from these events to ensure they are able to tackle the wide range of safety issues they are likely to encounter.

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 the Oregon Patient Safety Commission's (OPSC) Patient Safety Reporting Program (PSRP) can help ensure all of Oregon moves forward together.

In 2018, Oregon healthcare organizations—ambulatory surgery centers (ASCs), hospitals, nursing facilities, and community pharmacies—voluntarily contributed 339 adverse event reports to PSRP for learning. Through the information that healthcare organizations submitted to PSRP and through our evaluation of research in the field of patient safety, we have identified the following lessons:

- **An organizational culture of safety is foundational for success.** To build an effective patient safety program, an organization must first have a culture of safety. Without taking steps to create a culture of safety, well-intentioned patient safety improvement efforts are less effective and unsustainable.
- **Adverse events can happen to anyone and adverse events can happen anywhere.** Because adverse events are typically the result of system failures, healthcare organizations should consider safety processes, protocols, and guidelines in the larger context of the care environment, standardizing whenever possible.
- **Most adverse events are preventable.** How an organization views preventability may be an indication of their culture of safety. When an organization views an event as preventable, they may be more likely to do a thorough event review and analysis and identify opportunities to improve care.
- **Adverse events have common causes.** Patterns of adverse event causes are similar across event types, suggesting that the impact of changes made following a single event review and analysis can have far-reaching impacts.
- **Adverse events require ongoing problem solving.** Given the dynamic nature of healthcare, organizations must build and constantly refine their infrastructure to address the wide range of safety issues that will arise.

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 to learn about and improve systems of care for every patient they serve.

Introduction

Patient Safety in Oregon

Despite everyone's best intentions during healthcare, things don't always go as planned and adverse events or near misses occur. Sometimes these events result in no harm to a patient, while other times they may result in additional or prolonged treatment, disability, or death.

In 2003, the Oregon legislature created the Oregon Patient Safety Commission (OPSC) following recommendations from a workgroup that aimed to create a sense of urgency about reducing harm to patients and improving the quality of care in Oregon. The group represented a broad spectrum of healthcare providers, insurers, purchasers, and consumers. In the words of one of the workgroup's members, Ellen C. Lowe (public testimony in support of House Bill 2349):

> *"As I sought remedies that would support healthcare system improvements that would 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."*

The workgroup acknowledged that many of the challenges to improving patient safety could not be resolved in isolation by individual organizations; a coordinated and collaborative approach would be necessary. The vision for the organization was to create an independent voice for patient safety in the state that would encourage all representatives and users of the healthcare system to come together to work on shared goals that would make care safer for all Oregonians. This role could only be filled by an organization dedicated solely to serving the public health mission envisioned by the workgroup, free of other industry interests. OPSC was created as a non-regulatory, semi-independent state agency to carry out this vision.

ORS 442.820 (2): The mission of the commission is to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's health care system and by encouraging a culture of patient safety in Oregon. To accomplish this mission, the commission shall:

(a) Establish a confidential, voluntary serious adverse event reporting system to identify serious adverse events;
(b) Establish quality improvement techniques to reduce systems' errors contributing to serious adverse events; and
(c) Disseminate evidence-based prevention practices to improve patient outcomes.

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.

Through collaboration and partnerships, OPSC has grown its body of work to advance, support, and encourage patient safety in Oregon. Today, we are a multi-faceted, semi-independent state agency operating two mission-driven programs, the Patient Safety Reporting Program and Early Discussion and Resolution.[1]

The Patient Safety Reporting Program

Our 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—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.[2] 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 process and 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, Not Numbers

"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)

2018 PSRP data provide a picture of the quality improvement work that reporting organizations have done over the course of the year. This information can help us understand how organizations are learning from adverse events to prevent future harm, where support is needed, and where Oregon is on its journey to building a culture of patient safety.

[1] Learn more about OPSC at oregonpatientsafety.org.
[2] See Appendix I. PSRP Eligibility and Participation for more information.

Oregon Isn't Alone in Looking at How Organizations Learn

In 2012 the Dutch Healthcare Inspectorate moved from evaluating what reporting organizations learn from their investigations to evaluating how they learn (Leistikow et al. 2017). Their staff use the following questions to evaluate submitted reports:

Process

- How soon after the event was identified did investigation start?
- Is the investigating committee multidisciplinary?
- Were any members of investigating committee involved in the incident?
- Is the method for analysis specified? (e.g., root cause analysis (RCA))
- Was input sought from all personnel directly involved?
- Was input sought from other staff with knowledge about the care process?
- Was input sought from the patient/relatives?

Reconstruction

- Does the description of the event give a complete picture of the relevant 'scenes'?

Analysis

- Has the question 'why' been asked extensively enough to analyze the underlying cause and effect?
- Have the investigators searched relevant scientific literature?
- Does the report state whether applicable guidelines/protocols were followed?
- Was external expertise consulted?
- Does the report state whether the medical indication for the provided care was correct?

Conclusions

- Does the report identify root causes?
- Do the root causes fit the reconstruction and analysis?
- Are contributing factors considered and/or identified?
- Are contributing factors, not under the control of the hospital, considered and/or identified?
- Recommendations
- Does the report document recommendations for improving processes and systems?
- Do these corrective actions address the identified root causes?
- Have the corrective actions been formalized? (e.g., Specific, Measurable, Attainable, Realistic and Time-Sensitive (SMART))
- Does the hospital have an evaluation plan to determine if the recommendations are implemented?
- Will the impact of the recommendations be evaluated?

Aftercare

- Is the aftercare for the patient/relatives described?
- Is the aftercare for the professionals involved described?
- Has the report been shared with the patient/relatives?
- Reaction of hospital board
- Is the reaction of the board adequate?

What We've Learned

Both in the field of patient safety and in information contributed through PSRP, these cross-cutting lessons have emerged:

- An organizational culture of safety is the foundation for success.
- Adverse events can happen to anyone.
- Adverse events can happen anywhere.
- Most adverse events are preventable.
- Adverse events have common causes.
- Adverse events require ongoing problem solving.

An Organizational Culture of Safety is the Foundation for Success

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*, nearly 20 years ago. Adverse events stem from problems in the process of providing healthcare in a complex delivery system. These system-level causes are difficult to identify and improve, and they often require significant culture change before any efforts to address them can be successful. This is why patient safety experts look for ways to create the culture necessary for improvement to occur rather than focusing on individual solutions to individual problems (see callout box on page 5 for examples).

The Agency for Healthcare Research and Quality (AHRQ)'s Survey on Patient Safety Culture defines and contrasts organizational and patient safety culture as follows:

> *"Organizational culture refers to the beliefs, values, and norms shared by staff throughout the organization that influence their actions and behaviors. Patient safety culture is the extent to which these beliefs, values, and norms support and promote patient safety. Patient safety culture can be measured by determining what is rewarded, supported, expected, and accepted in an organization as it relates to patient safety."* (Famolaro et al. 2018)

To build an effective patient safety program, an organization must first have a culture of safety. Without first taking steps to create a culture of safety, well-intentioned patient safety improvement efforts are less effective and unsustainable. For example, 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 (David 2019). The relationship between a culture of safety and effective patient safety programs was also noted by Armstrong et al. (2018), who found that the use of a quality measurement tool expressly designed to avoid blame was, in practice, experienced as a "blame allocation device." Without a culture of safety, study participants could not use the tool to support their patient safety work, despite the intent and careful design of the tool.

Culture Change Must Occur for Patient Safety Improvements to be Effective

In 2007, the Lucian Leape Institute defined five concepts it felt were fundamental for culture change in healthcare, and without which system-level improvements would not be successful. These included **medical education reform**, **care integration**, **joy and meaning in work**, **patient and family engagement**, and **transparency** (Leape et al. 2009). While progress in these areas has been made (Gandhi et al. 2018), culture change takes time.

Oregon is the only state in the nation to approach long-term patient safety culture change with a voluntary program, independent of any regulatory functions.

What Organizations Need to Create a Culture of Safety

I. Ongoing leadership support for and direct involvement in patient safety work

To be successful, patient safety work requires not just leadership support, but leadership involvement (Agency for Healthcare Research and Quality 2016). Leadership must:

- **Carefully select who is on an adverse event review and analysis team** to ensure the team is well-suited to the work (Ginsburg et al. 2018). Braithwaite et al. (2006) found that "unwilling colleagues, difficulty with team members and interprofessional conflict" as well as "the failure of work schedules to provide time for RCA [root cause analysis] activities and work infrastructure to provide the necessary resources to enable teams to perform their job" were major difficulties encountered by providers participating in review and analysis teams.
- **Clearly define roles and responsibilities** for patient safety work, particularly adverse event review and analysis, to ensure the work is adequately resourced (Mitchell et al. 2016).
- **Foster a safe environment** in which adverse event review and analysis teams can ask uncomfortable questions about organizational culture and make strong recommendations, even if those recommendations are unpopular (Peerally et al. 2017; Trbovich and Shojania 2017). One aspect of fostering a safe environment is anticipating interpersonal conflict and intervening before it diverts or distracts from the work (Ginsburg et al. 2018).
- **Participate in action planning and implementation**. Adverse event analysis and action planning—the process of identifying actions to improve systems of care and prevent similar events—that does not involve leadership has little chance for success (Peerally et al. 2017).
- **Hold teams accountable to provide feedback**. Leadership must remain engaged in patient safety work after the analysis is complete to ensure that adverse event review and analysis teams close the loop with affected providers and staff, sharing feedback

on the results of their analysis and the progress on resulting patient safety improvements (Macrae 2016).

PSRP collects information about leadership involvement in the review and analysis process here in Oregon. Reports indicate that leadership is consistently involved in one of two ways: direct participation in adverse event reviews and analyses or post-analysis briefings about findings.[3]

II. Systems for adverse event identification and triage

Most organizations use voluntary internal reporting or review administrative (billing) data to identify adverse events (Classen et al. 2011). Those methods identify roughly 1%-14% and 9% of adverse events respectively (Classen et al. 2011; Levinson 2012). The value of internal adverse event reporting is to surface and address hazards (Pronovost et al. 2008) and is not a sufficient patient safety program on its own. When *To Err Is Human* was published in 2000, its authors had assumed internal reporting systems would build in effective event report triage to avoid overwhelming patient safety and quality improvement efforts, but that has not happened (Mitchell et al. 2016). As Pronovost et al. (2008) write, "The challenge is to migrate from investigations that go a mile wide and an inch deep, to an inch wide and a mile deep."

Oregon's PSRP is a retrospective data collection tool by design. It is structured to collect information after an investigation is completed, when it is closer to a mile deep. PSRP relies on organizations' internal reporting systems to identify adverse events for investigation.

Five Opportunities for Stronger Internal Adverse Event Reporting

Mitchell et al. (2016) interviewed 11 international experts in patient safety about their perspectives on patient safety 15 years after '*To Err is Human*.' They identified five challenges that they feel have kept adverse event reporting from reaching its full potential:

1. **Adverse event report processing** must be adequately resourced to triage, cluster, analyze, and act upon the large volume of reports they receive.
2. **Increased clinician engagement** in adverse event reporting would improve the current bias in reporting towards nursing adverse events, which likely under-identifies events related to medical decision-making, like diagnostic errors.
3. **Visible action and feedback** following review and analysis provides accountability to the reporter that their reports are taken seriously and acted upon.
4. **Adequate funding and institutional support** are needed to adequately resource adverse event reporting systems to process and learn from the reports they receive.
5. **Integration with other health information technology** could improve the availability of information for reporting, analysis, and information dissemination.

[3] See "Leadership participation in the event analysis" on page 20 for more information.

III. Dedicated staff to facilitate the event review and analysis process and follow-up

Organizations with staff dedicated to event review and analysis build the expertise and competency necessary to get past surface-level causes and start to identify the deeper, system-level issues that, if addressed, can prevent similar events from occurring (Peerally et al. 2017). With the incredible variation in the types of adverse events that occur all across a facility, and that involve various departments, services, and job roles, it would be impossible for a dedicated adverse event review and analysis team to have adequate clinical expertise for every situation. Therefore, the event review and analysis team should be:

- **Dedicated** to process facilitation rather than providing clinical expertise**.**
- **Independent** from any particular service in the organization and report directly to organizational leadership (Macrae 2016).
- **Well-trained.** Experts agree that formal training followed by practice are necessary for this team to do its job effectively and efficiently (Vincent et al. 2000; Agency for Healthcare Research and Quality 2016).

Any necessary clinical or operational expertise should come from ad-hoc team members, added as appropriate to the specific event. These team members should not be expected to be experts in adverse event review and analysis, but just-in-time training could be provided to prepare them for their role. For organizational learning to occur, the ad-hoc team members should include individuals responsible for implementation of any changes that result from the review and analysis process (Ramanujam and Goodman 2011), and they should be involved from the beginning of the process.

The role of the adverse event review and analysis team is to provide process structure following an adverse event. They would:

- **Coordinate and facilitate the review and analysis meetings.**
- **Facilitate the development of risk reduction strategies (sometimes called action planning) and implementation of those strategies**. "[…] some of the reasons for [poorly designed or implemented risk controls] lie in the limited expertise of local investigation teams in selecting and designing appropriate risk controls." (Peerally et al. 2017). Dedicated staff to support implementation planning can help ensure that all of the necessary components for a successful process or system improvement are in place (e.g., assigning responsibility, ensuring that necessary training is provided, developing a measurement and monitoring plan).
- **Track implementation over time**. Initially, the team would establish a time period for measurement and a threshold at which continuous measurement will no longer be necessary. Once continuous measurement is complete, the team would schedule spot-checks to make sure things are still being done correctly.
- **Provide feedback to providers and staff**. Following up with feedback to providers and other staff about what was learned through the review and analysis process and what is being done as a result, frequently does not occur (Braithwaite et al. 2006, Gandhi et al. 2018, Macrae 2016, Mitchell et al. 2016, Peerally et al. 2017). This

feedback helps providers and staff know that the organization took action when safety issues were reported or identified, helping to foster a culture of patient safety in the organization.

IV. A common understanding among all staff about the adverse event review and analysis process

The literature on successful adverse event review and analysis indicates that adverse event review and analysis training would benefit all staff. The goal of this larger-scale training is not to create expertise in event review and analysis among all staff; its purpose is to send a clear message that patient safety is valued by the organization, and that it is everyone's responsibility.

Integrating basic event review and analysis training into the organization's annual program will increase the efficacy of just-in-time training for ad-hoc staff who are selected to participate in a review. Additionally, event review and analysis skills benefit organizations in a variety of ways. This kind of training can promote a culture of safety, increase internal reporting, and improve "skills and commitment to safety" (Braithwaite et al. 2006).

V. Centralized efforts to avoid learning in isolation and duplication of efforts

With so many adverse events occurring each year across the continuum of care, cross-cutting so many different specialties and services, healthcare organizations must have strong systems in place to respond to and learn from adverse events.[4] Just as healthcare organizations need trained, dedicated staff to facilitate the process of event review and analysis so that the content experts can focus on implementing improvements, those same organizations need trained, dedicated staff at the state level to support event review, evaluate their processes, and offer recommendations for improvements. A central coordinating agency (like OPSC) can connect the dots between individual organizations (Pronovost et al. 2013), share best practices, hold workgroups, and offer event review and analysis training that can help lead to true system-level action.

While individual healthcare organizations will always be in the best position to determine what solutions are likely to be successful in their facilities, OPSC's role as Oregon's central coordinating patient safety organization gives us unique insight into the efficacy of organizations' processes and systems for learning from patient harm events to make care safer. We share what we learn statewide so broader process and system improvements can be put into place throughout Oregon, to the benefit of all Oregonians.

Collaboration is Key to Making Progress in Patient Safety

"Many challenges cannot be resolved by individual organizations, since they require whole-sector coordination and action. " (Dixon-Woods and Pronovost 2016)

[4] See Table 1 on page 7 for a list of the 23 different types of adverse events identified by Oregon healthcare organizations in 2018. See Appendix II for a list of reportable event types by facility type.

VI. Patient involvement

Experts agree that patients and families must be involved in adverse event review and analysis (Peerally et al. 2017; Vincent et al. 2017; National Advisory Group on the Safety of Patients in England 2013). Yet, it must be done in a way where the burden to speak up is not on patients (Mazor et al. 2016), who may feel that they will be labeled as "difficult" if they do so (Doherty and Stavropoulou 2012). In 2018, only 9% of reported events included the patient, patient's family, or patient's representative on the review and analysis team.

Don't Wait for Patients to Speak Up, Involve Them Proactively

"Providing truly patient-centered care is not about getting patients to speak up, but rather about health care institutions and providers stepping up and creating an environment in which patients suffering in silence after care breakdowns become the exception, not the norm." (Mazor et al. 2016)

Table 1. Adverse Event Type by Segment, 2018

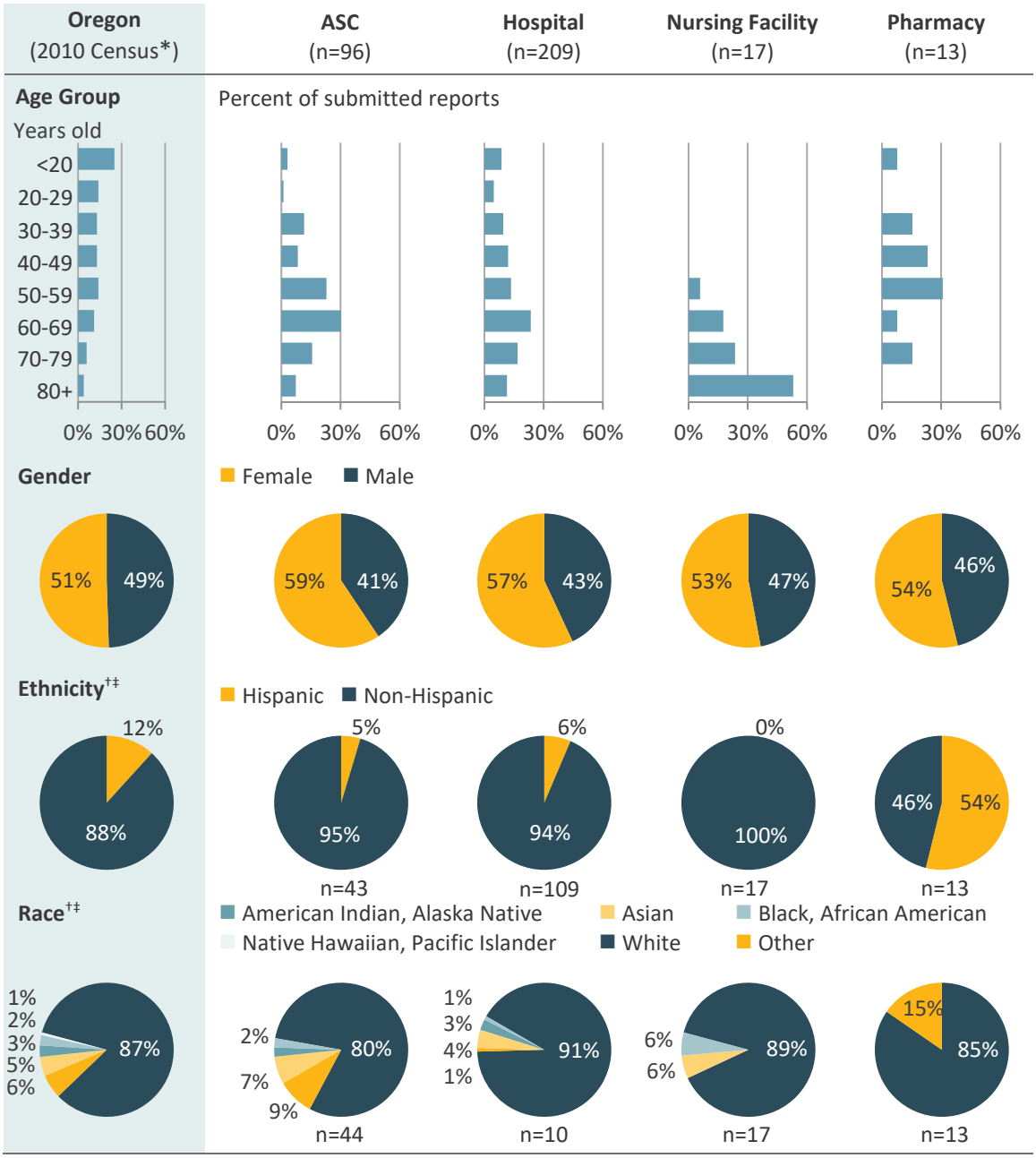
	ASCs (n=96)		Hospitals (n=209)		Nursing Facilities (n=17)		Pharmacies (n=13)		All Segments (n=335)	
Event Type	Num	%	Num	%	Num	%	Num	%	Num	%
Surgical or other invasive procedure	53	55%	12	6%					65	19%
Healthcare-associated infection	14	15%	30	14%	0	0%			44	13%
Medication or other substance	4	4%	20	10%	4	24%	13	100%	41	12%
Care delay	1	1%	33	16%	1	6%			35	10%
Fall	5	5%	19	9%	9	53%			33	10%
Device or supply	4	4%	15	7%	0	0%			19	6%
Retained object	1	1%	12	6%					13	4%
Other event	3	3%	8	4%	0	0%			11	3%
Aspiration	8	8%	2	1%	0	0%			10	3%
Suicide or attempted suicide			10	5%	0	0%			10	3%
Maternal			9	4%					9	3%
Perinatal			8	4%					8	2%
Pressure ulcer			7	3%	1	6%			8	2%
Failure to follow up or communicate test results			7	3%					7	2%
Anesthesia	2	2%	3	1%					5	1%
Irretrievable loss of irreplaceable specimen	0	0%	5	2%					5	1%
Contaminated drugs, devices or biologics	1	1%	3	1%					4	1%
Elopement			2	1%	2	12%			4	1%
Air embolism	0	0%	2	1%	0	0%			2	1%
Electric shock	0	0%	1	0%					1	0.3%
Blood or blood product	0	0%	1	0%					1	0.3%
Radiologic			1	0%					1	0.3%
Restraint or bedrail related	1	1%	0	0%	0	0%			1	0.3%
Total Events	97		210		17		13		337	

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 1).

Figure 1. Patient Demographics by Segment, 2018



* 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.

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

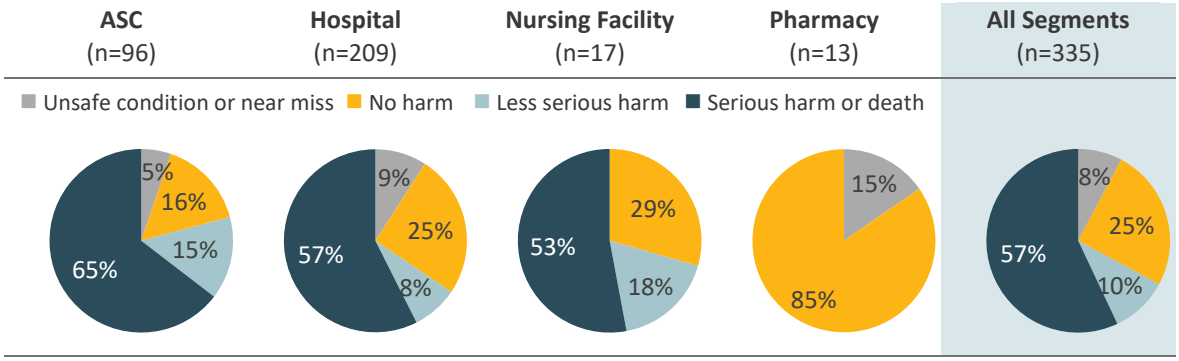
‡ Reports in which race and ethnicity were unknown are not represented in the summary figures.

The patients affected by adverse events reported in 2018 ranged in age from newborn to 100. Patients aged 60 and older accounted for more than half (53%) of reported events. National data on healthcare use (Agency for Healthcare Research and Quality 2019b) indicates that utilization goes up as we age, and more contact with the healthcare system presents more opportunity to experience an adverse event.

Patient Harm

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 (Vincent et al. 2017). As expected from the program's emphasis on serious adverse events, more than half of the reports submitted to PSRP in 2018 (57%) resulted in serious harm or death (harm categories F, G, H, or I)[5] (Figure 2).

Figure 2. Harm Category of Events Reported by Segment, 2018



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.

The harm category proportions found in PSRP are not representative of all adverse events. de Vries et al. (2008) estimate 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." *Patient Safety: Achieving a New Standard for Care* (Institute of Medicine Board on Health Care Services and Committee on Data Standards for Patient Safety 2004) states that near misses are estimated to be 7-100 times more frequent than adverse events. Variations in the severity of harm by reporting segment may be due to the patient populations served and the types of services provided.

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)

[5] See Appendix III for more information on harm categories.

Adverse Events Can Happen Anywhere

An adverse event can happen in any location and at any point during an episode of care. OPSC has received reports of adverse events occurring in every area of a healthcare organization, from registration to the recovery room. Adverse events have also occurred at the patient's home, both pre-admission and post-discharge. In 2018, the most frequent location of reported adverse events was *Operating/procedure room* (28%), followed by *Inpatient (adult)* (19%, Table 2).

Table 2. Top Five Event Locations by Segment, 2018

Location	ASC (n=96) Number (%)	Hospital (n=209) Number (%)	Nursing Facility (n=17) Number (%)	Pharmacy (n=13) Number (%)	All Segments* (n=335) Number (%)
Operating/procedure room	61 (64%)	34 (16%)			95 (28%)
Inpatient (adult)		64 (31%)			64 (19%)
Emergency department		26 (12%)			26 (8%)
Other	4 (4%)	21 (10%)	0 (0%)		25 (7%)
Critical care (adult)		18 (9%)			18 (5%)

* "All Segments" denominators are limited to segments for which this answer option is available.

Example: Looking Beyond Location When Implementing Standard Protocols or Guidelines

Some events reported to PSRP highlight how the use of a relevant protocol or guideline is limited by location or service in an organization, unintentionally overlooking areas of need. For example, labor and delivery operating rooms (ORs) may not adopt the Association of periOperative Registered Nurses (AORN) guidelines for the prevention of retained objects at the same time as other ORs in a facility because they belong to a different service. This has led to the retention of surgical sponges following c-sections. Similarly, limiting the implementation of a safe procedure checklist to ORs to prevent the retention of guidewires leads to the retention of guidewires in other locations in the facility.

Even adverse event types that seem necessarily limited to specific locations, like *surgical or other invasive procedure* events, can occur in many different locations in an organization. While most of the *surgical or other invasive procedure* events reported to PSRP occurred in an operating or procedure room (Table 3), they also occurred at registration, in the emergency department, at the patient's home following discharge, and in other areas of the facility (e.g., preop, diagnostic or procedure area, radiology, post-anesthesia care unit).

Table 3. Surgical or Other Invasive Procedure Event Locations, 2018

Location	ASC (n=53) Number (%)	Hospital (n=12) Number (%)	Both Segments * (n=65) Number (%)
Operating/procedure room	37 (70%)	4 (33%)	41 (63%)
Patient home, post discharge	8 (15%)		8 (15%)
Post anesthesia care unit	4 (8%)	0 (0%)	4 (6%)
Other	2 (4%)	2 (17%)	4 (6%)
Preop area	2 (4%)	1 (8%)	3 (5%)
Emergency department		2 (17%)	2 (17%)
Diagnostic/procedure area	0 (0%)	2 (17%)	2 (3%)
Radiology/imaging		1 (8%)	1 (8%)

* "Both Segments" denominators are limited to segments for which this answer option is available.

Before a procedure, registration and check-in are locations where staff may incorrectly identify the site or side for a surgery. After the procedure, while in the recovery area, the patient can have uncontrolled pain or other symptoms resulting from the procedure, requiring additional medical attention. And even at home, hours or days later, the patient can experience the effects of an adverse event, like appendicitis resulting from a rare set of circumstances following a colonoscopy. Standardizing protocols and guidelines across an organization can help minimize risk to patients created by unnecessary practice differences between departments or services.

It's the System, Not the People

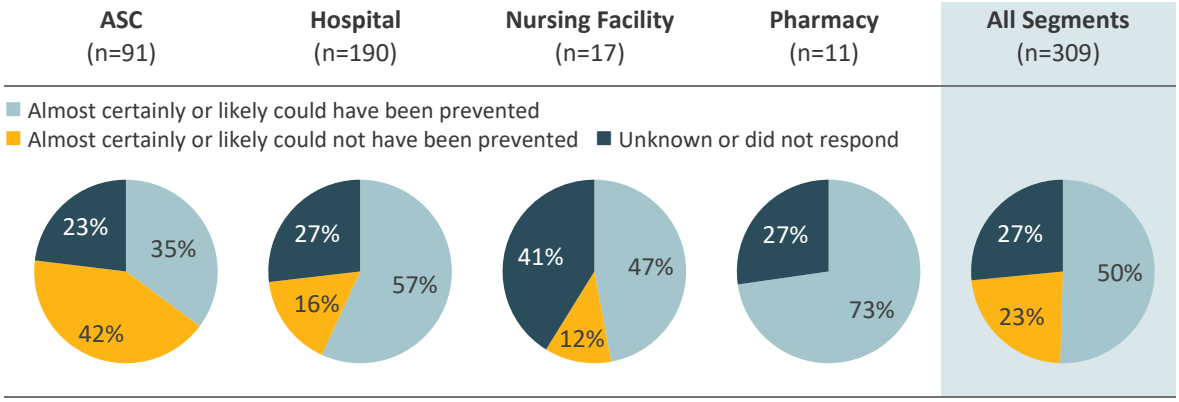
"People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer." (Institute of Medicine (US) Committee on Quality of Health Care in America 2000)

Most Adverse Events are Preventable

PSPR collects information about whether an organization believes an event is preventable. Typically, an adverse event is considered preventable if it is related to a patient's medical care rather than their underlying medical issue. Recent studies have estimated that 54% of adverse events that occur in long-term acute care hospitals (Levinson 2018), 59% that occur in nursing facilities (Levinson 2014), 50% that occur in ambulatory settings (Woods et al. 2007), and between 44% and 100% of adverse events that occur in hospitals (Levinson 2010; Landrigan et al. 2010; Classen et al. 2011) are preventable.

How an organization views preventability helps us understand where they are in their journey to a culture of safety. When an event is viewed as preventable, an organization may be more likely to do a thorough event review and analysis and identify opportunities to improve care. In 2018, we saw variation in preventability determination by segment and event type (Figure 3).

Figure 3. Preventability by Segment, 2018



Events that result in harm A or B are not asked about preventability because no event reached the patient.

Example: A Closer Look at Surgical Event Preventability

Among 2018 reports, *Surgical or other invasive procedure* events had the smallest percentage "almost certainly or likely could have been prevented" (30%). Hospitals were more likely than ASCs to indicate that a *surgical or other invasive procedure* event was preventable (Table 4).

Table 4. Preventability of Surgical or Other Invasive Procedure Events, by Segment 2018

	ASC (n=51) Number (%)	Hospital (n=12) Number (%)	Both Segments (n=63) Number (%)
Almost certainly or likely could have been prevented	12 (24%)	7 (58%)	19 (30%)
Almost certainly or likely could not have been prevented	29 (57%)	3 (25%)	32 (51%)
Unknown or did not respond	10 (20%)	2 (17%)	12 (19%)

In some cases, preventability can be difficult to determine. These are usually cases where it isn't possible to tease out which elements of the event were due to the patient's underlying health condition or anatomy and which were due to the care the patient received. For example, a patient that had fragile health status but met the criteria for undergoing a certain procedure experienced an adverse event. Because it was determined that the standard of care was met, the organization could not determine if the harm was related to the fragile health status or the care provided.

In many cases, organizations that struggled to separate these elements and determine preventability were still able to identify areas for improvement through their review and analysis processes. However, OPSC found that the solutions they identified were often not connected to what the event review and analysis uncovered, potentially leaving the underlying causes unaddressed and creating the opportunity for recurrence of a similar event. Additionally, in order to evaluate the success of an action plan, an organization must understand what problem the action plan is solving so it can select the correct measures of success.

Example: A Closer Look at Falls and Preventability

Falls are a frequent adverse event and occur in all care settings. Recent studies have found fall rates of 3.3-3.6 falls/1,000 patient days (Bouldin et al. 2013; Krauss et al. 2005; Staggs, Mion, and Shorr 2014) in acute care hospitals in the United States. Levinson (2014) estimates that 2.3% of Medicare beneficiaries in skilled nursing facilities experience a fall with injury. While there is some debate as to the preventability of falls and the efficacy of various falls prevention programs (DiBardino, Cohen, and Didwania 2012; Cameron et al. 2018), there is broad agreement that organizations must make a strong effort to prevent falls. Oregon healthcare organizations submitted 33 *fall* events to PSRP in 2018, 58% of which reporters felt were almost certainly or likely preventable (Table 5).

Table 5. Preventability of Falls, by Segment 2018

	ASC (n=5) Number (%)	**Hospital** (n=19) Number (%)	**Nursing Facility** (n=9) Number (%)	**All Segments** (n=33) Number (%)
Almost certainly or likely could have been prevented	4 (80%)	12 (63%)	3 (33%)	19 (58%)
Almost certainly or likely could not have been prevented	0 (0%)	2 (11%)	2 (22%)	4 (12%)
Unknown or did not respond	1 (20%)	5 (26%)	4 (44%)	10 (30%)

OPSC reviewed each of the 33 *fall* events submitted in 2018 and found five general causes:

- Choices made independently by the patient or resident
- Involvement of a physical object
- Normalization of deviance related to long-stay patients
- Omitted or incorrectly performed assessment
- Patient left alone

When we looked specifically at the events that were considered *almost certainly or likely not preventable*, we found that they grouped into a subset of the five general causes:

- Choices made independently by **cognitively impaired** patient or resident
- **Malfunction** of a physical object
- Unknown physical cause

Oregon healthcare organizations are willing to identify a fall as preventable, and they generally reserve the designation "not preventable" for specific circumstances where their review teams felt the root cause or contributing factors were outside of the facility's control.

Some Researchers Believe All Adverse Events Are Preventable

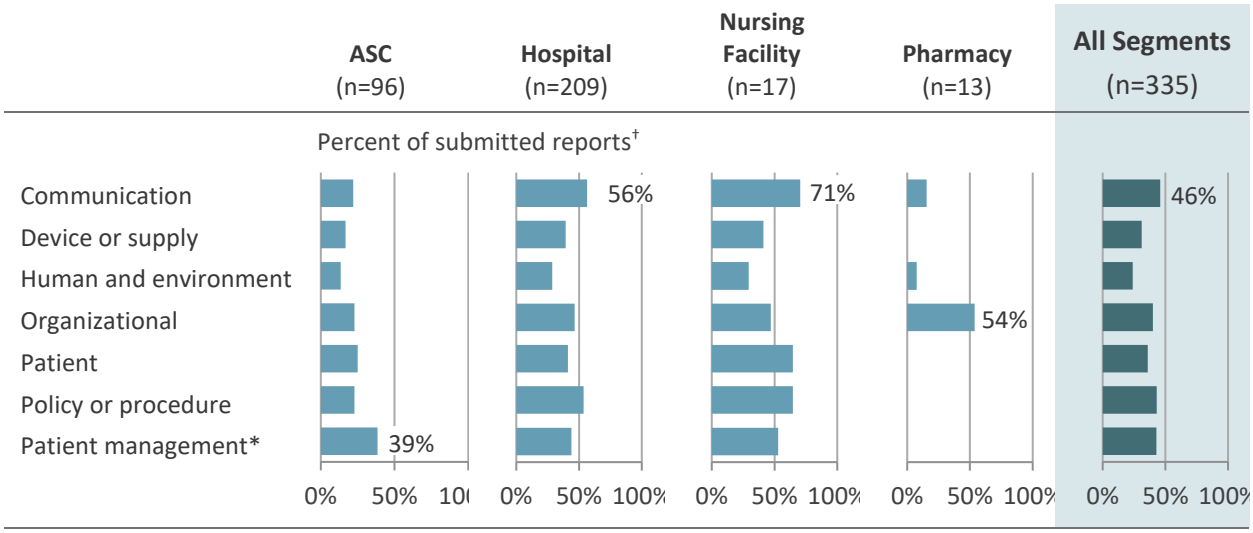
"Because of prior work with Trigger Tools and the belief that ultimately all adverse events may be preventable, we did not attempt to evaluate the preventability or ameliorability (whether harm could have been reduced if a different approach had been taken) of these adverse events." (Classen et al. 2011)

Adverse Events Have Common Causes

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.

PSRP organizes contributing factors into eight categories. The most frequently selected category of contributing factors in 2018 was *communication* factors (46%), followed by *policy or procedure* factors (43%), and *patient management* factors (43%) (Figure 4). The 335 events submitted in 2018 identified 67 unique contributing factors across the eight categories.

Figure 4. Contributing Factor Categories by Segment, 2018†



* Patient management is not available on pharmacy reports.

† Percents total more than 100 as reports may indicate contributing factors in multiple categories.

While there are many specific factors within each category that help OPSC understand what contributed to each reported event, looking more broadly across all the information contained within the reports we see some common patterns:

- Information wasn't available when it was needed, where it was expected to be, or in the form it was needed.
- A policy or procedure wasn't followed because staff were not familiar with it, it was unclear, or because of practice drift.
- The patient was not adequately assessed because assessment practices varied across the organization, the assessment or assessment practices were out of date and did not reflect current best-practice, or because of practice drift.
- There were not adequate staff available at the time of the event, or the staff that were available did not have the right training.
- There were not adequate resources available at the time of the event, or the resources were not in the right locations or easy to locate.

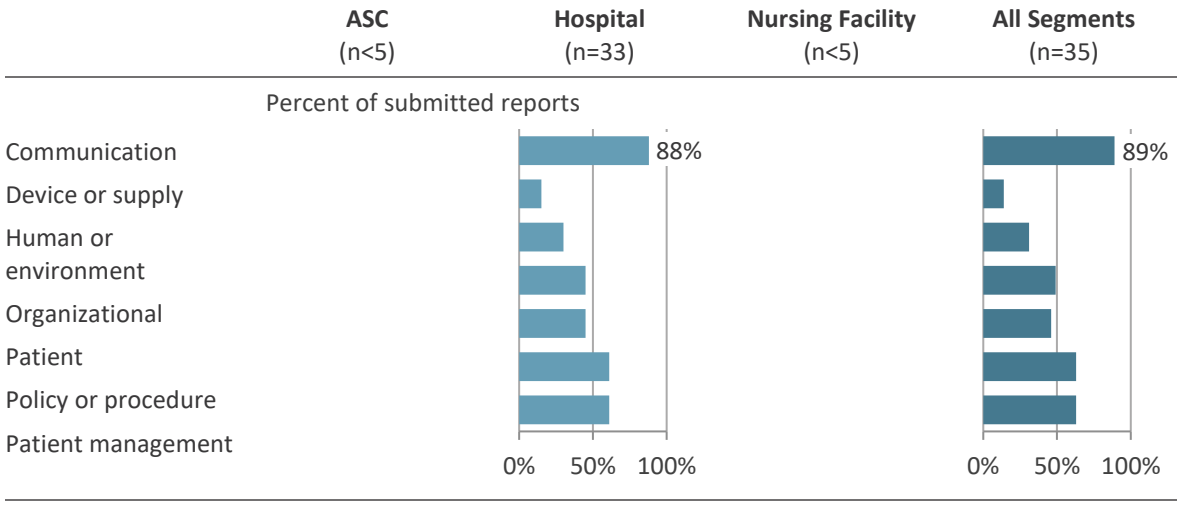
- The healthcare organization did not have a system to routinely track and audit staff competencies for standard procedures to ensure those procedures were being done correctly, or the organization did not have a system to routinely evaluate whether a standard procedure was still appropriate.
- Inadequate event review and analysis process did not routinely identify and address the root causes of adverse events due to a poor culture of safety, and events arising from similar root causes continued to occur.

In 2018, 88% of submitted PSPR reports identified at least one system-level contributing factor. (See "Relevant system-level contributing factors" on page 24 for more information.)

Example: Communication and Care Delay Events

The definition of *care delay* includes delay in treatment or intervention, delay in diagnosis, delay in recognizing changing condition, and failure to rescue in a reasonable timeframe. *Care delay* events submitted to PSRP occurred in a wide variety of locations within healthcare organizations and involved a multitude of systems and processes. Despite the variation among *care delay* events, *communication* has consistently been the most frequently identified contributing factor category for the past three years. In 2018, 89% of *care delay* reports identified at least one *communication* contributing factor (Figure 5).

Figure 5. Care Delay Contributing Factor Categories, 2018



These numbers may total more than 100% as reports may indicate multiple contirbuting factors.

Of the 31 care delays that identified at least one *communication* factor, 19 (61%) identified *Among interdisciplinary teams*. The investigation of a single event may prompt the adoption of a communication training program, which may in turn reduce the risk of recurrence of dozens of other seemingly unrelated events.

Adverse Events Require Ongoing Problem Solving

Healthcare is constantly changing and evolving. As we make healthcare safer, we also expand our concept of what is in our control, and things that seem unpreventable today will seem preventable tomorrow. In addition, the introduction of new processes, systems and technology may also introduce new unanticipated risks. Given the dynamic nature of healthcare, organizations must build and constantly refine their infrastructure to address the wide range of safety issues that will inevitably arise.

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)

Example: Solving One Problem May Create New Risk

Our solutions to old problems can create new, unanticipated risks. For example, infusion pump manufacturers developed “smart pumps” to reduce the risk of inputting the wrong units, rate or dose for a specific drug. An organization defines acceptable limits for specific drugs in the smart pump’s drug library and if values outside the pre-set limits are chosen, it alerts the provider. Smart pumps replace the problem of miscalculation with the problem of overriding alerts.

In PSRP, we have seen organizations adopt smart pumps as a solution to incorrect rate medication events. We have also seen organizations identify problems with programming smart pumps as the cause of incorrect rate medication events. One study found that nurses were significantly more likely to remedy dosing errors using a smart pump with a “hard limit” (an alert that cannot be overridden without re-programming the pump) than they were to remedy a dosing error using a smart pump with a “soft limit” (an alert that can be overridden) or using a traditional infusion pump (Trbovich et al. 2010).

Example: Our Changing Perspective on Healthcare-Associated Infections

Today, healthcare organizations recognize that most healthcare-associated infections (HAIs) are preventable. But that wasn’t always the case (Vincent and Amalberti 2015). “[Healthcare-associated infections] were long accepted by clinicians as an inevitable hazard of hospitalization” (Agency for Healthcare Research and Quality 2019a). 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 recent meta-analysis of 144 HAI prevention studies found that 30-50% of currently occurring HAIs could be prevented (Schreiber et al. 2018).

This finding is in keeping with the proportion of 2018 HAI reports to PSRP that the reporting organization felt were almost certainly or likely preventable. In 50% of the HAI reports, the reporting organization felt that the infection almost certainly or likely could have been prevented (Table 6).

Table 6. Preventability of Healthcare-Associated Infection Events, by Segment 2018

	ASC (n=14) Number (%)	**Hospital*** (n=28) Number (%)	**Both Segments** (n=42) Number (%)
Almost certainly or likely could have been prevented	5 (36%)	16 (57%)	21 (50%)
Almost certainly or likely could not have been prevented	4 (29%)	2 (7%)	6 (14%)
Unknown or did not respond	5 (36%)	10 (36%)	15 (36%)

* Two cases were harm A and are excluded.

Looking at the reports where a healthcare organization indicated that the infection was almost certainly or likely not preventable, or where preventability was unknown, we can see that, although there is increased understanding about preventability related to infection prevention, there is still work to be done. These 21 reports fell into four broad categories that may be opportunities to revisit how determinations about preventability are applied:

1. **Prevention efforts were hampered by patient choices**. Patients may pull out catheters or they may make hygiene choices that increase their risk for infection. Shifting blame to patient actions may be an indication of a review and analysis that did not seek to understand what organizational processes should be in place to support patient understanding and ability to effectively fulfill their self-care responsibilities.
2. **Too many possibilities**. In some cases, there were many competing possibilities for how the patient got the infection. The inability to pinpoint one specific cause was interpreted as inevitability, which may not be the case. Most adverse events are the result of not one single cause, but multiple causes (Peerally et al. 2017).
3. **Standard of care was met**. In some cases, the organization's review and analysis team focused on whether policies and procedures were followed. Having determined that they were, and that the standard of care was met, the review team either considered the infection unpreventable, or did not make a determination about preventability and closed their investigation. These are missed opportunities to evaluate whether the procedures and policies in place are adequate to protect patients from harm.
4. **Inadequate information to make a determination**. In some cases, the organization could not identify where the infection came from, and because the patient was extremely fragile and/or transferred one or more times during the course of care, the review and analysis team could not make a determination about preventability. These situations may be missed opportunities to identify and address risk for other patients.

Oregon's Capacity to Learn from Adverse Events

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:

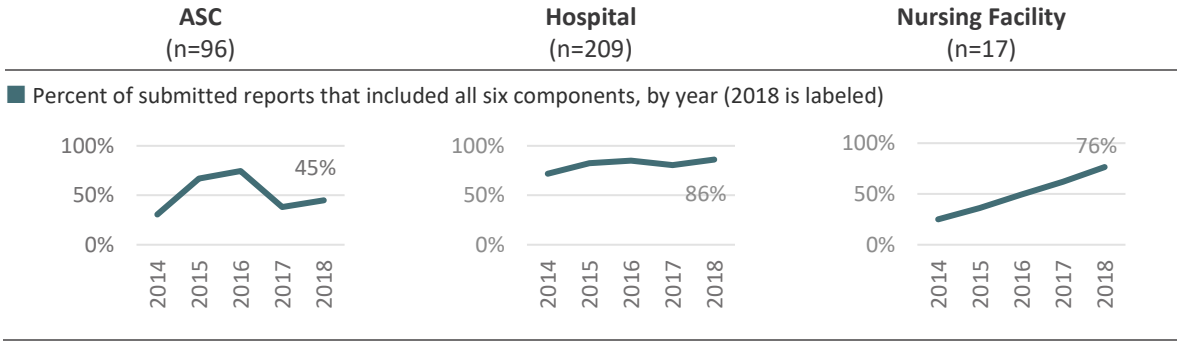
- Pertinent information to fully understand what happened
- Consistent information
- Leadership participation in the event analysis (only required for serious harm events)
- Relevant system-level contributing factors
- One or more root causes
- One or more system-level action plans designed to minimize risk

In 2018, 71% of all reports submitted by all segments contained all six quality components. Of the 96 reports that did not contain all quality components, 55 (57%) 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 6 provides a snapshot of the quality components by segment over the last five years.

Figure 6. Percent of Reports that Included All Six Components by Segment, 2014-2018



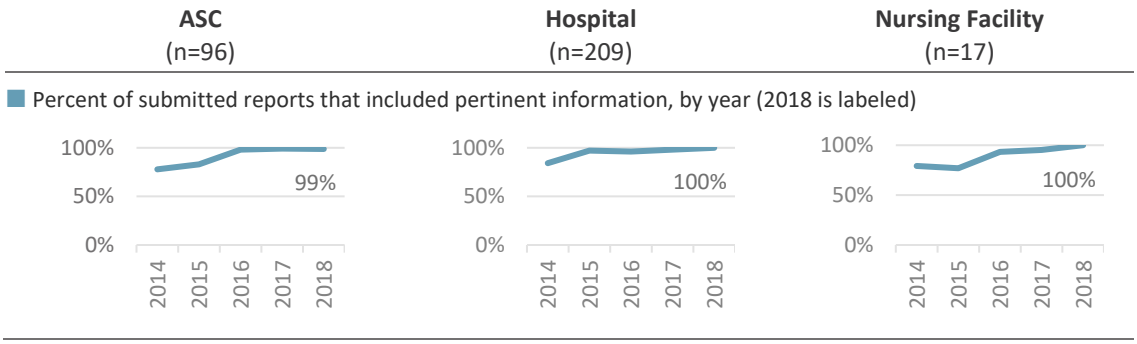
Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

The following provides a breakdown of each quality component by segment over the last five years.

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 7).

Figure 7. Percent of Reports that Included Pertinent Information to Fully Understand What Happened by Segment, 2014-2018

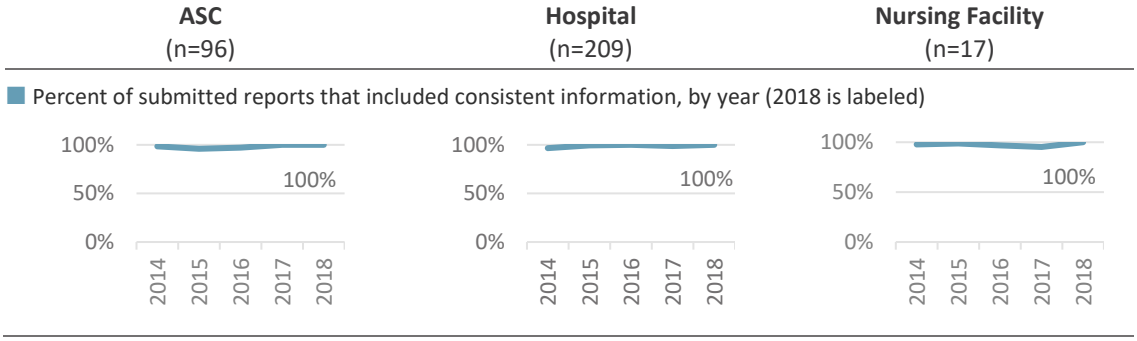


Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

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 8).

Figure 8. Percent of Reports that Included Consistent Information by Segment, 2014-2018



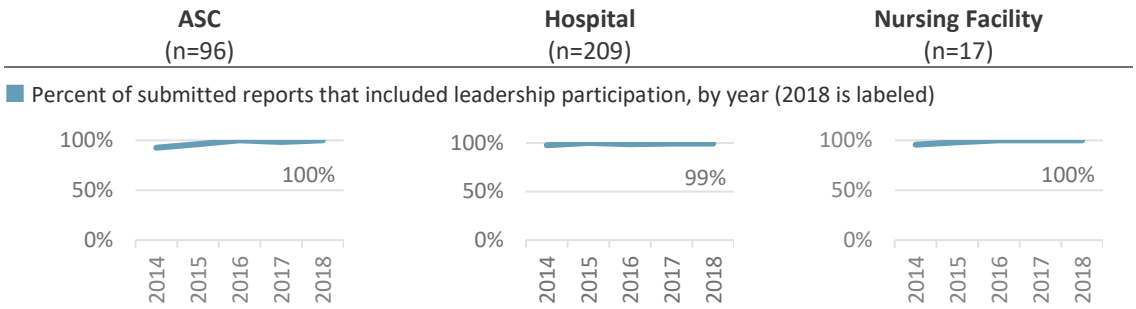
Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

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 to leadership, and staff's reports of safety issues and adverse events are taken seriously. Lack of leadership support and feedback are two of the main reasons that healthcare staff don't report these types of events internally. In 2018, reports from healthcare organizations indicate leadership involvement in the adverse event review and analysis process for serious adverse events. (Figure 9).[6]

[6] See "Ongoing leadership support for and direct involvement in patient safety work" on page 5 for more information on how leadership should be involved.

Figure 9. Percent of Reports that Included Leadership Participation in the Event Analysis* by Segment, 2014-2018



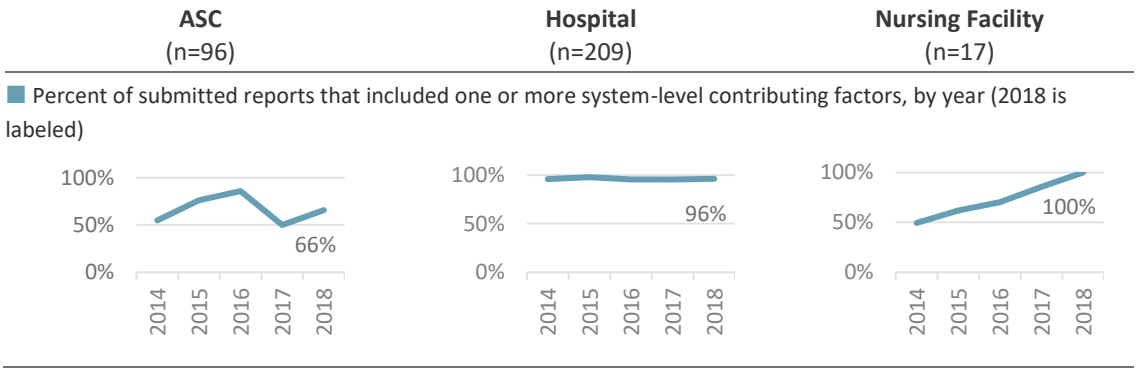
Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

* Only required for serious harm events

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. Eighty-eight percent of submitted reports identified at least one system-level contributing factor in 2018 (Figure 10).[7]

Figure 10. Percent of Reports that Included Relevant System-Level Contributing Factors by Segment, 2014-2018



Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

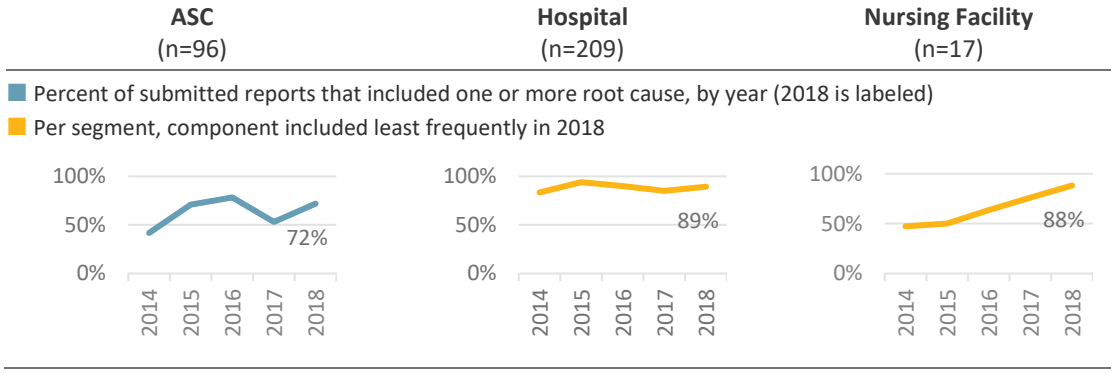
V. One or more root causes

Identification of contributing factors is the first step to uncovering the deeper system-level causes, or 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 root causes, not just one single root cause.

[7] See "Adverse Events Have Common Causes" on page 15 for detail about the specific categories and factors identified.

Reports that identified at least one root cause show a similar pattern to identification of relevant system-level contributing factors over time, and by segment (Figure 11).

Figure 11. Percent of Reports that Included One or More Root Cause by Segment, 2014-2018



Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

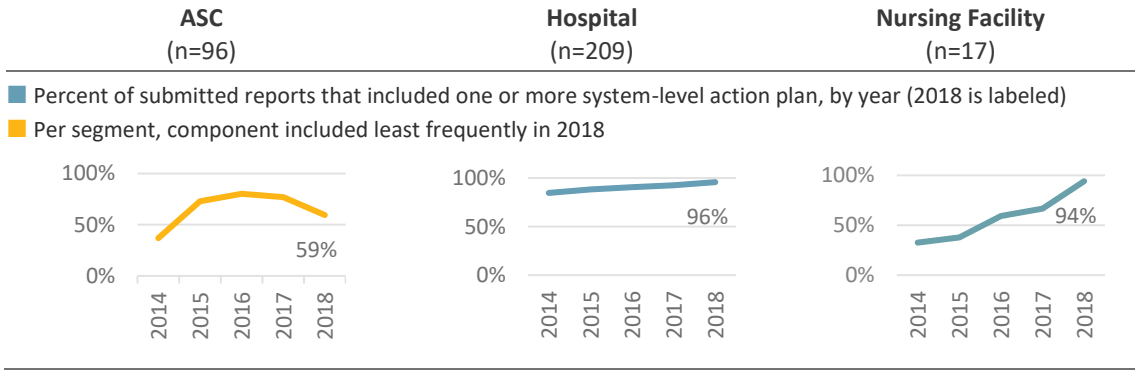
Identification of one or more root causes reflects a similar pattern to identification of relevant system-level contributing factors over time, and by segment (Figure 10).

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 making systems of care stronger for all patients, not just one patient. Action plans that will have the greatest chance of success (i.e., strong actions; see callout box on page 26) 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, 82% of reports submitted in 2018 contained at least one system-level action plan. When we break it down by segment, the pattern is similar to that seen in contributing factors and root causes (Figure 12). Organizations that were able to learn about what happened and why through their event review and analysis process were then often able develop action plans designed to minimize the risk.

Figure 12. Percent of Reports that Included One or More System-Level Action Plans Designed to Minimize Risk by Segment, 2014-2018



Pharmacy data is not included due to low reporting volume (i.e., less than 10 in more than one year).

Finding an Action Plan that Will Lead to Safer Care

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 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 2018, about half of reports (52%) were considered timely (submitted within 45 days of event discovery), which is an improvement over 2017 (44%) (Table 7).

Table 7. Timeliness of Reports by Segment, 2018

	ASC (n=90)	Hospital (n=190)	Nursing Facility (n=17)	Pharmacy (n=13)	All Segments (n=310)
Number of reports that were timely	60	81	14	5	160
Percent of reports that were timely	67%	43%	82%	38%	52%

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 2018, written notification was provided in 22% of the serious events for which it was required. Healthcare organizations also provided written notification in 12% of the cases where it was not required.

Conclusion

In our complex and constantly evolving healthcare delivery system, adverse events and other safety issues will continue to occur. And while there have been advances in healthcare, the causes of adverse events remain much the same today as they were nearly 20 years ago.

Because of the dynamic nature of healthcare, 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.

However, to build effective systems for responding to and learning from patient safety events, an organization must have a culture of safety in place. Without first taking steps to establish a culture of safety, well-intentioned patient safety improvement efforts may not be effective. To foster a culture of patient safety, organizations can strive for the following:

- Ongoing leadership support for and direct involvement in patient safety work
- Systems for adverse event identification and triage
- Dedicated staff to facilitate the event review and analysis process and follow-up
- A common understanding among all staff about the adverse event review and analysis process
- Centralized efforts to avoid learning in isolation and duplication of efforts
- Patient involvement

Patient safety work is ongoing, 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 to learn about and improve systems of care for every patient they serve.

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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, when hospitals became the first segment to have a reporting program. The other healthcare segments were added in later years. Among ASCs, hospitals, and nursing facilities, 82% of eligible facilities have enrolled in the program (Table 8).

Table 8. Facility Participation in Reporting Program by Segment, 2018

	ASC	Hospital	Nursing Facility	Pharmacy	All Segments
Number of facilities enrolled	67	59	113	118	354
Total eligible facilities	88	59	135	708	990
Percentage of participating facilities	73%	100%	84%	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 (59%) have submitted at least one report since the beginning of the program. In 2018, 67 (19%) of the enrolled facilities submitted one or more reports (Table 9).

Table 9. Number of Reporting* Facilities by Segment, 2018

	ASC	Hospital	Nursing Facility	Pharmacy	All Segments
Number of reporting facilities	19	35	8	5	67
Number of enrolled facilities	67	59	113	118	354
Percentage of enrolled facilities that reported	28%	59%	7%	4%	19%

* A facility that submitted at least one report in 2018.

Oregon facilities submitted 339 adverse event reports in 2018 (Table 10). The median number of reports per reporting facility was four, with a range of one to 34.

Table 10. Total Submissions by Segment, 2018

	ASC	Hospital	Nursing Facility	Pharmacy	All Segments
Total reports submitted*	99	209	18	13	339
Number of submitting facilities	19	35	8	5	67
Median reports per facility	5	4	2	2	4
Range of reports per facility	1-15	1-34	1-4	1-6	1-34

* 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

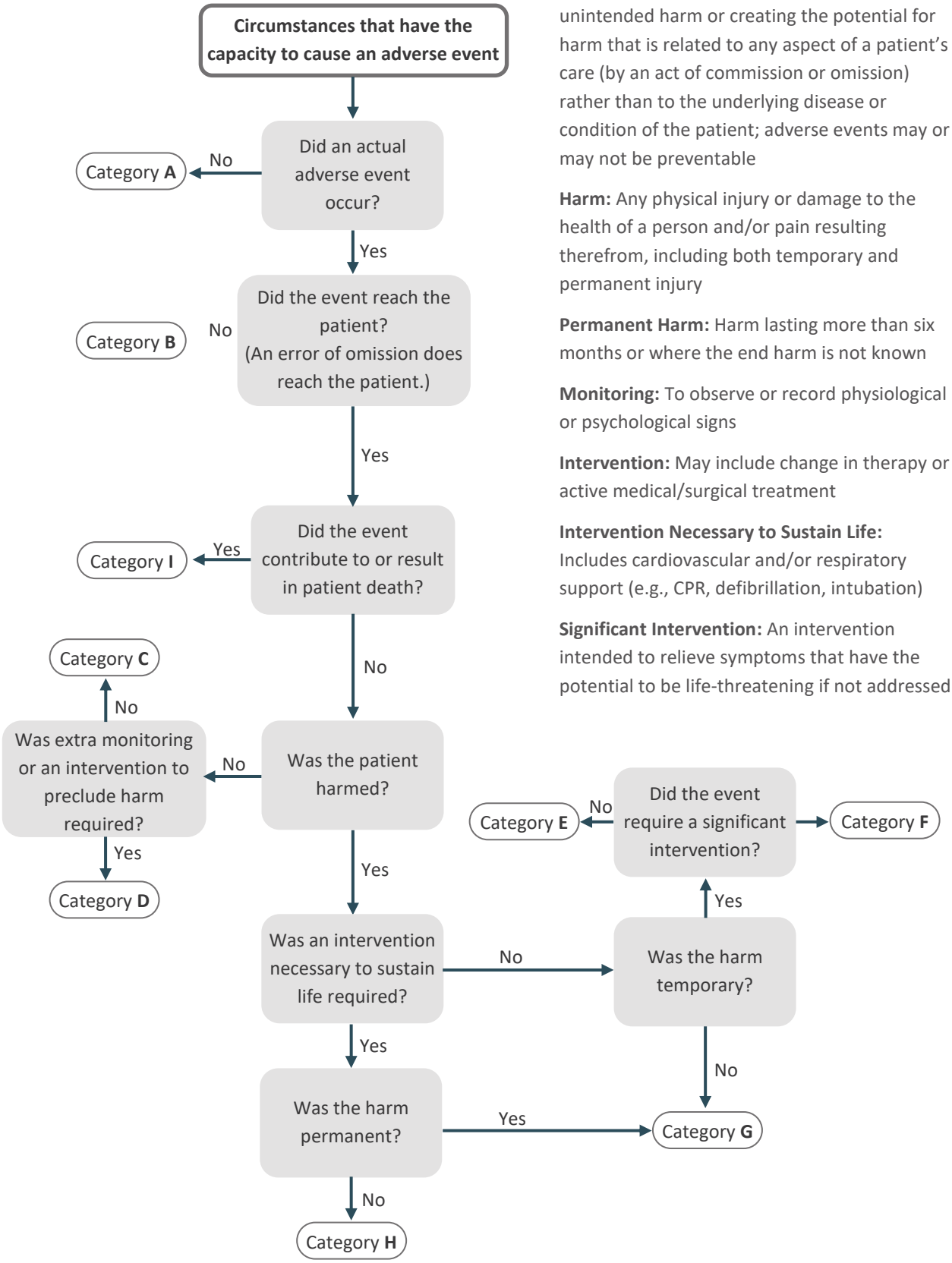
The Patient Safety Reporting Program (PSRP) has adapted the National Coordinating Council for Medication Error Reporting and Prevention's (NCC MERP) Medication Error Index (2001) to classify adverse events[8] according to the severity of the outcome. PSRP participants are required to report serious adverse 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	

[8] 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