Patient Safety Reporting Program

2012 ASC Annual Summary

Report. Learn. Improve Patient Safety.

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Executive Summary

In 2012, Oregon ambulatory surgery centers (ASCs) significantly improved reporting to the Oregon Patient Safety Commission compared to 2011. The increase in reports is not an indication that more adverse events are occurring, but rather, that Oregon ASCs are improving their ability to identify adverse events. However, ASCs continue to have opportunities for improvement as reporting in 2009 and 2010 saw higher reporting volume than 2012.

This annual summary provides an aggregate look at the adverse events reported by ASCs in 2012. Based on an analysis of these reports, this summary provides information regarding the type and characteristics of adverse events reported, as well as a clear set of recommendations to improve the quality of investigations and prevent recurrence of similar problems. The Commission provides aggregate reports so that ASCs can use the information as a tool, in conjunction with evidence-based best practices and quality improvement tools, to build and strengthen their organization's culture of patient safety.

The voluntary, confidential nature of the Patient Safety Reporting Program is unique. Each year, the Commission strives to provide robust information on statewide trends and meaningful feedback to help ASCs learn and improve. Adverse event reporting demonstrates a commitment to patient safety and helps to preserve the unique qualities of the program.

The Commission is dedicated to providing value to our Patient Safety Reporting Program participants. In addition to our work this year with the Patient Safety Reporting Program, the Commission offers many other programs specifically designed to support ASCs with their patient safety efforts:

- Educational opportunities – obtain training about infection prevention and other key patient safety practices online or in person
- Monthly newsletters – access news, resources, and essential information for patient safety
- Action Alerts – get important information about potentially serious patient safety concerns
- Oregon Ambulatory Surgery Center Infection Prevention & Control Toolkit – access tools and other resources that provide guidance on development and implementation of infection prevention programs
- Oregon Adverse Event Disclosure Guide – better understand the purpose of disclosure and get resources to develop/improve disclosure programs
- Statement on Preventing Harm from Oversedation – inform your efforts to decrease patient harm associated with sedation

The Commission appreciates the continued support of our partners and the Patient Safety Reporting Program participants who are actively engaged in patient safety efforts. We are pleased to provide this *2012 ASC Annual Summary* to inform efforts throughout Oregon to reduce the risk of serious adverse events and encourage a culture of patient safety.

Overview of Oregon's ASC Patient Safety Reporting Program

Each year, ASCs participating in Oregon's Patient Safety Reporting Program submit adverse event reports about the unintended harm (or potential harm) to patients that occur as a result of medical care. This annual summary provides a statewide, aggregate picture of the information reported by ASCs in 2012. The reporting program focuses on learning from adverse events rather than simply measuring the number of events reported and aims to:

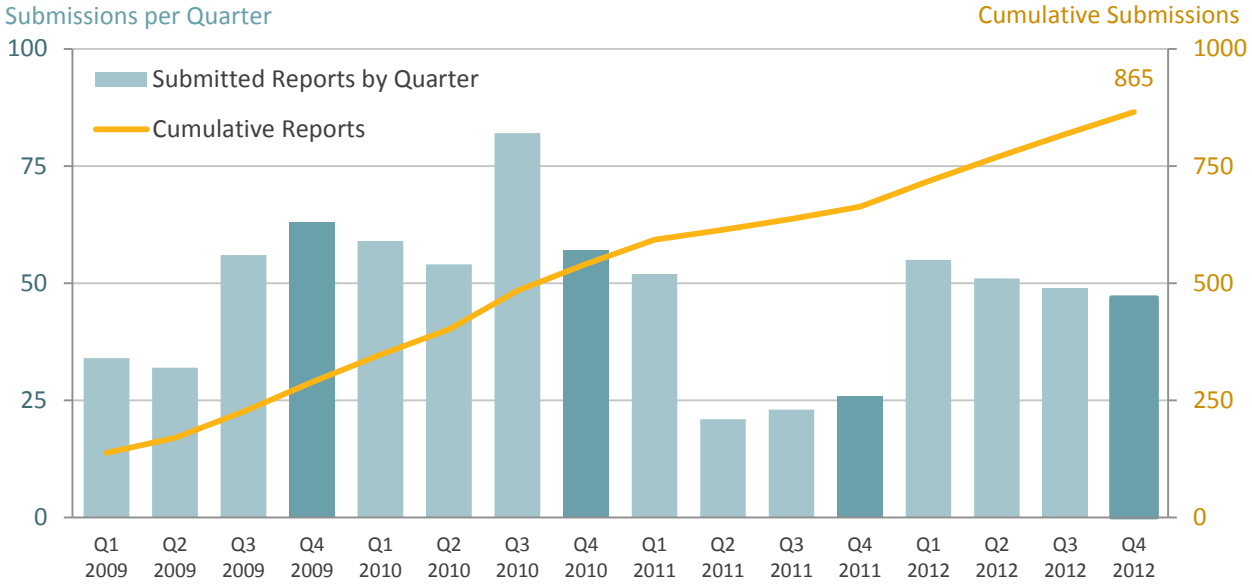
- Build a strong database for learning,
- Identify best-practices being used in Oregon to prevent adverse events, and
- Assist healthcare organizations with setting patient safety priorities and implementing improvement efforts.

ASCs participating in the reporting program are working to identify, investigate, and report adverse events. Through reporting, ASCs demonstrate a commitment to building a culture of patient safety that can effectively reduce preventable injury and harm. To continue building a culture of safety, ASCs must learn from, and capitalize on, opportunities to identify and correct the underlying system issues that lead to adverse events. ASCs can use this report, in conjunction with other services from the Oregon Patient Safety Commission, to support and improve their patient safety programs.

Reporting History

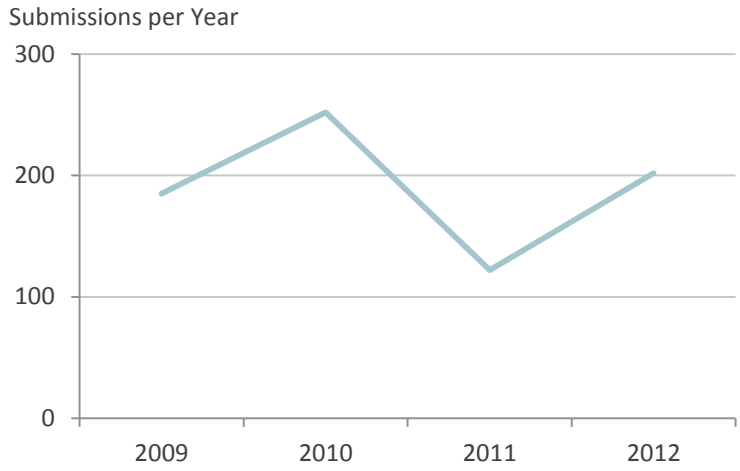
The Commission has seen fluctuation in ASC reporting from year to year since the reporting program began in 2007 (see Figure 1). ASC reports submitted to the Commission steadily increased from 2007 through 2010 but declined significantly in 2011. With 177 reports submitted in 2012, reporting has again begun to increase, although not yet to the levels of 2009 and 2010.

Figure 1. Reports Submitted 2009-2012 by Quarter and Cumulatively



We interpret the 2012 increase in reporting not as an increase in the number of reportable events occurring but rather as improvement on the part of Oregon ASCs in recognizing and reporting adverse events (see Figure 2). Similarly, we interpret the decrease in 2011 not as a decrease in the number of reportable events occurring, but as a decrease in the reporting of events. Reports of adverse events may be higher in a facility that is vigilantly searching for potential problems in an effort to strengthen systems.

Figure 2. Reports Submitted 2009 through 2012*



**Annual submission totals are based on the report submission date, whereas in previous years, totals were based on the event date. Differences in previous years' reporting totals may be noted due to this change.*

In 2012, the Commission provided ASCs with recognition targets designed to ensure that the goals of the program are achieved (including the optimization of shared learning at a statewide level) and to recognize healthcare organizations for their transparency efforts and commitment to patient safety. Patient safety evaluation systems (identification, investigation, and reporting of adverse events) are a necessary part of patient safety planning and culture development for all ASCs. The Patient Safety Reporting Program is designed to capture and responsibly share the patient safety improvements that Oregon ASCs are implementing. Additional information about program goals for ASCs is available in the Recognition Targets section on page 33.

2012 Reporting

The following section provides an aggregate overview of adverse event reports submitted to the Oregon Patient Safety Commission by ASCs in 2012, as well as selected comparisons with previous years.

Reported Adverse Events

When reporting adverse events, ASCs categorize events by type of event that occurred from a list of 20 event types, including an *Other* category (Appendix I provides a list of events reported by ASCs; Appendix II provides a comparison of PSRP event types with other sources). In 2012, the Commission received 177 reports, which included 180 events. A majority of those 2012 events were *Surgical or other invasive procedure events*, which represent 49% of all reported events. *Healthcare-associated infections* were the second most frequently reported event type in 2012 (17%). Table 1 provides an overview of the types of adverse events reported by Oregon ASCs during 2012.

Table 1. Number and Percent of Events Reported by Type, 2012

Event Type	Number	Percent of Events
Surgical or other invasive procedure	89	49%
Healthcare-associated infection (HAI)	31	17%
Medication or other substance	14	8%
Deep vein thrombosis with or without pulmonary embolism	13	7%
Fall	12	7%
Device or medical/surgical supply	7	4%
Anesthesia	6	3%
Aspiration	2	1%
Contaminated drugs, devices or biologics	2	1%
Other event	2	1%
Care delay	1	1%
Unintended retained foreign object	1	1%
Total Reports	**177**	
Total Events	**180**	

Not surprisingly, with surgeries and procedures being the primary function of the ASC care setting, *Surgical or other invasive procedure* events were the most frequently reported event type and have been each year since the inception of the program. This fact emphasizes the importance of safety throughout the surgical process (preoperative, operative, and postoperative) and opportunities for system-level improvements.

Surgical or Other Invasive Procedure Events

Participants reported on several different types of *Surgical or other invasive procedure* events. *Unplanned admission to hospital* or *emergency department visit (within 48 hours of discharge)* and

Postop bleeding requiring return to operating room were the most common *Surgical or other invasive procedure* events reported in 2012 and comprised 78% of this event type. Table 2 summarizes the types of *Surgical or other invasive procedure* events reported in 2012.

Table 2. Number and Percent of *Surgical or Other Invasive Procedure* Events Reported by Type, 2012

***Surgical or Other Invasive Procedure* Event Type**	**Number**	**Percent**
Unplanned emergency department visit	41	46%
Unplanned admission to hospital	15	17%
Postop bleeding requiring return to operating room	13	15%
Laceration, perforation, puncture, or nick	8	8%
Other	5	6%
Incorrect implant	2	2%
Intraop or immediately postop/postprocedure death	2	2%
Incorrect patient	1	1%
Incorrect procedure	1	1%
Postop nausea requiring hospital admission	1	1%

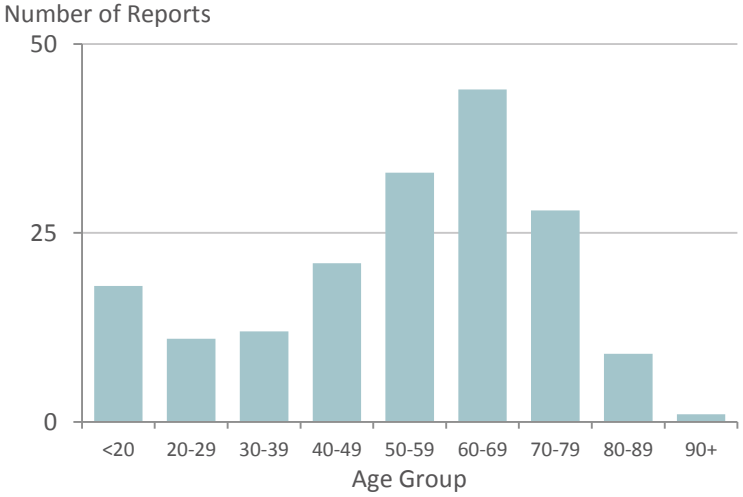
The majority of *Surgical or other invasive procedure* events submitted in 2012 by ASCs were related to unplanned emergency department visits or hospital admissions, which accounted for 63% of *Surgical or other invasive procedure* events. The remaining 33 events (37%) were related to various occurrences in operating or procedure rooms, many related to unanticipated bleeding or injury. A more in-depth look at *Surgical or other invasive procedure* events can be found in A Closer Look: How Data Informs Change on page 12.

Patient Age and ASA Class in Reported Events for 2012

Age

The patients impacted by adverse events reported in 2012 ranged in age from zero to 92. While reported adverse events were experienced by patients in every age group, the group experiencing the highest number of events were those ages 60 to 69 (see Figure 3).

Figure 3. Number of Reports by Patient Age, 2012



ASA Class

A patient's preoperative physical condition is determined using the American Society of Anesthesiologists' (ASA) Physical Status Classification System. The ASA classification is an assessment of the patient's pre-operative physical status and, on its own, is not a predictor of operative risk. Other factors impact operative risk such as age and obesity of the patient, nature and severity of the operative procedure, selection of anesthetic techniques (including the choice of anesthetic), skill and experience of the surgical team, and duration of surgery or anesthesia (Fitz-Henry, 2011). Patients can be categorized into one of six ASA classes based on their physical status; however, ASCs typically see patients in ASA classes one through three:

ASA 1: A normal healthy patient
ASA 2: A patient with mild systemic disease
ASA 3: A patient with severe systemic disease

While the ASA classification offers some guidance to ASCs related to a patient's preoperative physical status, evidence supporting the relationship between ASA classification and patient outcomes is inconsistent. Additionally, research has not yet provided clear criteria to guide patient selection decisions for the ASC setting (Pennsylvania Patient Safety Authority, 2009). However, given wide-spread use of the ASA classification system, ASCs can use the system in conjunction with other evidence-based surgical risk factors to determine appropriate patient selection for their facility. For additional discussion about patient selection, see A Closer Look at Surgical or Other Invasive Procedure Events, Preoperative Patient Screening and Assessment on page 15.

Of the adverse events reported in 2012, 143 (of 177 reports) indicated an ASA classification; more than half of which (52%) were identified as ASA class 2 patients (see Table 3). Reports submitted in 2012 represent a marked change in proportions by ASA class from prior years. Over the history of the reporting program, adverse event reports involving ASA class 2 and 3 patients have increased slightly and reports involving ASA class 1 patients have decreased considerably. Reports submitted in 2012 show a precipitous drop of adverse event reports involving ASA class 1 patients.

Table 3. Adverse Event Reports by ASA Class, 2012

	2007-2011		2012	
ASA Class	**Number**	**Percent**	**Number**	**Percent**
ASA Class 1	247	40%	37	26%
ASA Class 2	295	48%	75	52%
ASA Class 3	75	12%	29	20%
Total	**617**		**143**	

Note: Two reports submitted for ASA class 4 patients in 2012 are not represented in this table.

Due to the nature of the data collected by the Commission, specific reasons for ASA classification trends and their meaning are unknown.

Harm in Adverse Event Reports

When ASCs report adverse events, they assess harm related to the event. In 2012, the Commission adopted formally validated national harm categories established by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (see Table 4). Adoption of the national NCC MERP harm categories improves the Commission's ability to interpret the impact of adverse events in a standardized way. With the enhancements implemented in 2012, reporters now follow an algorithm embedded in the adverse event report and answer a series of yes/no questions to assign an appropriate harm category.

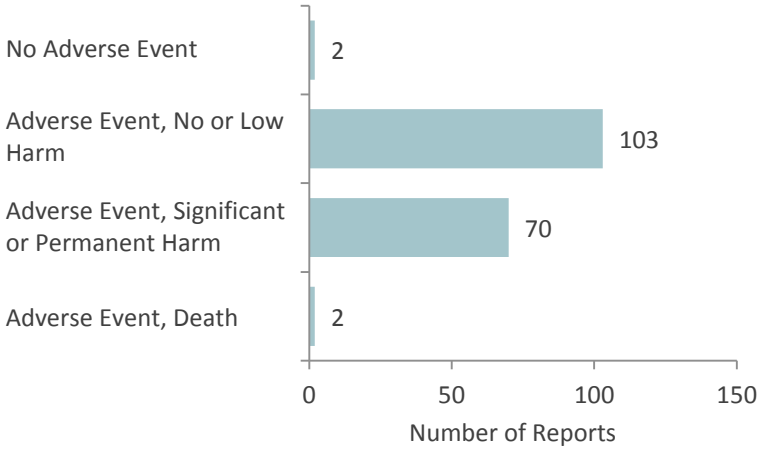
Table 4. NCC MERP Harm Categories

Category A	Circumstances that have the capacity to cause an adverse event	**No adverse event**
Category B	An event occurred that did not reach the patient (an "error of omission" does reach the patient)	**Adverse event, no harm**
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"*	
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"*	
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 *A significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	**Adverse event, harm**
Category F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required a significant intervention *A significant intervention is defined as "an intervention intended to relieve symptoms that have the potential to be life-threatening if not addressed"*	
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 *An 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	**Adverse event, death**

ASCs report any unanticipated, usually preventable consequence of patient care that results in patient harm and any serious adverse events. ASCs are encouraged to report less serious harm

events, no harm events, and near-miss events; doing so provides important opportunities to improve patient safety and helps prevent the likelihood of future serious adverse events. The number of reports submitted in 2012 by harm category can be found in Figure 4.

Figure 4. Number of Reports by Harm Category, 2012



In 2012, over half of events reported by ASCs (58%) were adverse events with low or no harm (harm categories B-E). Of those reports, 45 (25% of all reports) were less serious harm events (harm category E), 57 (32% of all reports) were no harm events (categories C and D), and 3 (2% of all reports) were near miss events (harm categories A and B) (see Table 5). The organizations that reported near miss events played a critical role in improving patient safety by investigating events that, although ultimately deemed near misses, allowed for the identification of system-level issues that could lead to an adverse event in the future. Rather than simply asking, "Did this system contribute to this patient's outcome?" these facilities went a step further and asked, "Could this system create or contribute to an adverse event for any patient?" Such willingness to look beyond the specific circumstances of an event to the broader context of patient care is commendable.

ASCs also reported 74 (41%) serious harm events, including two deaths. Although the events most frequently associated with serious harm were *Surgical or other invasive procedure* and *Healthcare-associated infection*, the percentage of low or no harm events within each of these event types was comparable to the percentage of serious harm events.

Table 5. Number and Percent of Serious Harm Events by Event Type, 2012*

Event Type	Number	Total	Percent
Surgical or other invasive procedure	43	89	49%
Healthcare-associated infection (HAI)	16	31	52%
Deep vein thrombosis	6	13	46%
Device or medical/surgical supply	3	7	43%
Anesthesia	2	6	33%
Aspiration	2	2	100%
Medication or other substance	1	14	7%
Contaminated drugs, devices or biologics	1	2	50%

**Appendix IV provides a table of all harms reported in 2012 by event type.*

Two harm category I events were reported in 2012 (see Table 6). One involved a patient who was more vulnerable (i.e., identified as having significant comorbidities), the other involved a patient who may have recklessly disregarded medical advice. These reports indicate that many ASCs are diligent about reporting serious events, particularly those events affecting more vulnerable patients. While these deaths may be considered unavoidable, reporting these types of events demonstrates a belief that all events should be investigated and examined to identify opportunities for prevention, regardless of the complexity of a patient's health status or extenuating circumstances. In fact, both of the 2012 investigations yielded system-level action plans—a clear indication that Oregon ASCs are committed to preventing significant harm even in situations where there may be no way to avoid the outcome. ASCs used these significant events to strengthen their systems and prevent future harm as much as possible.

Table 6. Number of Reports Resulting in Death (Harm Category I) by Year

	2007*	2008	2009	2010	2011	2012
Number of Harm I Reports	0	1	1	1	1	2
Percent of Total Reports	--	1%	0.5%	0.4%	0.9%	1.1%

**2007 includes only 6 months of data.*

Since 2007, six death events (harm category I) have been reported to the Commission by ASCs, which included:

- Five *Surgical or other invasive procedure* events
  - Two *Unplanned emergency department visits (within 48 hours of discharge)*
  - Two *Intraoperative or immediately postoperative/postprocedure deaths*
  - One perforation
- One deep vein thrombosis with pulmonary embolism

Half of the harm category I events indicated obstructive sleep apnea (OSA) as a factor, which, in one case, was undiagnosed prior to the event.[1]

Contributing Factors

In reporting an adverse event (or potential event), ASCs identify the factors that contributed to the occurrence of the event. The Agency for Healthcare Research and Quality defines contributing factors as circumstances that are retrospectively determined to have increased the likelihood of an adverse event. Contributing factors are generally external to the patient and frequently relate to the physical environment or to the care delivery system. When ASCs identify contributing factors, they are identifying opportunities to make improvements that create a more reliable system of care. Typically, there are multiple contributing factors for a single adverse event. The 177 reports submitted in 2012 identified 40 individual contributing factors across the eight categories used in the reporting program. Facilities can select multiple contributing factors in any category.

[1] The Commission has published the *Statement on Preventing Harm from Oversedation in Adult Hospitalized Patients* to identify strategies to decrease the risks associated with opioids and other sedating medications, which includes information related to OSA. The statement's Appendix C contains a sleep apnea risk guide to assess suitability for outpatient surgery.

Reports identified a range of zero to six contributing factors per report (see Table 7). Of the reports with at least one contributing factor, an average of two factors were identified across the eight categories. Thirty-four percent of reports did not indicate any contributing factors. Because adverse events may be precipitated by many different factors, understanding why an event occurred (beginning with identification of contributing factors) can facilitate identification of preventive strategies (i.e., action plans). The Commission encourages ASCs to make identification of system-level contributing factors a quality focus area. For additional discussion on the identification of contributing factors, see Identification of System-Level Contributing Factors on page 36. In 2012 reports, the most frequently identified contributing factors were *Communication* (38% of reports identified at least one *Communication* factor), *Patient factor*s (15%), *Patient management factors* (11%), and *Human or environmental* factors (11%) (see Table 8).

Table 7. Number and Percent of Reports by Contributing Factor Category, 2012

Category	Number	Percent
Communication	68	38%
Patient	26	15%
Patient management	20	11%
Human or environmental	19	11%
Policy or procedure	13	7%
Organizational	11	6%
Device or supply	9	5%
Health information technology (HIT)	2	1%

Table 8. Top Contributing Factor Categories by Factor, 2012

Category	Contributing Factor	Reports	% of Category
Communication	Understanding discharge instructions/plan	41	60%
(n=68)	Other communication factor	13	19%
	Miscommunication	11	16%
	Between providers/staff	10	15%
	Among interdisciplinary teams	7	10%
	Within units	3	4%
	Culture	2	3%
	Handoffs/handovers/shift reports	2	3%
	Language	2	3%
	Between supervisor/staff	1	1%
	With other organizations or outside providers	1	1%
Patient	Other patient factor	20	74%
(n=26)	Family dynamics/relationships	3	11%
	Behavioral status	2	7%
	Fragile health status	2	7%
	Mental status	1	4%
Patient Management	Response to changing condition/delay in care	7	35%
(n=20)	Follow-up care	6	30%
	Other patient management factor	4	20%
	Treatment/care plan	3	15%
	Patient assessment	2	10%
	Initial diagnosis	1	5%
Human or environmental	Interruptions/distractions	11	58%
(n=19)	Other human or environmental factor	7	37%
	Stress	1	5%
	Work area design and specifications	1	5%

The most frequently selected individual contributing factor across all categories was *Communication-Understanding discharge instructions/plan*, which represents 60% of all *Communication* factors and 23% of all submitted reports. Communication-related contributing factors offer an improvement opportunity for ASCs. By reviewing systems for communicating with patients (or the patient's care representative) before discharge, ASCs can develop a deeper understanding of why discharge instructions were not understood. Knowledge of why patients struggle with discharge instructions is necessary for the implementation of effective solutions for preventing similar adverse events in the future. ASCs may benefit from asking the following questions to better understand patient needs related to discharge information:

- Were instructions clearly given (including associated risks of adherence/non-adherence) both verbally and in writing?
- How did the ASC ensure instructions were fully understood (e.g., Teach Back)?
- Were the instructions culturally appropriate?

- Was the patient coming out of anesthesia or on a medication that may have made thinking or remembering difficult?

See A Closer Look at Surgical or Other Invasive Procedure Events, Effective Communication for Successful Postoperative Recovery on page 18 for a more detailed discussion, tools, and resources to support continued improvement related to patient understanding.

A Closer Look: How Data Informs Change

A closer look into reported adverse events reveals a detailed picture of what ASCs can learn from adverse event reports. The Commission's in-depth analysis uses events reported in 2012 to highlight opportunities for ASCs to improve patient safety efforts and offers recommendations and improvement strategies in three areas:

1. *Surgical or Other Invasive Procedure* Events
2. *Healthcare-Associated Infection* Events
3. *Medication or Other Substance* Events

Patient Safety Culture: The Foundation for Safe Care

While this report offers recommendations to improve patient safety, all improvement efforts rely on an organization's culture of safety. Establishing a "culture of safety" means creating a work environment where all staff are supported by leadership to practice teamwork effectively, communicate clearly, and openly discuss and learn from adverse events. ASCs with a strong culture of safety:

- Are skilled at proactive identification of risk for patient harm
- Use root cause analysis to investigate adverse events
- Review care delivery processes to identify the potential for breakdowns so that unanticipated harm is prevented and a more reliable care delivery system is nurtured

Early identification and response to potential risks demonstrates an organization's dedication to improve and create a strong culture of safety. Extensive tools and resources are available for organizations looking to improve their culture of safety. In particular, the Commission promotes the use of: *safety briefings* that strengthen and promote clear communication, *Comprehensive Unit-based Safety Programs (CUSP)* that provide a structure for identification and resolution of safety issues, and *Healthcare Failure Mode Effects Analysis* that proactively identifies the steps in organizational processes that could inadvertently contribute to harm (see box on page 13).

Culture of Safety Tools & Resources

Safety Briefings
Increase staff awareness of safety issues and create an environment where staff can share information without fear of reprisal
Safety Briefings Tool, Institute for Healthcare Improvement

Comprehensive Unit-based Safety Program (CUSP)
Change workplace culture by empowering staff to assume responsibility for safety
The Comprehensive Unit-based Safety Program (CUSP), Johns Hopkins Center for Innovation in Quality Patient Care
Using a Comprehensive Unit-based Safety Program to Prevent HAI, Agency for Healthcare Research and Quality

Healthcare Failure Mode and Effects Analysis
Proactively identify needed improvements and strengthen systems
Using Healthcare Failure Mode and Effects Analysis, VA National Center for Patient Safety
Failure Mode and Effects Analysis Tool, Institute for Healthcare Improvement

A Closer Look at
Surgical or Other Invasive Procedure Events

ASCs provide surgical/procedural care to patients who do not require hospital admission for their postoperative care. In many cases however, patients must seek additional care in the hospital setting following care in an ASC. In 2012, of the 89 *Surgical or other invasive procedure* events reported, 63% were *Unplanned emergency department visits* or *Unplanned hospital admissions* (46% and 19% respectively) (see Table 9).

Table 9. Reported *Surgical or Other Invasive Procedure* Event Types, 2012

Event Type	Number	Percent of Events
Unplanned emergency department visit	41	46%
Unplanned admission to hospital	15	17%
Postop bleeding requiring return to OR	13	15%
Laceration, perforation, puncture, or nick	8	9%
Other surgical or other procedure event	5	6%
Incorrect implant	2	2%
Intraoperative or immediately postop/postprocedure death	2	2%
Incorrect patient	1	1%
Incorrect procedure	1	1%
Postop nausea requiring hospital admission	1	1%

Identifying and understanding why patients need additional care following a surgery/procedure in the ambulatory setting will better equip ASCs to focus their improvement efforts appropriately. Contributing factors identified in *Surgical or other invasive procedure* events provide a starting point to begin to learn more about these events. *Communication* was identified most frequently as a contributing factor (38%) followed by *Patient factors* (21%) and *Patient management* (15%) (see Table 10). The following Preoperative Screening and Assessment section takes a closer look at *Surgical or other invasive procedure* events to better understand potential reasons why they may be occurring.

Table 10. Reported Contributing Factor Categories for *Surgical or Other Invasive Procedure* Events, 2012

Contributing Factor Category	Number	Percent of Events
Communication	34	38%
Patient	19	21%
Patient management	13	15%
Human or environmental	4	4%
Policy or procedure	3	3%
Device or supply	1	1%
Health information technology (HIT)	1	1%

Preoperative Screening and Assessment

Due to surgical technology and other medical advances, procedures traditionally performed in the hospital setting are now routinely performed in ASCs. As the volume and complexity of procedures has grown, so has the medical complexity of the patients seen in the ASC setting. Having a thorough patient screening and assessment process enables ASCs to identify risks and concerns for each patient and evaluate the appropriateness of ambulatory care. ASCs with a strong culture of safety are diligent in identification of risk within their organization and seek to minimize that risk wherever possible. This includes strengthening patient screening and assessment processes to ensure the best outcomes for patients receiving care in outpatient settings.

Current literature lacks clear guidance on patient selection criteria in the ASC setting; however, research is available to inform the initial screening and assessment process. The first step in establishing patient selection criteria is identification of any risk factors or "red flags"—meaning, the disease processes or other concerns that could potentially cause intraoperative or postoperative problems.

A 2007 study identified risk factors for predicting hospital admission or death following outpatient surgery (Fleisher, Pasternak, & Lyles). The study concluded that patients with four or more of the following risk factors would be more appropriate candidates for care in a center connected to a hospital:

- Patient age greater than 85 years
- Peripheral vascular disease
- Operating room time greater than one hour
- Malignancy
- Positive HIV status
- Heart disease
- A requirement for general anesthesia

Additionally, a Medicare claims study found that the strongest predictor for postoperative hospital admission was a previous hospitalization within the last six months. Risk increased two-fold for cases involving multiple prior inpatient hospitalizations (Pennsylvania Patient Safety Authority, 2005).

Other factors that may place patients at greater risk in the ASC setting should also be carefully considered as a part of the screening and assessment process (see Table 11).

Table 11. Factors Placing Patients at Greater Risk in the ASC Setting

Cardiovascular disease	The most common adverse events occurring in ASCs are those related to cardiovascular disease (Melloni, 2005). Assessing patients for the presence of symptoms that may indicate cardiac disease, per risk assessment guidelines such as those by the American Heart Association and the American College of Cardiology, is important. In particular, ASCs should consider incorporating the following into their screening and assessment process: • Patients with coronary artery disease should have a baseline cardiac assessment • Patients with unstable coronary syndromes or decompensated heart failure would not be considered appropriate for surgery in the ASC setting (Fleisher et al., 2007)

Hyperactive reactive airway disease	Hyperactive reactive airway disease has been associated with an increased risk for perioperative complications during outpatient surgery. Specific risks include: • Patients with asthma and smokers were identified as having increased risk for postoperative respiratory events • Patients with asthma and chronic obstructive pulmonary disease had an increased risk of bronchospasm • Patients with symptomatic asthma have a 50% incidence of postoperative respiratory complications (delay of surgery/procedure is recommended for these patients) (Pennsylvania Patient Safety Authority, 2009)
Obesity	Obesity has been associated with an increased risk for intraoperative respiratory events (including desaturation and bronchospasm). Lower respiratory events are also more common in obese patients. *Note: Obesity is defined as an "excess of adipose tissue or body weight greater than or equal to 20% more than ideal weight or a BMI of greater than or equal to 30 kg/m^{-2}"(Pennsylvania Patient Safety Authority, 2009).*
Obstructive sleep apnea	The prevalence of obstructive sleep apnea (OSA) in the general population is estimated at 20% (Young, Peppard, & Gottlieb, 2002) and approximately 93% of women and 82% of men with moderate to severe OSA are undiagnosed (Young, Evans, Finn, & Palta, 1997). Thus, screening for OSA is imperative to ensure patient selection is appropriate for the type of procedure and anesthesia planned. Pre-procedure screening and preparedness should include an assessment of the existence/severity of OSA to ensure appropriate patient selection for the procedure and anesthesia planned. The following OSA pre-screening options are recommended: • The Society for Ambulatory Anesthesia recommends the use of STOP-BANG criteria along with patient comorbidities[2] (e.g., arrhythmias, congestive heart failure, cerebrovascular disease, and metabolic syndrome) • The American Society of Anesthesiologists suggests that positive sleep studies or clinical indicators (e.g., STOP-BANG criteria) be considered, along with – The level of invasiveness of surgery and anesthesia – The potential need for post-procedure opioids (Accreditation Association for Ambulatory Health Care, 2012)

ASCs should also be cognizant of the diabetic patients they serve. Although diabetes is not a major independent predictor of morbidity in the ASC setting specifically, patients with diabetes are at an increased risk for having perioperative cardiac and respiratory events in inpatient settings. Additionally, Lermitte and Chung have shown that wound infections are more prevalent in patients with diabetes, primarily when postoperative glucose readings are high (2005).

With the increasing popularity of ASCs, the importance of strong screening and assessment systems to ensure safe patient outcomes is becoming more apparent. Although the evidence currently does not support the use of a specific screening and assessment tool for the ASC setting, consideration for risk factors associated with postoperative hospital admission, along with comorbidities that have been associated with increased risks of complications, can inform ASC's screening and assessment processes. ASCs should also consider risk factors associated with the surgery/procedure itself.

[2] STOP-BANG is an OSA screening tool that identifies patients with a high probability of OSA and has been widely adopted because of its ease of use. A sample of the STOP-BANG tool is available in Appendix A of the Commission's publication *Statement on Preventing Harm from Oversedation in Adult Hospitalized Patients*.

Recommendation

Evaluate your ASC's patient screening and assessment process to ensure that systems are in place to support safe patient outcomes (including consideration for risk factors associated with postoperative hospital admission, comorbidities that have been associated with an increased risk for complications, and risk factors associated with the surgery/procedure itself).

Implementation Strategies

- **Incorporate risk factors associated with hospital admission or death following outpatient surgery into your pre-screening/assessment process**
  Patients with four or more of the following risk factors would be more appropriate candidates for care in a center connected to a hospital:
  - Patient age greater than 85 years
  - Peripheral vascular disease
  - Operating room time greater than one hour
  - Malignancy
  - Positive HIV status
  - Heart disease
  - A requirement for general anesthesia
- **Consider comorbidities that have been associated with increased risk for complications in the ASC setting (see Table 11)**
  Use the identified comorbidities in conjunction with other patient screening and assessment information to allow for an informed decision about the appropriateness of surgery in the ASC setting. Incorporate the following requirements into the pre-screening checklist:
  - A baseline cardiac assessment will be done for all patients with coronary artery disease
  - Patients with unstable coronary syndromes or decompensated heart failure will not be considered appropriate candidates for surgery in the ASC setting
  - Surgery/procedure will be delayed for patients with symptomatic asthma until they are asymptomatic
  - A STOP-BANG sleep apnea assessment will be conducted on ALL patients prior to surgery/procedure

Effective Communication for Successful Postoperative Recovery

The ambulatory surgery setting heavily relies on individuals to actively manage their own, often complex, care. Patients may struggle to understand medications, instructions and consents, self-care pre/post-surgery, and follow-up plans. Lack of patient understanding often leads to unplanned emergency department visits or hospital admissions. In 2012, 33 (38%) reported *Surgical or other invasive procedure* events identified at least one *Communication* contributing factor (see Table 12). Of those reports citing communication as a contributing factor, 25 (76%) cited one or more factors related to *Communication with patients/families*; the most frequently reported patient/family communication factor was *Understanding discharge instructions/plan*.

Table 12. Reported Communication Contributing Factors for *Surgical or Other Invasive Procedure* Events, 2012

Contributing Factor Category	Number	Percent (n=33)
Understanding discharge instructions/plan	20	61%
Other	8	24%
Miscommunication	6	18%
Between providers/staff	5	6%
Culture	2	6%
Handoffs/handovers/shift reports	2	6%
Language	2	6%
Between supervisor/staff	2	6%
Among interdisciplinary teams	1	3%
Within units	1	3%
With other organizations or outside providers	1	3%

A deeper dive into *Surgical or other invasive procedure* events, specifically *Unplanned emergency department visits* and *unplanned hospital admissions,* sheds light onto potential areas of opportunity for strengthening communication with patients and families.

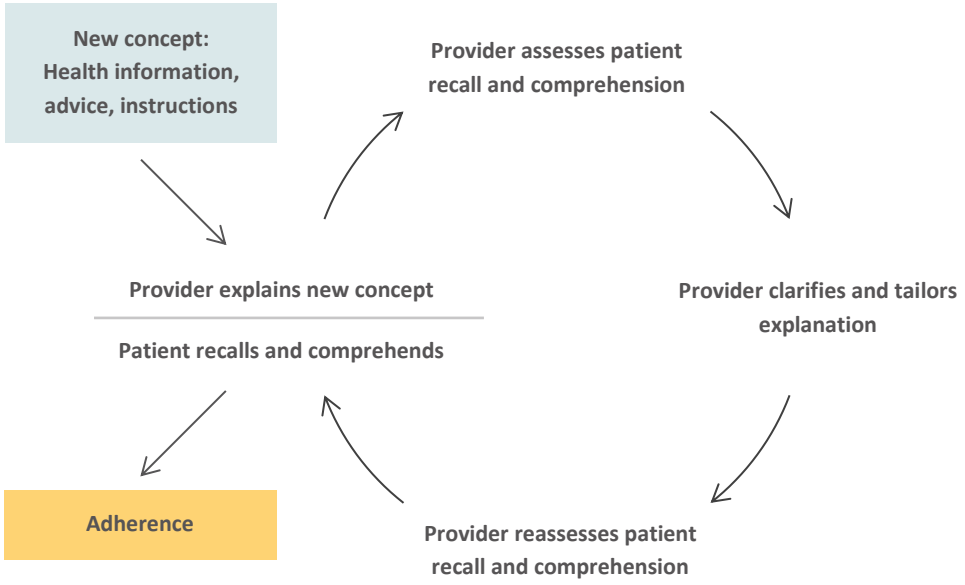
Patients Seeking Post-Discharge Medical Intervention

Reports indicate that patients sought post-discharge medical intervention (i.e., emergency department visit or hospital admission) for a variety of reasons. Pain was the most frequently mentioned reason and was present in 50% of *Unplanned emergency department visits* and *Unplanned hospital admission* events. Other reasons included, but were not limited to, inadequate communication of discharge instructions, the patient's perception/expectations of post-discharge condition, bleeding, and sleep apnea.

Typically, pain after ambulatory surgery can be managed at home. Successful management hinges on a variety of factors such as the patient's understanding of postoperative pain management (including monitoring and when to seek additional care or advice), expectation of pain levels, anticipated relief from postoperative pain medications and their potential side-effects. ASCs may reduce the possibility that a patient will seek post-discharge medical intervention for pain-related reasons by improving communication with the patient.

Studies have shown that 40-80% of the medical information patients receive is forgotten immediately and nearly half of the information retained is incorrect (DeWalt et al., 2010). Clear communication and confirmation of patient understanding through patient (or family/caregiver) education during the discharge process are essential in transitioning care responsibility over to the patient or caregiver. One method that can be used to confirm that a patient understands what they need to know from the health information they receive (both written and verbal) is "teach-back." With "teach-back," patient understanding is confirmed when they are able to explain information back to the individual providing discharge instructions. Figure 5 provides a visual explanation of how "teach-back" is used to confirm patient understanding.

Figure 5. Teach-Back: Closing the Loop



Schillinger et al. (2003)

Following surgery, patients, particularly those who underwent general anesthesia, may have more difficulty understanding discharge instructions. Additionally, health literacy—the degree to which individuals have the capacity to obtain, process, and understand basic health information to make informed decisions about healthcare—can have an impact on a patient's (or caregiver's) understanding of discharge instructions. In the United States, more than 36% of the adult population (approximately 80 million people) has poor health literacy. Taking steps to improve communication and patient understanding as it relates to health literacy can both minimize the risk that a patient will not understand the health information received and lead to better health outcomes. Research suggests that clear communication practices and removal of literacy-related barriers will improve care for all patients regardless of their level of health literacy (DeWalt et al., 2010). ASCs should ensure that systems are in place to promote better understanding for all patients, not simply those with low health literacy.

ASCs can adopt approaches to support clear communication with all patients for improved understanding of discharge instructions. Use of the following strategies supports patient understanding, ensuring they are able to act on the health information they receive.

Recommendation

Ensure your ASC's discharge process provides the patient with the necessary information to effectively manage their own care at home and confirms the patient's understanding of provided information.

Implementation Strategies

- **Provide postoperative information using objective parameters**
  Eliminate language or decision points that can be subjectively interpreted by patients. For example, provide patients with a pain scale similar to what is used in the ASC prior to discharge. An objective pain scale will help eliminate ambiguity when communicating with physicians, interpreting postoperative pain and timeframes for pain medications, or seeking additional care.
- **Confirm patient understanding when discharge instructions are given**
  Use methods such as "teach-back" to confirm that the patient easily understands what they need to know from the health information and materials. Patient understanding is confirmed when they explain it back to you (see Figure 5).
  Teach-Back, Agency for Healthcare Research and Quality
- **Evaluate discharge instructions and other health information materials to ensure they are easy to understand and act upon**
  Healthcare providers rely heavily on print materials to communicate with patients. Many health-related documents are complex and difficult for patients to understand.
  Health Literacy: Checklist for Creating or Evaluating Materials, ECRI Institute
- **Use plain, non-medical language**
  Most patients do not understand the medical jargon used by providers. Incorporate the use of plain language into communication so patients are more likely to understand.
  Plain Language Thesaurus for Health Communications, Centers for Disease Control and Prevention
- **Determine readability of heath information material**
  Most adults read at an eighth-grade level and 20% of the population reads at or below a fifth-grade level; however, most healthcare materials are at a tenth-grade level.
  Text Readability Consensus Calculator, Readability Formulas

Adverse Event Report Example: Surgical or Other Invasive Procedure

This example is based on an actual report received by the Commission and is a particularly strong example of effective system-level action plans (highlighted below). Report content has been modified to maintain confidentiality.

Complete account: A 63 year old male with iron deficient anemia and heme positive stools was seen in clinic and scheduled for an EGD and colonsocopy. Patient's medical history included dysrhythmias (pacer/implanted defibrillator), CHF, CAD, OSA, obesity, and difficult intubation. The patient was assessed in the clinic to be an ASA 3. Cardiac clearance was obtained from the cardiologist along with a defibrillator letter regarding magnet usage and reprogramming.

✓ Relevant clinical information

✓ System-level contributing factors directly associated with the event

✓Sequence of actions and relevant surrounding circumstances/conditions

During EGD patient began coughing. Suction was administered, pt. began to desat quickly. Airway assistance provided (chin lift, O2 up to 10 L via mask, nasal airway pieced). Rhythm was erratic. Pt. became blue. Ambu bag used to administer breaths with O2 at 15L/min. His defibrillator was noted to fire, he appeared to be in pulseless electrical activity. EMS was called and CPR started with good pulse. After multiple tries, the patient was intubated and transferred to hospital via emergent transport. Following a 3 day hospital stay, patient was discharged home.

✓ Relevant clinical information

Cause 1: The patient's medical history was extensive, with multiple cardiopulmonary comorbidities, and previous history of difficult intubation. According to the selection guidelines currently in place, the patient was eligible to have a procedure in ASC. However, a review by the Peer Review (PR) Committee and the Quality Assurance (QA) Committee, found that the patient selection criteria in place at the time of the event may not have been adequate.

✓ At least one relevant root cause identified

> *Through this investigation the facility was able to identify a system-level cause related to current process(es) and systems. This is critical for the development of strong action plans that are more likely to be effective in preventing the recurrence of similar events.*

Action Plan 1: The QA and PR committee submitted a summary review of the case and a list of recommendations to our board of directors. As a result, additional patient selection criteria has been instituted that should guide providers when choosing to schedule patients at this ASC vs. a hospital.

✓ Plans clearly link to the identified cause

Patients with any of the following conditions must be scheduled at the hospital:

✓ System-level solutions that decrease the likelihood of such events in the future

- Need for cardiac clearance (not passed, will consider requiring additional office visit once clearance is received, prior to procedure, undecided at this time)
- Implanted defibrillators
- History of difficult intubation
- Significant number of comorbidities, especially cardiopulmonary. No specific restrictions, but providers are encouraged to review history closely and use their clinical judgment.

Patients scheduling colonoscopies through open access program will be required to have an office visit if they have:

- Diagnosed sleep apnea
- BMI greater than 35

In addition, the board will meet with referring providers to discuss the updated patient selection criteria.

✓ Additional system-level action plans or action plans that fit the description of strong actions

As a result of our investigation and analysis, additional potential improvements were identified that, although not contributing factors to this event, were reviewed and corrective actions and/or policy updates have been put in place as appropriate. Management and staff have been informed and educated on the changes along with the new selection criteria.

This strong action plan focused on improvements to processes and systems that support a more robust patient selection process to decrees the likelihood of similar events in the future. While this action plan may not completely eliminate the vulnerability, it provides very strong controls (i.e., uses system fixes). An important component of this plan was transparency and communication of the new processes to all staff, regardless of whether their role was directly impacted by the change.

A consideration to strengthen this action plan further would be the addition of a required STOP-BANG sleep apnea test for all patients who will be undergoing general anesthesia. Given the number of undiagnosed cases of sleep apnea, this action has the potential to improve the safety of care for all patients, not just those who have a previous sleep apnea diagnosis. Once a STOP-BANG score is obtained, the Sleep Apnea Risk Guide to Assess Suitability for Outpatient Surgery Patients can guide the decision to determine appropriateness of outpatient surgery.

A Closer Look at
Healthcare-Associated Infection Events

Oregon ASCs recognize the negative impact a healthcare-associated infection (HAI) can have on the patients they serve and have made infection prevention a priority through participation in infection prevention education and training provided by the Commission. Since training offerings began in 2011, more than half of Oregon ASCs have sent representatives to ASC-specific infection control trainings or an infection prevention professional training; some have attended both. ASCs have also been participating in monthly infection prevention webinar trainings. Attendance at these events from ASCs across the state highlights the value that ASCs are placing on efforts to prevent HAIs.

As the second most frequently reported event type (31), healthcare-associated infections present a unique challenge in the ASC environment. According to the Centers for Medicare and Medicaid Services (CMS), infection control can be difficult because "patients remain in common areas, often for prolonged periods of time; surgical prep, recovery rooms and ORs are turned around quickly; patients with infections/communicable diseases may not be identified; and there is a risk of infection at the surgical site" (2011). In 2012, the majority of HAIs reported by Oregon ASCs were *Surgical-site infections* (90%) (see Table 13). The reasons why so few other infection types are reported by ASCs are unclear. Recent literature is mixed about whether infection rates are lower for ASCs compared to other care settings. However, according to a 2010 Journal of the American Medical Association (JAMA) article, "the incidence is almost certainly underreported; reflecting a sampling bias, patient selection, and poor compliance with voluntary reporting by surgeons of events (i.e., infections) that occur long after the ASC no longer has contact with the patient" (Barie).

Table 13. Reported *Healthcare-Associated Infection* Event Types, 2012

Type of HAI	Number	Percent of Events
Surgical site infection (SSI)	28	90%
Pneumonia	2	6%
Other type of infection	2	6%
Total HAIs	**31**	

Note: one event involved two different types of healthcare-associated infection.

Infections, particularly those at the surgical site, have the potential to cause serious harm (see Table 14). Fifty-two percent of the reported HAIs resulted in harm category F, where harm to the patient occurred and a significant intervention was necessary. Of those, 25% resulted in hospitalization, 63% required medication therapy, and 69% resulted in a surgical or procedural intervention.

Table 14. Significant Interventions in Harm F HAI Events, 2012 (n=16)

Significant Intervention	Number	Percent
Significant intervention: surgical/procedural intervention	11	69%
Significant intervention: medication therapy	10	63%
Significant intervention: hospital admission	4	25%

Identifying and Addressing the Causes of Infection

Of the 31 HAIs reported, 18 (61%) indicate the cause of infection to be unknown. Understanding why infections occur in the ASC setting can be challenging. A recent Center for Disease Control and Prevention (CDC) report published by JAMA provides insight into some of the causes of infections in the ASC setting and key infection control practice areas: hand hygiene, reprocessing (e.g., sterilization and high-level disinfection), environmental cleaning, use of single-dose medication vials, and handling of blood glucose monitoring equipment (Schaefer et al., 2010). Of the 68 ASCs assessed, two-thirds (67.6%) had at least one lapse in infection control (see Table 15). Oregon ASCs can look to these common lapses to inform infection prevention efforts.

Table 15. Common Lapses in ASC Infection Control (Schaefer et al., 2010)

Infection Control Lapses	Percent
Lapses in handling of blood glucose monitoring equipment	46.3%
Failure to adhere to recommended practices regarding reprocessing of equipment	28.4%
Using single-dose medication vials for more than one patient	28.1%
Lapses in adherence to hand hygiene or appropriate use of personal protective equipment (i.e., gloves)	19.4%
Failure to clean high-touch surfaces in patient care areas	18.8%

Note: The denominator varied slightly for each category, ranging from 62-68.

In 2012, the top contributing factor category for HAI events reported by Oregon ASCs was *Communication* (32%)—a majority of which (80%) were related to communication with the patient or the patient's family (see Table 16). ASCs heavily rely on patients (or their care representatives) to actively manage their own, often complex, care. Patients often struggle to understand self-care instructions following surgery, which can lead to adverse events such as HAIs. For additional information on strategies to improve patient understanding, see A Closer Look at Surgical or Other Invasive Procedure Events on page 14.

Table 16. Reported Contributing Factor Categories for *Healthcare-Associated Infection* Events, 2012

Contributing Factor Category	Number	Percent of Events
Communication	10	32%
Policy or procedure	4	13%
Patient management	3	10%
Patient	3	10%
Device or supply	2	6%
Human or environmental	2	6%
Organizational	2	6%

Understanding why HAIs might be occurring is the first step toward reduction and prevention. Without effective follow-up after an adverse event occurs (e.g., investigation, tracking and trending, use of audit tools to identify practice issues), causes to surgical site infection cannot be determined. For many ASCs, an inability to identify how the event happened was problematic in developing strong action plans to prevent future events. Given the uniqueness of the ASC environment, internal

investigation to determine causes of infections is critical in developing effective infection prevention and management programs. (The example adverse event report on page 27 highlights identification of relevant root causes—an element of reporting that drives the development of effective action plans.)

Recommendation

Evaluate your infection prevention and control systems to identify areas where lapses are occurring (use the common lapses from Table 15 to guide your process). Use what you learn to inform your improvement efforts.

Implementation Strategies

- **Identify areas of potential risk/weakness in your systems.** Use the tools available in the Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit.
  - ASC Environmental Rounds Survey Tool
  - Endoscope Reprocessing Competency Checklist
  - General Environmental Cleaning Checklist Audit Tool
  - Hand Hygiene Compliance Audit Tool
  - Instrument Cleaning, Wrapping/Packaging & Sterilization Competency Checklist
  - Operating/Procedure Room Observation Tool
  - Operating/Procedure Room Cleaning Checklist Audit Tool
  - Sterile Processing and High-level Disinfection Rounds Tool
- **Use occurrences of HAIs as an opportunity to investigate and uncover potential root causes to the infections.** Conducting deeper investigations when HAIs occur will aid in the development of system-level action plans to prevent similar events.
- **Track and trend your infection rates.** Tracking and trending infection rates over time will help uncover causes (Resource: National Healthcare Safety Network (NHSN) reporting (CDC))
- **Monitor for ongoing adherence.** Perform routing "spot checks" to ensure ongoing adherence to infection prevention and control standards of practice.
  - Perform spot checks randomly on a consistent basis (e.g., at least monthly)
  - Spot checks should gather data for at least one week to avoid a one-day Hawthorne effect and to expose as many staff as possible to the question[3]
- **Educate staff**. Ensure staff routinely receives current, best-practice information related to infection prevention and control in the ASC environment
  - Participate in infection prevention and control educational offerings provided by the Patient Safety Commission (see the Commission's educational offerings)

[3] The Hawthorne effect is the alteration of behavior by the subjects of a study because they are being observed.

Adverse Event Report Example: HAI

This example is based on an actual report received by the Commission and is a particularly strong example of effective cause identification (highlighted below). Report content has been modified to maintain confidentiality.

✓Sequence of actions and relevant surrounding circumstances/conditions

Complete account: On 3/8, a 64 yo male had a left knee repair without problems, some pain in PACU, responded to medication given. Patient was discharged home and received a F/U call @ 2200 (evening of procedure), per protocol. At 1 week postop, patient had a reddened wound with purulent drainage. Per records from [hospital], patient was admitted one-week postop with a superficial fluid collection. Infectious disease MD consulted and recommended irrigation & drainage of the superficial abscess given patient's elevated WBC and CRP. Purulent matter was expressible and cultures were done in the hospital on admission and repeated during the surgical I & D on 3/16, which found probable cellulitis; cultures were taken (no growth and a gram stain from swab showed normal skin flora and rare gram positive cocci in pairs). Infectious disease MD thought it was possibly a staphylococcus or streptococcus. Pt placed on 14-day course of oral antibiotics, responded well to medication, and recovered without future incidence.

✓ Relevant clinical information

✓ Relevant clinical information

No charting indicated wound-care instructions were provided to the patient. Also, the IC RN has been trying unsuccessfully to implement a policy that requires MDs have their patients take showers with Phisohex soap the night before, followed by clean clothes and clean sheets.

✓ System-level contributing factors directly associated with the event

Text includes information about the patient's course and the role of important contributing factors noted in the report's Contributing Factors section. This provides detail about context of care and decisions that help explain how the event occurred. Minor contributing factors can be noted in the Contributing Factors section only.

✓ At least one relevant root cause identified

Cause 1: Documentation is unclear regarding if the patient received any discharge self-care information. Currently, no process is in place to check for patient receipt and understanding of discharge instructions (written or verbal).

Appropriately identifies risk and its potential contributions to the event and focuses on the sytem of care rather than on individual performace.

Action Plan 1: Remind staff to chart all teaching and to verify patient understanding of discharge instructions.

✓ Plans clearly link to the identified cause

In general, changing practice through a focus on individual learning and memory is important but is a relatively weak approach. Developing a standardized process for providing and documenting discharge instructions to ensure patient understanding (e.g., using evidence-based methods such as teach-back or Ask Me 3) will have a higher likelihood of success.

✓ Presence of additional root or proximal causes

Cause 2: The patient did not receive instructions to shower with Chlorhexidine (followed by clean clothes and clean sheets) the night before surgery.

An even deeper cause would identify the reason why the patient did not receive appropriate pre-op instructions.

✓ System-level solutions that decrease the likelihood of such events in the future

Action Plan 2: Incorporate the Phisohex shower (followed by clean clothes and clean sheets) into the pre-op checklist provided to the patient. Also, incorporate into pre-op screening checklist the day of surgery to ensure adherence. This will be a requirement to proceed with scheduled surgery.

✓ Plans clearly link to the identified cause

Changes to practice such as adding a hard-stop are a strong plan.

A Closer Look at

Medication or Other Substance Events

Medication is a central element in the care of all ASC patients. The system through which a medication order moves is complex and has numerous process steps. Although these steps provide opportunities to ensure accuracy, as the number of medication orders and prescriptions increases and the complexity of the medication system grows, so does the risk of an adverse event. In 2012, medication-related events originated in several phases of the process—most frequently at administration (43%) (see Table 17 for a complete list).

Table 17. Number and Percent of *Medication or Other Substance* Events by Phase of Origin, 2012

Phase of Origin	Number	Percent of Events
Administering	6	43%
Preparing	2	14%
Other	2	14%
Prescribing/ordering	1	7%
Transcribing	1	7%
Unknown	1	7%
Monitoring	1	7%

Both internal and external opportunities exist to standardize and improve medication management systems. ASCs must work across internal and external units and disciplines to identify areas of concern and standardize processes. In particular, ASCs have an opportunity to strengthen systems to support staff in accurate identification and verification of medications and doses prior to administration.

In 2012, medication-related events were the third most frequently reported adverse events by ASCs, with 14 *Medication or other substance* reports submitted (see Table 18). The 14 reports, containing 16 medication events, described six different types of medication events. A majority (93%) of the medication events were low or no harm events, which offer an opportunity for ASCs to strengthen their systems to prevent potentially serious medication events from occurring.

Table 18. Number and Percent of Reported *Medication or Other Substance* Event Types, 2012

Medication or Other Substance Event Types	Number	Percent of Events
Incorrect dose	4	29%
Incorrect medication or substance	4	29%
Allergic reaction due to unknown allergy	3	21%
Medication or other substance contraindicated	2	14%
Adverse reaction not due to allergy or known contraindication	1	7%
Incorrect/incomplete labeling	1	7%
Medication or other substance omitted	1	7%

Several opportunities exist for ASCs to improve medication administration in order to avoid patient harm due to *Incorrect dose* and *Incorrect medication*. Seventy-five percent of the *Incorrect dose*

events involved high-alert medications—medications that pose greater risk to patients if used incorrectly. All of the *Incorrect medication or substance* events involved intravenous or ophthalmic medications that were, in many cases, prepared prior to the surgery/procedure by one individual and administered by another. This division of labor can be particularly problematic with similar looking products or in cases where multiple doses or variations of a medication (e.g., medication with and without additives) are kept in stock. Strong systems are needed to verify that the appropriate medication is given at the time of administration. The following sections provide more information on high-alert medication events and opportunities to strengthen medication administration.

High-Alert Medication Resources

Institute for Safe Medication Practices
(ISMP) High-alert Medication Lists:

- Institutional and Inpatient Healthcare Settings
- Community/Ambulatory Healthcare
- Consumer Leaflets

The Joint Commission

- Standards Sampler for Ambulatory Surgery Centers (ASCs)

High-Alert Medications

High-alert medications—medications that pose greater risk to patients if used incorrectly—were involved in 6 of the 16 *Medication or other substance* events. These medications included opioid narcotics (fentanyl, hydrocodone), an anesthetic agent (diprivan), an antiarrhythmic (lidocaine), a moderate sedation agent (versed), and one other high-alert medication (bupivacaine). Of the events involving high-alert medications, three were *Incorrect dose* events (in each case, the patient received a higher dose of medication than had been prescribed), one was an *Incorrect medication* event, and two were *Allergic reaction due to unknown allergy* events.

The Joint Commission provides standards for ASCs related to performance expectations and/or structures or processes that must be in place in order for an organization to provide safe, high-quality care. To meet the 2010 Joint Commission standard for management of high-alert medications (*Elements of Performance for MM.01.01.03)*, an ASC must:

- Identify, in writing, its high-alert and hazardous medications
- Have a process for managing high-alert medications
- Implement its process for managing high-alert and hazardous medications
- Minimize risks associated with managing hazardous medications

Additional information is available in the Joint Commission's Comprehensive Accreditation Manual for Ambulatory Care (CAMAC).

Strengthening Systems for Medication Safety

Most of the medication events submitted in 2012 stemmed from similar issues: products with similar names or packaging, labeling issues (e.g., not labeled, incorrectly labeled, similar labels), and lack of confirmation of medication and dose prior to administration. Because of the similarities in

why medication events occur, many of the same system-level improvement strategies can have a positive impact on reducing medication events across the board.

Goal three of the Joint Commission's National Patient Safety Goals (NPSG) focuses on improving the safety of using medications (2012). Specifically, NPSG.03.04.01 provides strategies that are applicable to ASCs in perioperative and other procedural settings, both on and off the sterile field. The following includes a selection from the *Elements of Performance* for NPSG.03.04.01 that is applicable to the types of medication events reported by ASCs in 2012:

- Label medications and solutions that are not immediately administered
- Label any medication or solution that is transferred from the original packaging to another container. Labels should include the following:
  - Medication name
  - Strength
  - Quantity
  - Diluent and volume (if not apparent from the container)
  - Expiration date when not used within 24 hours
- Verify all medication or solution labels both verbally and visually. Verification is done by two individuals qualified to participate in the procedure whenever the person preparing the medication or solution is not the person who will be administering it.
- Label each medication or solution as soon as it is prepared, unless it is immediately administered.

ASCs can strengthen their medication systems through implementation of evidence-based strategies to prevent recurrence. In 2012, many ASCs developed strong, system-level action plans that are worthy of consideration by other ASCs looking to improve their medication system. Action plans of note included:

- Instituted a medication verification process with the administering provider
- Removed all multi-dose vials. The formulating pharmacy now provides pre-filled, labeled, single-use vials.
- Converted to using the decimal system for taking all verbal orders (e.g., saying “0.5 mg” instead of “one half mg”)
- Listed generic names in addition to brand name on all medication labels

Some action plans are stronger than others. The strongest action plans are those that make system-level changes to prevent the recurrence of adverse events. A number of action plans involved education regarding appropriate documentation, protocols, and practices. While education is an essential element of patient safety efforts, education alone is not an adequate response to an adverse event because it is an individual-level action, not a system-level action. Education is an important element that allows standardization of processes; however, education will only be effective when it occurs in conjunction with monitoring to reinforce practice and maintain accountability.

Recommendation

Strengthen medication systems to ensure each patient receives the correct medication in the correct dose every time a medication is administered.

Implementation Strategies

- **Require labels.** Label all medications, medication containers or other substances (e.g., solutions, chemicals and reagents) on and off the sterile field. Avoid interruptions and distractions during the labeling process and while dispensing medications. Make labeling easy for staff by providing labeling supplies for procedures and in other areas where medications are prepared (e.g., sterile markers, blank labels, and preprinted labels).
- **Verify medications and labels.** Visually and verbally verify all medications (i.e., medication name, strength, dosage, and expiration date) upon receipt from the circulating nurse (or similar). When passing a medication to the individual who will be administering it, visually and verbally confirm the medication, strength, and dose by reading the label aloud.
- **Differentiate look-alike and sound-alike medications or other substances.** If medication or other substance names or packaging are similar, use tall man lettering (e.g., EPINEPHrine) on the labels to differentiate them, or highlight or circle the distinguishing information on the label.
- **Storage of medications or other substances.** Store medications safely with consideration given to separate look-alike and sound-alike products. Label storage areas with both the mediation's generic and brand names. This includes separating by generic name and packaging.
- **Standardize medications or other substances.** Standardize and minimize, to the extent possible, the variety of strengths and concentrations of medications available.

(Association of periOperative Registered Nurses, 2008)
(Grissinger & Dabliz, 2011)

Adverse Event Report Example: Medication

This example is based on an actual report received by the Commission and is a particularly strong example of effective system-level action plans (highlighted below). Report content has been modified to maintain confidentiality.

Complete account: 69 year old female was having a left eye cataract removal surgery. It is our policy to mix several of the eye medications into a slurry (antibiotics, dilating meds, and numbing meds). The nurse who prepared this solution is relatively new. She did use the recipe of ordered medication; however, due to generic names that varied from the drug named in the recipe, she did not put in proparacaine (numbing meds). The slurry of medications was prepared and a pledget inserted in patient eye without error having been realized. Following administration, it was noticed that the slurry was unlabeled and the proparacaine was absent from the container (the slurry contents are kept in the container). The patient was given a dose of the proparacaine and the procedure was completed without incident. The slurry mixture was discarded and redone using the correct drugs in the correct dosing amounts.

✓ Sequence of actions and relevant surrounding circumstances/conditions

✓ System-level contributing factors directly associated with the event

✓ Relevant clinical information

Cause 1: We order medication from providers that vary with the use of generic vs. brand names of drugs.

✓ At least one relevant root cause identified

Action Plan 1: We updated the recipe for the "slurry" mixture to include a listing of all the generic names of each medication. This should help eliminate any confusion. Nursing staff confirmed that this was very helpful.

✓ System-level solutions that decrease the likelihood of such events in the future

✓ Plans clearly link to the identified cause

This action plan appropriately identifies potential improvements in processes or systems rather than focusing on individual performance. Action plans that are directed toward individual-level changes have little chance of making lasting improvements.

Cause 2: The slurry mixture was unlabeled and the contents were not verified prior to administration.

✓ Presence of additional root or proximal causes

Action Plan 2: Because the slurry mixture recipe does not change, pre-printed labels are now available in the preparation area. A verification process has now been implemented prior to administration to visually and verbal verify all medications.

✓ Additional system-level action plans or action plans that fit the description of strong actions

By eliminating one opportunity for error by preprinting labels, staff are able to easily label mixtures. Adding a verification process serves as another check-point to ensure the patient receives the correct medication; the process should include the correct dose and strength and an additional verification point should be implemented when the medication is received from the circulating nurse who mixed the medication.

An opportunity exists to further reduce the possibility of a patient receiving the incorrect mixture by finding a pharmacy that can provide premixed slurry.

Recognition Targets

The Oregon Patient Safety Commission has established recognition targets to guide healthcare organizations participating in the Patient Safety Reporting Program. Targets are designed to change each year as organizations build their reporting programs to meet the State of Oregon's reporting requirements (Oregon Revised Statute 442.820-442.835, Oregon Administrative Rules 325) (see Table 19). Recognition targets are also designed to ensure that the Commission receives enough adverse event reports to build a strong database for learning and to recognize healthcare organizations for their transparency efforts and commitment to patient safety.

Each year, the Commission identifies leading participants and issues awards to the top performers based on established recognition targets. The Commission's website identifies all ASCs that meet or exceed recognition targets. Recognition targets focus on the quantity, quality, and timeliness of reports submitted.

Table 19. 2012 ASC Recognition Targets

Quantity	Four or more
Quality	75% meet acceptable quality criteria
Timeliness	75% submitted within 45 days

For more information about the 2013 targets and the criteria for meeting or exceeding those targets, see the *Patient Safety Reporting Program 2013 Recognition Targets*.

Quantity

In 2011, the Commission established annual quantity targets for the first time. The targets are designed to increase the number of reports submitted each year to ensure that the Commission has enough adverse event reports to build a strong database for learning, and to recognize healthcare organizations for their transparency efforts. The Commission measures quantity as the number of reports submitted by a reporting program participant. The quantity target for 2012 was four reports per participating ASC.

Oregon ASCs submitted 177 adverse event reports in 2012. For the 48% of ASC program participants that reported 2012 events, the median number of reports per facility was 2.5 and with a range of 1–56. Although many ASCs are working to meet the Commission's quantity targets, these numbers illustrate that, while adverse events are occurring in ASCs, many organizations are not reporting those events.

Quality

For ASCs, 2012 was the first year that report quality was incorporated into the annual recognition targets. Although the quality criteria has always been a part of the reporting program, the Commission recognizes that facilities need time to build reporting expertise and sophistication and developed the measurement system with this in mind. For 2012, the ASC quality target requires that at least 75% of submitted reports meet the quality criteria. The quality of submitted adverse

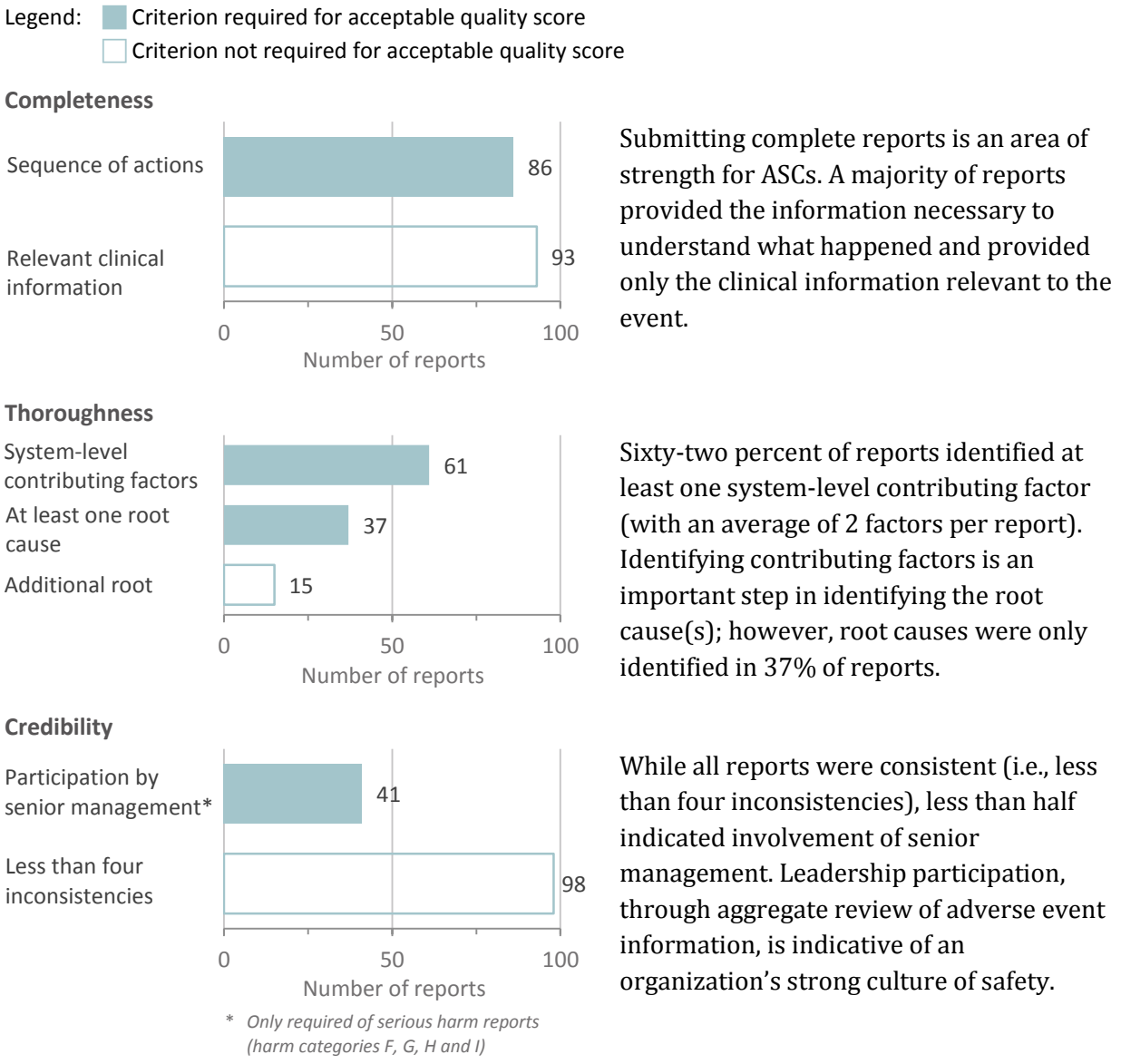
event reports are evaluated by the Commission using four Joint Commission criteria to determine if reports meet acceptable quality criteria: complete, thorough, credible, and having effective action plan(s).

When the Commission moved to an online reporting system in 2012, facilities communicated a need for increased transparency and support around how the Commission evaluates report quality. In response, the Commission integrated a highly transparent quality scoring tool into the Patient Safety Reporting Program's (PSRP) online reporting tool (see Appendix III). While the quality criteria remain the same, participants are required to earn specific points in each of the four criteria. Participants can now view their overall scores, how the points were attributed, and, when relevant, receive suggestions from the Commission's patient safety consultant around how to improve.

In 2012, only 23% of the reports submitted by ASCs were determined to be of acceptable quality. The Commission hopes that ASCs will use the feedback provided by the new transparent quality scoring system to inform their investigation process; therefore, the quality target for 2013 will remain the same as 2012—75% of reports are of acceptable quality.

Figure 6 shows the quality criteria breakdown for 2012 reports and indicates the number of submitted reports that met individual quality measures. 2012 quality criteria data is limited (includes 98/177 reports) and does not include reports submitted prior to May 1, 2012 (the publication date of the 2012 recognition targets), harm category A events, and significant harm event reports (harm category F-I) that did not provide enough information to correctly ascribe points.

Figure 6. Number of Reports that Met Quality Measures by Quality Criteria, 2012 (n=98)



Submitting complete reports is an area of strength for ASCs. A majority of reports provided the information necessary to understand what happened and provided only the clinical information relevant to the event.

Sixty-two percent of reports identified at least one system-level contributing factor (with an average of 2 factors per report). Identifying contributing factors is an important step in identifying the root cause(s); however, root causes were only identified in 37% of reports.

While all reports were consistent (i.e., less than four inconsistencies), less than half indicated involvement of senior management. Leadership participation, through aggregate review of adverse event information, is indicative of an organization's strong culture of safety.

Less than half of reports identified potential improvements in processes or systems that may decrease the likelihood of such events in the future. This lack of system-level action plans may have stemmed from investigations that did not identify the root cause(s) necessary for effective action plan development.

Quality Focus Areas

Identifying adverse events is only the first step in improving patient safety. Understanding why adverse events occur through identification of root causes and the development of effective action plans is critical. The majority of reports that were determined to be "Not Acceptable" fell short in three key areas necessary for a strong investigation and an acceptable quality report:

- System-level contributing factors directly associated with the event
- At least one relevant root cause identified
- A system-level action plan that decreases the likelihood of such events in the future

High-quality reports play a vital role in the success of the Patient Safety Reporting Program (PSRP). Reports that are complete, thorough, credible, and contain strong action plans have the greatest potential to contribute to shared learning across healthcare organizations. The PSRP reporting form is a tool that ASCs can use to guide event investigations and ensure that in-depth analysis provides valuable feedback for improving systems and preventing future adverse events.

Identification of System-Level Contributing Factors

Typically, multiple system-level contributing factors can be identified for a single adverse event if a thorough investigation is conducted. Contributing factors, as defined by the Agency for Healthcare Research and Quality, are circumstances that are retrospectively determined to have increased the likelihood of an adverse event. Contributing factors are generally external to the patient and frequently relate to the physical environment or to the care delivery system. When ASCs identify contributing factors, they are identifying opportunities to make improvements that create a more reliable system of care. This annual summary provides three adverse event report examples that contain thorough investigations, identify system-level contributing factors, and can serve as a model for ASCs who have not received full credit for the thoroughness of their reports (see pages 21, 27, and 32). Several useful strategies are available to help ASCs identify system-level contributing factors (see box).

Strategies for

Identifying System-Level Contributing Factors

- Identify the factors most directly associated with the event and the related process(es) and systems
- Do not focus on individual performance or the perception of patient compliance
- Seek to identify risks and their potential contributions to the event

See Appendix III for additional information on identifying root causes and submitting a thorough report

Identification of a Relevant Root Cause

Adverse event reports should identify at least one relevant root cause—the most basic reason for why an adverse event occurred. Many reports uncover only surface-level contributing factors and not root causes. Failure to identify the relevant root cause(s) of an adverse event most often occurs because an ASC prematurely ends their investigation and does not examine specific contributing factors more thoroughly. Once contributing factors have been identified, an organization must

continue the investigation until the root cause(s) have clearly been identified (see box). Ultimately, a successful investigative process can provide meaningful information about root causes that can be translated into ongoing system-level improvements.

Strategies for
Identifying Relevant Root Causes

- **Use the Five Whys** – To uncover the contributing factors and root causes of an event, continue to ask "why" until it is no longer reasonable.
- **Clearly show a cause and effect relationship** – Ask, if you eliminate this cause, will you minimize/prevent future events?
- **Identify the preceding causes, NOT the "human error" or potential policy/procedure violations** – Seek to understand why a "human error" or mistake was made or why a policy/procedure was not followed.

See Appendix III for additional information on identifying root causes and submitting a thorough report

System-Level Action Plans

Action plans outline the steps an organization will take to prevent future adverse events and are a critical component of the root cause analysis. Many action plans do not effectively address the root cause(s) of an adverse event because they are focused on individual-level actions and not system-level actions. Strong, system-level action plans have a clear link to an event's root cause(s) and contributing factors, are easily understood, and are more likely to be successful in achieving system-level changes (see box). Stronger actions do not depend on staff to remember to do the right thing. Although strong actions may not totally eliminate the vulnerability, they provide very strong controls (i.e., system fixes).

Strategies for
Developing Effective Action Plans

- Address the identified root cause(s)/contributing factors
- Focus on systems, not on individuals
- Be specific and concrete
- Include stronger actions, which are more likely to eliminate or greatly reduce the likelihood of an event

See Appendix III for additional information on identifying root causes and submitting a thorough report

Timeliness

After an adverse event, an immediate response is needed to collect full and reliable information on the circumstances surrounding the event. Timeliness is defined as the amount of time that passes between the date an event was discovered and the date a report is submitted to the Oregon Patient Safety Commission. The State of Oregon requires that ASCs submit a completed adverse event report within 45 calendar days of discovery of a reportable serious adverse event (Oregon

Administrative Rules, 325-025-0025(3) (2007)). This standard promotes timely responses to adverse events in effort to reduce delays and aid the development of plans to prevent future events.

For events that occurred in 2012, the average time between event discovery and report submission for all reports was 49 days, with a median of 32 days. Although the median does not reflect the wide range of discovery-to-submission time (0-271 days, including four outliers that were not submitted for more than eight months after the event was discovered), it does reflect the majority of reports submitted.

Of the reports submitted in 2012, 67 (39%) did not meet the state's timeliness standard (see Table 20). ASCs that met the state's timeliness standard (103 reports) took an average of 15 days from event discovery to submission—well under the 45 day requirement. However, ASCs that did not meet the timeliness standard took an average of 102 days—more than twice as long as the 45 day requirement.

Table 20. Number and Percent of Reports by Compliance with State Timeliness Standard and Average Number of Days between Discovery of Event and Submission, 2012

	Number	Percent (n=170)	Average Number of Days
Met State Standard (submitted report within 45 days of event discovery)	103	61%	15
Did Not Meet State Standard (submitted report more than 45 days after event discovery)	67	39%	102

Note: seven reports are not represented due to missing information or an exclusion based on extenuating circumstances as approved by the Commission.

In 2012, the Commission's recognition target for timeliness was for ASCs to submit 75% of all reports within 45 days of discovery. Over half of the ASCs (54%) met the timeliness target for 2012 (see Table 21).

Table 21. Number of Facilities that Achieved Timeliness Target, 2012

	Number of Facilities	Percent (n=26)
Met Target (75% or more of reports submitted within 45 days of event discovery)	14	54%
Did Not Meet Target (less than 75% of reports submitted within 45 days of event discovery)	12	46%

To better understand where timeliness delays are occurring, each phase in the reporting process was analyzed. The Commission collects four pieces of time-related data for adverse events regardless of harm category: date event occurred, date event was discovered, date review team completed their investigation and analysis, and date report was submitted. These data points provide important information on an ASC's patient safety processes and highlight several noteworthy phases in the reporting timeline:

- Event to discovery
- Discovery to review completion

- Review completion to report submission

Time between Event and Discovery

To some extent, the period between event and discovery reflects the robustness of an ASC's internal event identification and reporting system. If an ASC's patient safety culture is weak, providers and staff are less likely to report events or may delay the report. However, in some cases, a delay in discovery is a result of the nature of the event. For example, HAIs may not be discovered until follow-up contact is made with the patient. In the case of 2012 ASC reports, *Healthcare-associated infection* events had one of the longest time-frames between the events' occurrence to discovery (28.1 days). Other events are often discovered when an ASC conducts chart reviews or uses the Global Trigger Tool to identify events. The Commission recognizes the vigilance of ASCs in identifying these types of cases and does not include them in calculations of the time between event and discovery.

Time between Discovery and Review Completion

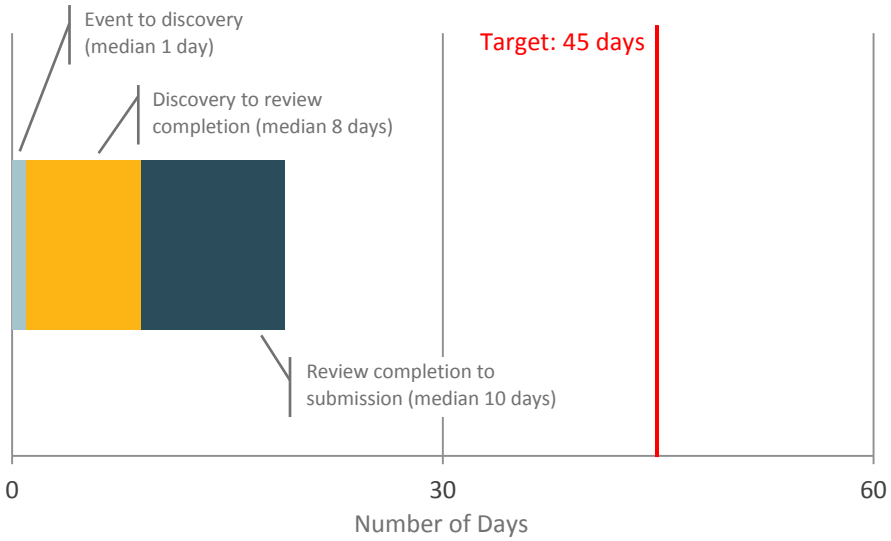
The period between discovery and review completion reflects the provider and staff commitment to patient safety as an aspect of their professional responsibilities. Difficulties in coordinating schedules or reluctance to participate in the reviews will lengthen this time. On rare occasions, the event is so complex and involves so many different departments that the investigation and review will take longer.

Prior to the release of the PSRP online reporting tool, ASCs were only required to report the review completion date for serious harm events. ASCs now report the review completion date for all events, regardless of harm category. Due to the change in reporting, 2012 timeliness data is limited (includes 47/177 reports) and does not include reports submitted prior to September 25, 2012 (the release of the PSRP online reporting tool). For the subset of reports that provided a completion date for their review and analysis process (n=47), the process took a median of 8 days to conduct and complete after the event was discovered.

Time between Review Completion and Submission

The time between review completion and submission reflects how well the ASC has integrated reporting into its patient safety processes. Once the review and analysis were complete, the median number of days ASCs took to submit adverse event reports to the Commission was 10 days (see Figure 7).

Figure 7. Median Days Spent from Event Discovery to Report Submission, 2012 (n=47)*



**The median represents the midpoint of all data points.*

Information presented in this annual summary is based on data submitted to the Commission through the adverse event reporting program for ASCs. While a great deal can be learned from the adverse events that occur, it is important to note that without true denominators (e.g., for the number of patients receiving services in ASCs, the number of specific surgical procedures, etc.) the data presented in this annual summary cannot be used to draw conclusions about all Oregon ASCs nor should it be compared to other healthcare settings. The Commission encourages ASCs to use reporting as a tool to monitor their performance over time in relation to specific patient safety goals.

References

Association of periOperative Registered Nurses. (2008). AORN Guidance Statement: Safe Medication Practices in Perioperative Settings across the Life Span. *AORN Journal*, 88(6): S115-S122.

Barie PS. (2010). Infection Control Practices in Ambulatory Surgical Centers. *Journal of the American Medical Association*, 303(22): 2295-2297.

Centers for Medicare and Medicaid Services (CMS). (2011). State Operations Manual Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers. CMS publication 42 C.F.R. § 416. Retrieved from http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html

DeWalt DA, Callahan LF, Hawk VH, Broucksou KA, Hink A, Rudd R, Brach C. (2010). Health Literacy Universal Precautions Toolkit. (Report No. 10-0046-EF). Rockville, MD: Agency for Healthcare Research and Quality.

Fitz-Henry J. (2011). The ASA Classification and Peri-Operative Risk. *Annals of the Royal College of Surgeons of England*, 93(3): 185-187.

Fleisher LA, Beckman JA, Brown KA, Calkins H, Chaikof EL, Fleischmann KE, Freeman WK,...Robb JF. (2007). ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery: Executive Summary: a Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American Heart Association*, 116: 1971-1996.

Fleisher LA, Pasternak LR, Lyles A. (2007). A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery. *Archives of Surgery*, 142(3): 263-8.

Grissinger M, Dabliz R. (2011). Ambulatory Surgery Facilities: A Comprehensive Review of Medication Error Reports in Pennsylvania. *Pennsylvania Patient Safety Advisory*, 8(3): 85-93.

Lermitte J, Chung F. (2005). Patient Selection in Ambulatory Surgery. *Current Opinion in Anaesthesiology*, 18: 598-602.

Melloni C. (2005). Morbidity and Mortality Related to Anesthesia Outside the Operating Room. *Minerva Anestesiologica*, 71(6): 325-34.

Pennsylvania Patient Safety Authority. (2005). Expecting the Unexpected: Ambulatory Surgical Facilities and Unanticipated Care. *Pennsylvania Patient Safety Advisory*, 2(3): 6-8.

Pennsylvania Patient Safety Authority. (2009). Patient Screening and Assessment in Ambulatory Surgical Facilities. *Pennsylvania Patient Safety Advisory*, 6(1): 3-9.

Schaefer M, Jhung M, Dahl M, Schillie S, Simpson C, Llata E,...Link-Gelles R. (2010). Infection Control Assessment of Ambulatory Surgical Centers. *Journal of the American Medical Asso*ciation, 303(22): 2273-2279.

Schillinger D, Piette J, Grumbach K, Wang F, Wilson C, Daher C,…Leong-Grotz K. (2003). Closing the Loop Physician Communication With Diabetic Patients Who Have Low Health Literacy. *Archives of Intern Medicine*, 163(1): 83-90.

Accreditation Association for Ambulatory Health Care Institute for Quality Improvement. (2012). Patient Safety Toolkit: Ambulatory Surgery and Obstructive Sleep Apnea. Skokie, Illinois: Accreditation Association for Ambulatory Health Care. Retrieved from http://www.aaahc.org/Documents/Institute/aaahc_workmat_11-8-12%20pdf.pdf

The Joint Commission. (2012). National Patient Safety Goals Effective January 1, 2013. Illinois: The Joint Commission. Retrieved from http://www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_HAP.pdf

Young T, Peppard PE, Gottlieb D. (2002). Epidemiology of Obstructive Sleep Apnea. *American Journal of Respiratory and Critical Care Medicine*, 165(8): 1217-1239.

Young T, Evans L, Finn L, Palta M. (1997). Estimation of the Clinically Diagnosed Proportion of Sleep Apnea Syndrome in Middle-Aged Men and Women. *Sleep*, 20(9): 705-706.

Resources

Culture of Safety

Patient Safety Primers: Safety Culture, Agency for Healthcare Research and Quality

Safety Briefings Tool, Institute for Healthcare Improvement

The Comprehensive Unit-based Safety Program (CUSP), Johns Hopkins Center for Innovation in Quality Patient Care

Using a Comprehensive Unit-based Safety Program to Prevent HAI, Agency for Healthcare Research and Quality

Using Healthcare Failure Mode and Effects Analysis, VA National Center for Patient Safety

Failure Mode and Effects Analysis Tool, Institute for Healthcare Improvement

HAI

Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit, Oregon Patient Safety Commission

National Healthcare Safety Network (NHSN), Centers for Disease Control and Prevention (CDC)

Medication or Other Substance

AORN Guidance Statement: Safe Medication Practices in Perioperative Settings across the Life Span, Association of periOperative Registered Nurses (AORN)

High-alert Medication List for Institutional and Inpatient Healthcare Settings, Institute for Safe Medication Practices

High-alert Medication List for Community/Ambulatory Healthcare, Institute for Safe Medication Practices

High-alert Medication List: Consumer Leaflets, Institute for Safe Medication Practices

National Patient Safety Goals (Goal 3), The Joint Commission

Standards Sampler for Ambulatory Surgery Centers (ASCs) (Element of Performance: MM.01.01.03), The Joint Commission

Statement on Preventing Harm from Oversedation in Adult Hospitalized Patients, Oregon Patient Safety Commission

Root Cause Analysis

NCPS Root Cause Analysis Tools, The VA National Center for Patient Safety (NCPS)

Five Whys, National Health Service Institute for Innovation and Improvement

Surgical or Other Invasive Procedures

Teach-Back, Agency for Healthcare Research and Quality

Health Literacy: Checklist for Creating or Evaluating Materials, The ECRI Institute

Patient Safety Toolkit: Ambulatory Surgery and Obstructive Sleep Apnea, The Accreditation Association for Ambulatory Health Care (AAAHC)

Plain Language Thesaurus for Health Communications, The Centers for Disease Control and Prevention

Text Readability Consensus Calculator, Readability Formulas

Appendix I: Reportable Adverse Events for ASCs

Ambulatory surgery center (ASC) participants are required to report:

a. Any unanticipated, usually preventable event that results in patient harm listed below
b. Any serious adverse events—events that result in patient death or serious physical injury[4]
c. Any of the thirteen events in **bold** regardless of patient harm

The Commission encourages participants to report all adverse events (including non-serious events) that may not be included in the "Reportable Adverse Events" list but that highlight a valuable patient safety lesson. If your ASC has an event that does not fit into one of the pre-defined categories, please select "Other" and provide a brief description.

Air embolism
Anesthesia
Aspiration
Blood or blood product (including hemolytic reactions)
Burn (unrelated to use or misuse of a device or product)
Care delay (including delay in treatment, diagnosis)
Contaminated drugs, devices, or biologics
Contaminated, wrong, or no gas given to patient
Deep vein thrombosis with or without pulmonary embolism
Device or medical/surgical supply (including use error)
Electric shock
Fall
Healthcare-associated infection (HAI) (**including surgical site infections up to 30 days postoperatively**)
Health information technology (HIT)
Irretrievable loss of an irreplaceable biological specimen
Medication or other substance (including hypoglycemia)
Restraint or bed rail related
Surgical or other invasive procedure →
Unintended retained foreign object
Other adverse events

Reportable surgical or other invasive procedure events include:

Incorrect patient
Incorrect procedure
Incorrect site or side
Intraoperative or immediately postoperative/ postprocedure death
Postop bleeding requiring return to operating room
Postop nausea requiring hospital admission
Unanticipated blood transfusion
Unplanned admission to hospital (within 48 hours of discharge)
Unplanned emergency department visit (within 48 hours of discharge)

[4] "Unanticipated, usually preventable" refers to adverse events that are caused by an issue of medical or patient management, rather than the underlying disease. "Serious physical injury" includes, but is not limited to, injuries that require a patient to be transferred to a higher level of care.

Appendix II: Comparison of Patient Safety Reporting Program (PSRP) Events, Administrative Rules Appendix A, Original Reporting Form, and NQF 2012 Update

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Air embolism	3C) Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Intravascular air embolism that occurred while being cared for in an ambulatory surgery center	2C) Product or device: Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.	
Anesthesia	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	PSRP event type added in 2012 to differentiate *Anesthesia* events from *Surgical or other invasive procedure* events
Aspiration	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	PSRP event type added in 2012 based on prior reporting patterns and to better align with other reporting segments
Blood or blood product (including hemolytic reactions)	4B) Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	Hemolytic reaction due to the administration of ABO-incompatible blood or blood pressure products	4B) Care management: Patient death or serious injury associated with unsafe administration of blood products	Appendix A defines this event as *Hemolytic reaction*; however, the PSRP accepts reports associated with any unsafe administration of blood products.
Burn (unrelated to use or misuse of a device or medical/surgical supply)	5C) Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility	Burn	5C) Environmental: Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	Appendix A defines this event as *Burns incurred from any source*; however, the PSRP focuses on burns not associated with a product or device. Burns associated with a product or device are collected under *Device or medical/ surgical supply* event *(including use error)*.
Care delay (including delay in treatment, diagnosis)	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	PSRP event category added in 2012 based on prior reporting patterns

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Contaminated drugs, devices or biologics	3A) Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	Contaminated drugs, devices, or biologics provided by the ambulatory surgery center	2A) Product or device: Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	--
Contaminated, wrong or no gas given to a patient	5B) Any incident in which a line designated for oxygen, or other gas to be delivered to a patient, contains the wrong gas or is contaminated by toxic substances	Line with the wrong gas or toxic substances delivered to patient	5B) Environmental: Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances	PSRP updated in 2012 to reflect NQF 2011 Update; added *No gas* Appendix A defines this event as *Wrong or contaminated gas* only; however, the PSRP also accepts reports of no gas. Reportable regardless of patient harm
Deep vein thrombosis with or without pulmonary embolism	1E) Deep vein thrombosis with or without pulmonary embolism	Deep vein thrombosis with or without pulmonary embolism	--	Reportable regardless of patient harm Addressed in NQF's list of recommended safe practices (see ***Error! Reference source not found.*** or link)
Device or medical/surgical supply (including use error)	3B) Patient death or serious physical injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended, or is difficult to use as intended	Equipment/device malfunction or misuse	2B) Product or device: Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	PSRP updated in 2012 to clarify what is included in this event type
Electric shock	5A) Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility	Electric shock	5A) Environmental: Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting	
Fall	5D) Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility	Fall	4E) Care management: Patient death or serious injury associated with a fall while being cared for in a healthcare setting	Addressed in NQF's list of recommended safe practices (see ***Error! Reference source not found.*** or link)

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Healthcare-associated infection (HAI) (including surgical site infections up to 30 days postoperatively)	2A) Surgical site infection up to 30 days postoperatively	Surgical infection up to 30 days postoperatively	--	*CLABSI*, *CAUTI*, *SSIs*, and *Care of the ventilated patient* are addressed in NQF's list of recommended safe practices (see ***Error! Reference ource not found.*** for link) SSI: Reportable regardless of patient harm
Health Information Technology (HIT)	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Equipment/device malfunction or misuse	--	Appendix A does not include *HIT*; however, the PSRP accepts reports of *HIT* events in order to be more inclusive and align with AHRQ Common Formats
Irretrievable loss of an irreplaceable biological specimen	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	4H) Care management: Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen	PSRP event type added in 2012 to reflect NQF 2011 Update
Medication or other substance	4A) Patient death or serious physical injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Medication error	4A) Care management: patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Contrast media-induced renal failure, anticoagulation therapy, medication reconciliation, and glycemic control addressed in NQF's list of recommended safe practices (see ***Error! Reference source not ound.*** for link)
Medication or other substance event	4C) Patient death or serious physical injury associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	Hypoglycemia	4A) Care management: patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	As of 2011, NQF considers *Hypoglycemia* to be the result of a medication error; related events should be reported to the PSRP as a *Medication event*. *Glycemic control* is also addressed in NQF's list of recommended safe practices (see ***Error! Reference ource not found.*** for link)

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Restraint or bedrail related	5E) Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility	Restraints or bedrails	5D) Environmental: Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	--
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1C) Any blood product transfusion	Any blood product transfusion	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved unplanned transfusion into a secondary question—"Type of surgical or other invasive procedure event" Reportable regardless of patient harm
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1G) Death postoperatively directly attributable to surgical procedure	Postoperative death directly attributable to surgical procedure	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*: report as *Intraoperative or immediately postoperative/postprocedure death* in the secondary question *Type of surgical or other invasive procedure event*, and mark "yes" in response to the question "Was the patient's death directly attributable to the surgery or procedure?" Reportable regardless of patient harm

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1D) Immediate postoperative bleeding that requires surgical treatment in the operating room (before discharge)	Immediate postoperative bleeding requiring surgical treatment (before discharge)	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Postop bleeding requiring return to operating room* into a secondary question—"Type of surgical or other invasive procedure event," Reportable regardless of patient harm
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1H) Intraoperative or immediately postoperative death	Intraoperative or immediate post-operative death	1E) Surgical: Intraoperative or immediately postoperative/ post-procedure death in an ASA Class 1 patient	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; report as *Intraoperative or immediately postoperative/postprocedure death* in the secondary question "Type of surgical or other invasive procedure event," and mark "no" in response to the question "Was the patient's death directly attributable to the surgery or procedure?" Reportable regardless of patient harm
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1B) Postoperative nausea that requires hospital admission	Postoperative nausea requiring hospital admission	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Postop nausea requiring hospital admission* into a secondary question—"Type of surgical or other invasive procedure event" Reportable regardless of patient harm

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1I) Surgery performed on the wrong body part	Surgery performed on the wrong body part	1A) Surgical: Surgery or other invasive procedure performed on the wrong site	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Incorrect patient*, *Incorrect site or side*, *Incorrect procedure*, and *Intraoperative or immediately postoperative death in an ASA Class I patient* into a secondary question—"Type of surgical or other invasive procedure event" Addressed in NQF's list of recommended safe practices (see references for link) Reportable regardless of patient harm
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1J) Surgery performed on the wrong patient	Surgery performed on the wrong patient	1B) Surgical: Surgery or other invasive procedure performed on the wrong patient	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Incorrect patient*, *Incorrect site or side*, *Incorrect procedure*, and *Intraoperative or immediately postoperative death in an ASA Class I patient* into a secondary question—"Type of surgical or other invasive procedure event" Addressed in NQF's list of recommended safe practices (see references for link) Reportable regardless of patient harm

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1A) Unplanned admission to the hospital within 48 hours of discharge from an ambulatory surgery center	Unplanned admission to the hospital within 48 hours of discharge from an ambulatory surgery center	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved admission to the hospital within 48 hours of discharge from an ambulatory surgery center into a secondary question—"Type of surgical or other invasive procedure event" Addressed in NQF's list of recommended safe practices (see references for link) Reportable regardless of patient harm
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1A) Unplanned emergency department visit within 48 hours of discharge from an ambulatory surgery center	Unplanned emergency department admission within 48 hours of discharge from an ambulatory surgery center	--	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Unplanned emergency department visit within 48 hours of discharge from an ambulatory surgery center* into a secondary question—"Type of surgical or other invasive procedure event" Addressed in NQF's list of recommended safe practices (see references for link) Reportable regardless of patient harm

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including unplanned admission to hospital, unplanned emergency department visit, incorrect site, incorrect patient, incorrect procedure, etc.)	1K) Wrong surgical procedure performed on a patient	Wrong surgical procedure performed on patient	1C) Surgical: Wrong surgical or other invasive procedure performed on a patient	PSRP updated in 2012 to reflect NQF's category *Surgical or other invasive procedure*; moved *Incorrect patient*, *Incorrect site or side*, *Incorrect procedure*, and *Intraoperative or immediately postoperative death* into a secondary question—"Type of surgical or other invasive procedure event" Addressed in NQF's list of recommended safe practices (see references for link) Reportable regardless of patient harm
Unintended retained foreign object	1F) Unplanned retention of a foreign object in a patient after surgery or other procedure	Unplanned retention of a foreign object in patient	1D) Surgical: Unintended retention of a foreign object in a patient after surgery or other invasive procedure	PSRP updated in 2012 to reflect NQF 2011 Update; definition includes non-surgical retained foreign objects, which would otherwise be covered by Appendix A's *Other* category
Other	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	--

Appendix III: Quality Criteria

Reports submitted to the Commission are evaluated for acceptable quality by program consultants with the intent of supporting healthcare organizations in conducting in-depth investigations that focus on prevention of future events. Acceptable quality is determined using four criteria: complete, thorough, credible, and having effective action plan(s) (as outlined in OAR 325-010-0035). An asterisk (*) indicates a quality measure that is required for a report to meet the acceptable quality criteria.

Complete

Report provides all information pertinent to understanding what happened

Characteristics of Complete Investigations	Quality Measures	Applicable Report Information
• Provides information pertinent to understanding what happened • Provides only clinical information that is relevant to understanding the event	☐ Sequence of actions and relevant surrounding circumstances/ conditions* ☐ Relevant clinical information	**All Tabs** • Pertinent fields **Summary Tab** • Complete account

Tips for Submitting a Complete Report

In the Summary Tab's *Complete account*, summarize the sequence of activities and circumstances leading up to the event in a way that someone unfamiliar with the event could easily understand. Include decisions and other rationale that influenced the occurrence of the event.

Thorough

Report represents an analysis that considered system-level contributing factors and identified root cause(s)

Characteristics of Thorough Investigations	Quality Measures	Applicable Report Information
• Identifies the factors most directly associated with the event and the related process(es) and systems • Does not focus on individual performance • Identifies risks and their potential contributions to the event • Analyzes the underlying systems through a series of why questions to determine where changes might reduce risk	☐ System-level contributing factors directly associated with the event* ☐ At least one relevant root cause identified* ☐ Presence of additional root or proximal causes	**Contributing Factors Tab** • All **Summary Tab** • *Complete account*† • Cause(s) • Is this a root cause?

† Although the quality measures for a thorough report are not specifically found in the *Complete account*, the *Complete account* may include information that supports or explains identified contributing factors and causes.

Tips for Submitting a Thorough Report

- **Use the Five Whys** – Continue to ask "why"—until it is no longer reasonable—to uncover the contributing factors and root causes of an event.
- **Clearly show a cause and effect relationship** – Ask, if you eliminate this cause, will you minimize/prevent future events?

- **Identify the preceding causes, NOT the "human error" or potential policy/procedure violations** – Seek to understand why a "human error" or mistake was made or why a policy/procedure was not followed.

Credible

Report contains evidence that the investigation included leadership participation and was internally consistent

Characteristics of Credible Investigations	Quality Measures	Applicable Report Information
• Includes participation by leadership and by the individuals most closely involved in the processes and systems • Is internally consistent; i.e., does not contradict itself or leave obvious questions unanswered	☐ Participation by senior management either through notification of individual/aggregate events, as a member of review team, or in a post-review briefing (only for serious harm events; i.e., F, G, H, and I) ☐ Less than four inconsistencies*	**Review Tab** • Who was notified of the event? • Did the review and analysis team have a post-analysis briefing with senior management? **Summary Tab** • All

Tips for Submitting a Credible Report

- Leadership review of aggregate information satisfies the criteria for participation by senior management (e.g., review of aggregate quarterly event data or report)
- Ensure there is a clear and logical connection between the major components of the report; e.g., the *Complete account*, *Contributing factors*, *Causes*, and *Action plans*

Action Plans

Report includes system-level plans that address identified causes and are likely to decrease the risk of future occurrence

Characteristics of Effective Action Plans	Quality Measures	Applicable Report Information
• Identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future • Does not focus on individual performance	☐ A system-level action plan that decreases the likelihood of such events in the future*[†] ☐ Additional system-level action plans or action plans that fit the description of stronger actions[†] ☐ Plans clearly link to the identified cause	**Summary Tab** • *Cause(s)*[††] • Action plan(s)

There may be cases where no strong action plans are found since the root cause(s) could not be found. If the report shows a thorough investigation then points may be awarded for action plans.

[†] Based on the VA National Center for Patient Safety's root cause analysis tools, *Recommended Hierarchy of Actions*. The VA categorizes action plans into three categories based on their likelihood of reducing vulnerability: stronger, intermediate, and weaker. http://www.patientsafety.gov/CogAids/RCA/index.html#page-14

[††] Although the quality measures for action plans are not specifically found in the *Cause(s)*, the link between action plans and identified causes will be evaluated.

Tips for Developing an Effective Action

Develop action plans that:

- Address the identified root cause(s)/contributing factors
- Focus on systems, not on individuals
- Are specific and concrete
- Include stronger actions, which are more likely to eliminate or greatly reduce the likelihood of an event. Stronger actions do not depend on staff to remember to do the right thing. Although strong actions may not totally eliminate the vulnerability, they provide very strong controls (i.e., system fixes).

Stronger, Intermediate, and Weaker Action Plans

Stronger Action Plans	Actions that do not depend on staff to remember to do the right thing; the action may not totally eliminate the vulnerability but provides very strong controls (uses system fixes)	• Simplify the process and remove unnecessary steps • Standardize equipment or process • Tangible involvement and action by leadership in support of patient safety • Forcing functions† • New device with usability testing before purchasing • Architectural/physical plant changes
Intermediate Action Plans	Actions are somewhat dependent on staff remembering to do the right thing, but they provide tools to help staff to remember or to promote clear communication	• Increase in staffing/decrease workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look-alikes and sound-alikes • Read back • Independent verification • Enhanced documentation/communication • Redundancy
Weaker Action Plans	Actions depend on staff to remember their training or remember what is written in the policy	• Training/education • Additional study/analysis • New policy/memorandum • Double checks • Warnings and labels

Weaker action plans alone DO NOT meet the acceptable quality criteria

The VA National Center for Patient Safety's root cause analysis tools. Available at: http://www.patientsafety.gov/CogAids/RCA/index.html#page-14

† An aspect of a design that prevents an unintended or undesirable action from being performed or allows its performance only if another specific action is performed first (e.g., a single dose vial)

Appendix IV: Harm Categories in Reported Adverse Events

The following table presents all harms reported in 2012 (n=177) by event type according to harm categories from the National Coordinating Council for Medication Error Reporting and Prevention.

						Serious Harm					
Event Type	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**Total**	**Percent**
Anesthesia			1	2	1			2		6	3%
Aspiration						2				2	1%
Care delay				1						1	1%
Contaminated drugs, devices or biologics				1		1				2	1%
Device or medical/surgical supply				1	3	2	1			7	4%
Deep vein thrombosis with or without pulmonary embolism				4	3	6				13	7%
Fall			10		2					12	7%
Healthcare-associated infection				7	8	16				31	17%
Medication or other substance			4	7	2			1		14	8%
Other event			1		1					2	1%
Surgical or other invasive procedure	2	1	5	12	26	41			2	89	49%
Unintended retained foreign object			1							1	1%
Total Events	**2**	**1**	**22**	**35**	**46**	**68**	**1**	**3**	**2**	**180**	
Percent of total events (n=180)	1%	1%	12%	19%	26%	38%	1%	2%	1%		