Patient Safety Reporting Program

2011 ASC Annual Summary

Report. Learn. Improve **Patient Safety.**

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Executive Summary

In 2011, Oregon Ambulatory Surgery Centers (ASCs) submitted fewer reports compared to previous years. This decrease is not an indication that fewer adverse events are occurring, but rather, that fewer events are being reported. While over 56% of the ASCs in Oregon participate in the Patient Safety Reporting Program, only 47% are currently reporting adverse events. To facilitate and encourage reporting, the Commission has:

- Created a quick reference guide on *What, When, and How to Report*[1]
- Established targets to recognize leading participants[2]
- Invested in improvements to an online reporting tool (released September, 2012)

As ASCs are aware, 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 to learn and improve. Adverse event reporting demonstrates a commitment to patient safety and helps to preserve the unique qualities of the program.

This annual summary provides an aggregate look at the adverse events reported by ASCs in 2011. 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. It is the goal of the Commission that ASCs will use the information in this report 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 Commission is dedicated to providing value to our Patient Safety Reporting Program participants[3]. In addition to our work this year to enhance the Patient Safety Reporting Program, the Commission is offering programs specifically designed to support ASCs with their patient safety efforts. Information regarding Commission programs is available online (http://oregonpatientsafety.org). The Commission also offers a monthly newsletter that provides essential patient safety information to professionals across the healthcare continuum.[4]

The Commission appreciates the continued support of our partners and Patient Safety Reporting Program participants that are actively participating. We are pleased to provide this *2011 ASC Annual Summary* to inform efforts throughout Oregon to reduce the risk of serious adverse events and encourage a culture of patient safety.

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[1] *What, When, and How to Report* is available at http://oregonpatientsafety.org/reporting-programs/asc-submit-reports/

[2] *Patient Safety Reporting Program Recognition Targets for 2012* are available at http://oregonpatientsafety.org/reporting-programs/asc/

[3] A complete list of Patient Safety Reporting Program participants is available at http://oregonpatientsafety.org/reporting-programs/asc/

[4] Subscribe to the Commission's newsletter at http://oregonpatientsafety.org/news-events/subscribe/

Overview of Oregon's ASC Patient Safety Reporting Program

Oregon Ambulatory Surgery Centers (ASCs) have been submitting adverse event reports to the Oregon Patient Safety Commission since 2007. This report summarizes those submissions and provides a platform to share aggregate data with ASCs across the state. It is our goal that ASCs will use the information in this report 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.

One of the primary goals of the Patient Safety Reporting Program is to identify these events and learn from them in order to improve the healthcare system. While the reporting program is a mechanism to share/learn from adverse events, organizations must still seek to identify these events.

The Patient Safety Reporting Program is based on root cause analysis (RCA), which strengthens understanding of why adverse events occur. RCA requires a systematic, in-depth review to learn the most basic reasons an adverse event occurred. The goal is to understand the problem in sufficient depth to effectively eliminate the chance of future occurrence. The adverse event report walks the investigator though the RCA process to:

(1) Determine **what** happened.
(2) Determine **why** it happened.
(3) Develop an **action plan** to prevent similar events.

56% of Oregon's ASCs were participants in the Patient Safety Commission's adverse event reporting program as of December 2011; however, only 47% of those submitted a report in 2011.

Through reporting, participating ASCs identify opportunities to learn from and correct system-level issues. As of year-end 2011, 56% of Oregon's ASCs are participants in the Patient Safety Reporting Program. Participants are required to report (a) any unanticipated, usually preventable event that results in patient harm as listed in *Appendix I*; (b) any serious adverse events—events that result in patient death or serious physical injury; or (c) any one of 13 specific event types regardless of the severity of harm (see *Appendix I*). However, the Commission encourages participants to report all adverse events that highlight a valuable patient safety lesson. Adverse events are events resulting in unintended harm or creating the potential for harm (e.g., near miss or close call) related to any aspect of a patient's care rather than to the underlying disease or condition of the patient.

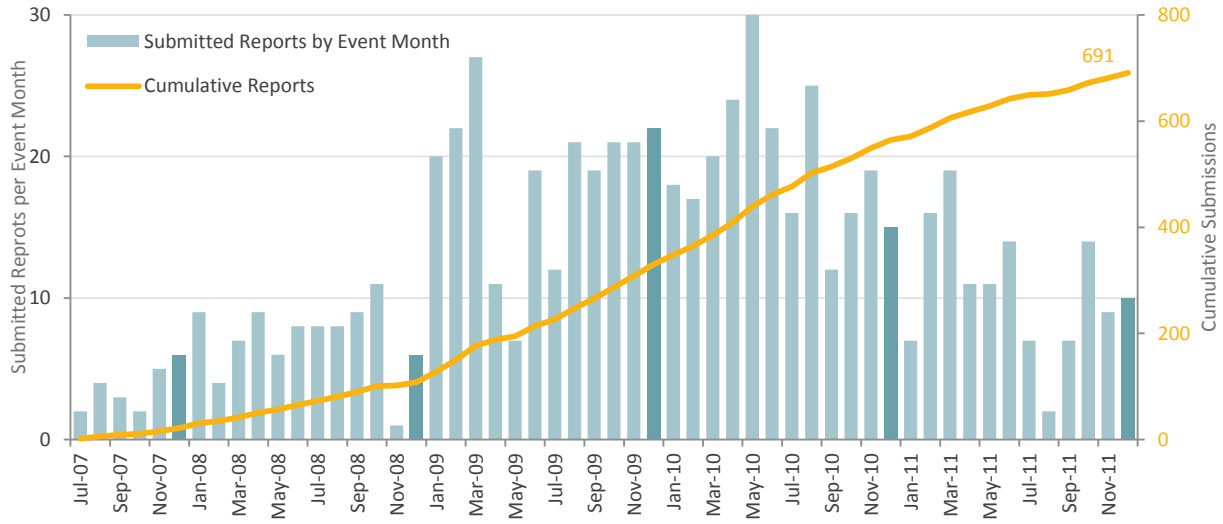
Participating ASCs are demonstrating a commitment to learning and improvement, which is the cornerstone of creating a culture of patient safety. Reporting adverse events is not, in itself, sufficient to ensure patient safety, but is only the beginning. Through reporting, organizations identify and learn from opportunities to improve patient safety and develop action plans to prevent future recurrence. Sustaining successful change requires ongoing efforts to implement action plans by redesigning systems and engaging in continuous improvement processes.

Additionally, reported events and findings from the investigation can be aggregated with similar incidents to identify common underlying causes as well as lessons learned.

Reporting History

ASC reports submitted to the Commission steadily increased from 2007 through 2009 but declined significantly in 2010 and 2011, with only 47% of ASC participants submitting a report in 2011 (see Figure 1).

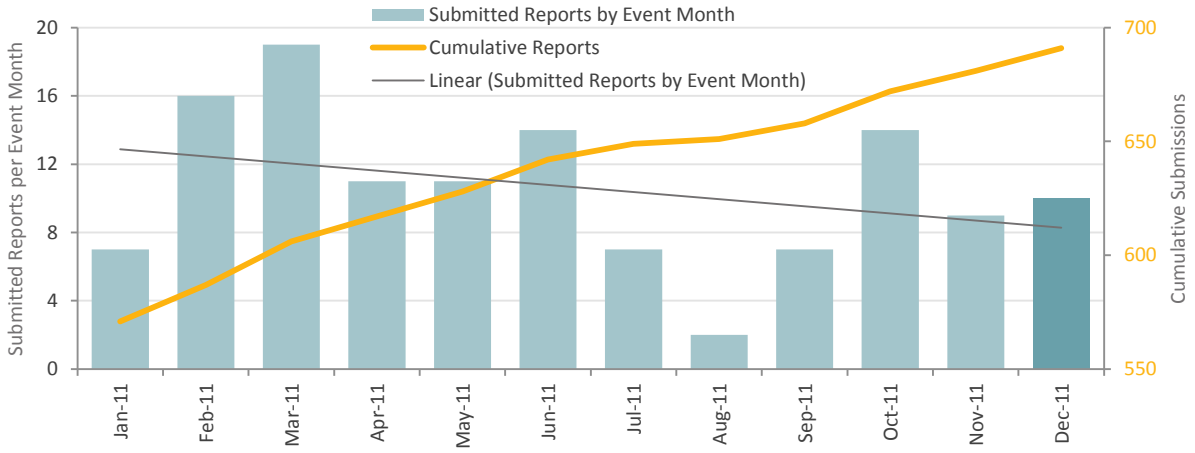
Figure 1. Reports Submitted 2007-2011 by Month and Cumulatively



We interpret the initial rise 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. Similarly, we interpret the decrease in 2011 (see Figure 2), not as a decrease in 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. An ASC's commitment to identify, submit, and learn from adverse events demonstrates a commitment to patient safety. To support the participating ASCs in their identification and reporting of adverse events, a quick reference guide- *What, When, and How to Report* [5]- was developed to help ASCs better understand what to report to the Commission.

[5] *What, When, and How to Report* is available at http://oregonpatientsafety.org/reporting-programs/asc-submit-reports/

Figure 2. Reports Submitted 2011 with Linear Trend line



Because it is possible for multiple events to be included in one adverse event report (e.g., a perforation that resulted in both a blood transfusion as well as admission to the hospital), the total number of events is greater than the number of reports. Take note of the difference in Table 1, as both are used throughout this report.

Table 1. Adverse Event Reporting 2007-2011: Submitted Reports vs. Events

	2007	2008	2009	2010	2011	Total
Reports	22	87	222	232	117	680
Events	26	101	256	259	124	766

To ensure that sufficient adverse event reports are received to build a strong database for learning and to recognize healthcare organizations for their transparency efforts and commitment to patient safety, reporting recognition targets have been established. The targets focus on the quantity of reports submitted as well as the quality and timeliness of those reports.[6] *Appendix II* provides guidance for ASCs on meeting the quality portion of the recognition targets.

[6] The *Patient Safety Reporting Program Recognition Targets for 2012* are available at http://oregonpatientsafety.org/reporting-programs/asc/

2011 Reporting

The following section provides an aggregate overview of adverse event reports submitted to the Oregon Patient Safety Commission by ASCs in 2011, as well as selected comparisons with previous years.

Reported Adverse Events

When reporting adverse events, ASC must indicate the type of event that occurred. ASCs select an event type from a list of 20 different types of events, which includes an *Other* category. As part of the 2012 reporting system enhancements, the Commission updated the list of adverse event types to align with the National Quality Forum's (NQF) revised list of serious reportable events. For example, we grouped *incorrect site or side*, *incorrect patient*, and *incorrect procedure* under one event type—*Surgical or other invasive procedure* event. Participants now indicate the specific nature of the *Surgical or other invasive procedure* event in a separate question. We also added one of NQF's new events applicable to the ASC setting—*Irretrievable loss of an irreplaceable biological specimen*. Please see *Appendix I* for a complete list of reportable events. *Appendix III* provides a comparison of the reporting program's original and revised event types. The following provides data from 2011 event reports using the newly revised event types.

In 2011, the Commission received 117 reports, which included 124 events. A majority of the events reported by ASCs in 2011 were *Surgical or other invasive procedure* events, which represent 60% of all reported adverse events. Healthcare-associated infections were the second most frequently reported event type in 2011. Table 2 offers an overview of the types of adverse events reported by Oregon ASCs.

Table 2. Number and Percent of Events Reported by Type, 2007-2010 and 2011

Event Type	2007	2008	2009	2010	2011	Total Events	% of Events	% of Reports
Surgical or other invasive procedure	9	50	149	162	60	430	60%	63%
Healthcare-associated infection	5	14	38	41	25	123	17%	18%
Medication or other substance	3	7	11	10	14	45	6%	7%
Deep vein thrombosis	3	1	11	10	4	29	4%	4%
Device or medical/surgical supply	2	5	7	5	7	26	4%	4%
Other event	1	7	7	3	5	23	3%	3%
Fall	1	6	5	9	1	22	3%	3%
Unintended retained foreign object	0	1	1	2	3	7	1%	1%
Anesthesia	1	1	1	0	2	5	1%	1%
Contaminated drugs, devices or biologics	0	1	0	1	3	5	1%	1%
Aspiration	0	2	0	1	0	3	0.4%	0.4%
Burn	0	0	0	1	0	1	0.1%	0.1%
Total events	25	95	230	245	124	719	0	0
Total reports	22	86	222	232	117	679	0	0

Because surgeries and procedures are the primary function of this care setting, the new online reporting system now collects more detailed information on *Surgical or other invasive procedure* events to better understand these types of events.

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* events were the most common *Surgical or other invasive procedure* events reported in 2011 and comprised 85% of this event type. Table 3 summarizes the types of *Surgical or other invasive procedure* events reported in 2011.

Table 3. Number and Percent of Surgical or Other Invasive Procedure Events Reported by Type, 2011

Type of *Surgical or other invasive procedure* Event	Number	Percent
Unplanned admission to hospital (within 48 hours of discharge)	24	38%
Unplanned emergency department visit (within 48 hours of discharge)	24	38%
Postop bleeding requiring return to operating room	7	11%
Laceration, perforation, puncture, or nick	2	3%
Unanticipated blood transfusion	2	3%
Postop nausea requiring hospital admission	2	3%
Incorrect site or side	2	3%
Other	1	2%

*Please note: a single report could mark multiple surgical event types

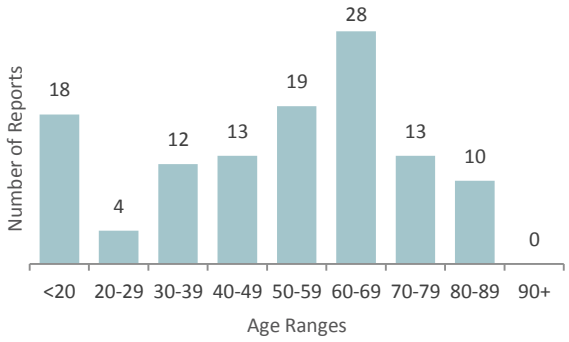
The majority of *Surgical or other invasive procedure* events submitted in 2011 by ASCs were related to unplanned emergency department visits or hospital admissions, accounting for 75% of *Surgical* events. The remaining 16 events were related to various occurrences in operating or procedure rooms, many related to unanticipated bleeding or injury.

Patient Age and ASA Class in Reported Events for 2011

Age

The patients impacted by adverse events reported in 2011 ranged in age from zero to 88. 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, 2011



ASA Class

A patient's preoperative physical condition is determined using the American Society of Anesthesiologists' (ASA) Physical Status Classification System. It is often regarded by health care organizations as a scale to predict risk, although there are other factors that impact operative risk (e.g., age and obesity of the patient, nature and severity of the operative procedure, selection of anesthetic techniques, competency of the surgical team [surgeon, anesthesia providers, assisting staff], duration of surgery or anesthesia, etc.). While there are six ASA classes, ASCs typically see ASA class 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

Of the adverse events reported in 2011, 115 (of 117 reports) indicated an ASA classification; roughly half of those were identified as ASA class 2 patients. Overall, for all reporting years (2007-2011), the Commission has seen a similar number of reports for ASA class 1 and 2, with ASA class 3 patients identified on far fewer reports (see Table 4 for details).

Table 4. Adverse Event Reports by ASA Class, 2011

	2007-2010		2011	
ASA Class	**Number**	**Percent**	**Number**	**Percent**
ASA Class 1	206	37%	41	35%
ASA Class 2	238	42%	57	49%
ASA Class 3	58	10%	17	15%
Total	502		115	

Harm in Adverse Event Reports

When ASCs report adverse events, they assess harm related to the event. Historically, ASCs assigned each adverse event a harm level using nine numerical categories ranging from no harm to death. The Commission summarized the reported harms in two ways: serious harm (levels 7-9) and less serious harm (levels 2-6).[7] 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 3).[8] Under the NCC MERP system of harm categories used in the new online reporting system, serious harm is defined as categories F, G, H or I (see Table 5 for definitions). ASCs report any unanticipated, usually preventable consequence of patient care that results in patient harm, including the events described in *Appendix I* and any serious adverse events. ASCs are encouraged to report less serious harm events, no harm events, and "near-miss" events; this provides important opportunities to improve patient safety and helps prevent the likelihood of future serious adverse events. The goal of the Patient Safety Reporting Program is to learn and improve from adverse events, regardless of the level of harm.

[7] Participants in the Patient Safety Reporting Program are only required to submit adverse event reports for any unanticipated, usually preventable consequence of patient care that results in patient harm, including the events described in *Appendix I* and any serious adverse events (Oregon Administrative Rules 325-025-0001, 2007). Serious harm is defined as NCC MERP harm categories F through I (see Table 5).

[8] In 1999, NCC MERP developed a classification for standardizing harm from adverse drug events. The classification's use has been extended to other types of adverse events, most notably by the Institute for Healthcare Improvement, which uses the Medication Error Reporting and Prevention categories with its trigger tools.

Table 5. Number of Reports by NCC MERP Harm Categories, 2011

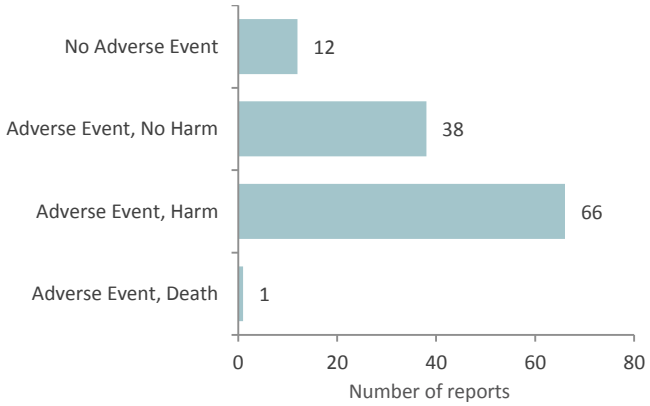
Number	Category	Category Description	Adverse Event/Harm
12	**Category A**	Circumstances that have the capacity to cause an adverse event	**No adverse event**
1	**Category B**	An event occurred that did not reach the patient (an "error of omission" does reach the patient)	**Adverse event, no harm**
15	**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"*	
22	**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"*	
25	**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"*	
Serious Harm			
39	**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"*	**Adverse event, harm**
0	**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')"*	
2	**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)"*	
1	**Category I**	An event occurred that may have contributed to or resulted in patient's death	**Adverse event, death**

Adoption of the national NCC MERP harm categories increases the Commission's ability to interpret the impact of adverse events on patients and provides the Commission with a richer understanding of reported harms. While the original harm levels were a scale from lower harm to greater harm, the new NCC MERP system consists of mutually exclusive categories assigned by following a standardized NCC MERP Harm Category Algorithm.[9] Although there will always be some level of subjectivity in assessing the harm associated with a specific adverse event, the algorithm standardizes the assessment of harm across facilities. Use of the NCC MERP categories will strengthen data analysis and provide a clearer picture of what may have happened to the patient.

To transition from the Commission's original process for categorizing harm to the NCC MERP categorization system, the Commission assigned a harm category, using the NCC MERP algorithm, to each event reported in 2011. A more detailed explanation of how the Commission converted from old to new harm categories and how the transition impacted 2011 reports is available in Appendix IV. While original harm levels and the new NCC MERP harm categories do not correspond on a one-to-one basis, most events labeled as serious harm by the original harm levels (7-9) are also considered serious harm events (F, G, H and I) under the new categorization.

Through the assignment of harm categories, we are better able to understand events and their impact on patients. The Commission believes that the NCC MERP algorithm will allow participants across all reporting segments to easily and accurately apply a standardized set of harm levels. Figure 4 shows harm levels for 2011 reports based on the Commission's application of the NCC-MERP algorithm.

Figure 4. Number of Reports by Harm Category, 2011



In 2011, a majority of events reported by ASCs (56%) were adverse events with harm (harm categories E-I). Of those events, 25 (44%) were less serious harm events (harm category E) and there was a single death, the same as in almost all previous years (see Table 7). ASCs also reported 37 (32%) no harm events (categories C and D) and 13 (11%) near miss events (harm

[9] Harm Category Algorithm available at http://oregonpatientsafety.org/reporting-programs/asc-submit-reports/

categories A and B). The eight 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.

Table 6 shows the number of serious harm events by event type for 2011. The events most frequently associated with serious harm were *Surgical or other invasive procedure* and *Healthcare-associated infection*; these were also the most commonly reported event types. Appendix V provides a table of all harm categories reported in 2011 by event type.

Table 6. Number and Percent of Serious Harm Events (F-I) by Event Type, 2011

Event Type	Number of Serious Harm Events	Percent of Total Events
Surgical or other invasive procedure	25	20%
Healthcare-associated infection	12	10%
Thrombosis	3	2%
Device or medical/surgical supply (including use error)	2	2%
Anesthesia	1	1%
Fall	1	1%
Medication or other substance	1	1%
Unintended retained foreign object	1	1%
Total Events Resulting in Serious Harm	46	37%
Total Events	124	

Since 2007, four death events have been reported to the Commission by ASCs. Of the four death events, three were *Surgical or other invasive procedures*- two *Unplanned emergency department visits (within 48 hours of discharge)* and one *Perforation* - and the fourth was a *Thrombosis* (with pulmonary embolism). The two *Unplanned emergency department visits (within 48 hours of discharge)* indicated obstructive sleep apnea (OSA) as a factor; in one case, it was undiagnosed prior to the event.[10]

[10] The Commission provides a statement on oversedation to identify strategies to decrease the risks associated with opioids and other sedating medications, which includes information related to OSA. *Appendix C* contains a sleep apnea risk guide to assess suitability for outpatient surgery. The statement on preventing harm from oversedation is available at http://oregonpatientsafety.org/healthcare-professionals/preventing-oversedation/

Table 7. Number of Reports Resulting in Death (Harm Category I) by Year

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

*2007 includes only 6 months of data

Contributing Factors

In reporting an adverse event (or potential event), ASCs identify the factors that contributed to the occurrence of the event. Identification of contributing factors helps to develop an understanding of why the event occurred. Typically, there are multiple contributing factors for a single adverse event. Contributing factors are grouped into eight categories (see box). The 117 reports submitted in 2011 identified 24 individual contributing factors across the eight categories. Facilities can select multiple contributing factors in any category. For comparison purposes, Table 8 counts a category only once per report (e.g., two communication contributing factors identified on a single report are counted once under communication). Table 9 takes a more detailed look at the total number of contributing factors identified for the three most common contributing factor categories.

Contributing Factor Categories

- Communication
- Device or supply
- Health information technology (HIT)
- Human and environmental
- Organizational
- Policy/procedure
- Patient management
- Patient

When ASCs identify contributing factors, they are identifying opportunities to make improvements that create a more reliable system of care. On average, reports identified 1.4 contributing factors across the eight categories, with a range of one to five factors per report. Thirty-eight percent of reports did not indicate 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).

Table 8. Number and Percent of Reports by Contributing Factor Category, 2011

Category	Number	Percent
Patient management	32	27%
Communication	20	17%
Patient	15	13%
Human and environmental	11	9%
Organizational	8	7%
Device or supply	6	5%
Policy or procedure	2	2%
Health information technology (HIT)	1	1%

As part of the 2012 reporting system enhancements, the Commission updated the list of contributing factors to:

- Add factors based on *Other factors* frequently identified in previous reports
- Update contributing factor language to reflect current terminology
- Replace broad, difficult-to-analyze contributing factors with more specific options

The most frequently selected individual contributing factor across all categories was *Patient management - response to changing condition*, representing 18% of all selected contributing factors. Our analysis showed there was a clear difference between an ASC's interpretation of the meaning of this contributing factor and that of the Commission. ASCs have predominantly interpreted this factor to mean, "patient's response to his or her own changing condition" rather than its intended meaning, "facility's response (or lack thereof) to patient's changing condition." This confusion has been clarified in the enhanced reporting system as *Response to changing condition/delay in care*. As part of the recent reporting system enhancements, the Commission has created a data dictionary as a resource to help prevent these kinds of inconsistencies. ASCs are encouraged to use available resources and ask questions when any reporting tool question or answer option is unclear. Through participant feedback, we can identify areas where we can improve the depth and detail of the resources we make available.

Table 9. Top Three Contributing Factor Categories by Factor, 2011

Category	Contributing Factor	Reports	% of Category
Patient Management (n=32)	Response to changing condition	18	56%
	Other	6	19%
	Treatment/care plan	4	13%
	Initial diagnosis	3	9%
	Follow-up care	3	9%
	Patient assessment	1	3%
Communication (n=20)	Among interdisciplinary teams	8	40%
	Miscommunication with patient/family	6	30%
	Other	4	20%
	Within units	3	15%
	Handoffs/handovers	2	10%
Patient (n=15)	Other	10	67%
	Mental status	3	20%
	Behavioral status	1	7%
	Fragile health status	1	7%

Of the ten *Patient – Other* factors, three were related to non-compliance. Although ASCs have identified non-compliance as a factor over time, it was not considered for addition in the new reporting system. The Commission found that a non-compliance factor did not facilitate a closer look into why an adverse event occurred, nor did it aid ASCs or the Commission in developing effective solutions for preventing similar adverse events in the future. A deeper understanding of why the patient may not have complied with instructions is necessary. For instance, were instructions clearly given (including associated risks of complying/not complying), verbally and in writing? How did the patient's care providers ensure instructions were fully understood (e.g.,

Teach Back[11])? Were the instructions culturally appropriate? Was the patient coming out of anesthesia or on a medication that may have made thinking or remembering difficult?

Of the other seven *Patient – Other* factors, there were four with contributing factors related to misdiagnoses or unknown diagnoses. One of the unknown diagnoses was sleep apnea. Surgical patients with obstructive sleep apnea (OSA) are at particularly high risk for oversedation (Adesanya, Lee, Greilich, and Joshi 2010), in part due to the physiologic stresses of surgery (Liao, Yegneswaran, Vairavanathan, Zilberman, and Chung 2009). Screening tools such as the STOP BANG questionnaire can be used to identify patients who may be at risk for OSA prior to surgery to ensure safety measures can be taken.[12]

[11] Teach-back is a method used to confirm that you have explained to the patient what they need to know in a manner that the patient understands. Patient understanding is confirmed when they explain it back to you. More information on how to use teach-back is available in the Agency for Healthcare Research and Quality's *Health Literacy Toolkit* available at http://www.ahrq.gov/qual/literacy/healthliteracytoolkit.pdf

[12] The Commission provides a statement on oversedation to identify strategies to decrease the risks associated with opioids and other sedating medications, which includes information related to OSA. *Appendix A* contains a sample STOP BANG patient questionnaire to identify patients at risk for OSA. *Appendix C* contains a sleep apnea risk guide to assess suitability for outpatient surgery. The statement on preventing harm from oversedaton is available at http://oregonpatientsafety.org/healthcare-professionals/preventing-oversedation/

Recommendations and Improvement Strategies

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 highlights opportunities for ASCs to improve patient safety efforts and offers recommendations and improvement strategies based on reported events in 2011.

(1) Recommendation: Ensure Consistent Use of a Safe Surgical Checklist
(2) Recommendation: Eliminate "Known Complication" from Your Vocabulary
(3) Recommendation: Eliminate Unintended Retained Foreign Objects
(4) Recommendation: Strengthen Healthcare-Associated Infection Prevention and Control Programs
(5) Recommendation: Improve Patient Understanding
(6) Recommendation: Conduct Deeper Investigations
    a. Root Cause Identification
    b. Effective Action Plan Development

While this report offers recommendations to improve patient safety, all improvement efforts rely on an organization's culture of safety. Establishing a robust "culture of safety" means creating a work environment where staff effectively works as a team, communicate clearly, and openly discuss adverse events when they occur. Extensive tools and resources are available for organizations looking to improve their culture of safety (for more information, see *Resources* section). In particular, the Commission promotes the use of safety briefings to strengthen and promote clear communication (see *Safety Briefings* box to right).

Safety Briefings

Daily or weekly safety briefings are a tool used by frontline staff to share information about potential safety problems and concerns on a regular basis.

Briefings increase staff awareness of safety issues and create an environment where staff can share information without fear of reprisal.

For more information, visit the Institute for Healthcare Improvement www.ihi.org

Recommendation: Ensure Consistent Use of a Safe Surgical Checklist

ASCs reported two *Incorrect site or side* events in 2011. Currently, using a safe surgery checklist is a best practice for the prevention of *incorrect site*, *incorrect side*, and *incorrect patient* events. Both The Joint Commission and the World Health Organization recommend key checklist elements to address the continuing occurrence of incorrect site, incorrect procedure, and incorrect patient surgery (for more information, see the Resources section)

Use of a safe surgical checklist provides benefits beyond ensuring the correct patient and site/side. According to the World Health Organization (WHO), the safe surgical checklist was originally introduced to "help ensure that teams consistently follow a few critical safety steps and thereby minimize the most common and avoidable risks endangering the lives and well-being of surgical patients" (WHO (2008)). A safe surgical checklist facilitates communication among surgical team members to support healthcare-associated infection prevention (27 reported events in 2011), recognition of known allergies, safe anesthesia, anticipation of need for a blood transfusion (two reported events in 2011), and avoids unintended retained foreign objects (two reported events in 2011).

In 2012, The Centers for Medicare and Medicaid Services (CMS) also reinforced the value of using a safe surgical checklist by calling on all ambulatory surgery centers to use one. CMS's new Medicare quality reporting program will require all Medicare-certified ASCs to report whether or not they used a "safe surgery checklist" in 2012. No financial penalties will be given if an ASC does not comply with the requirement; however, CMS plans to make reports available to the public that indicate whether an ASC complied with the requirement. ASCs will be subject to financial penalties associated with this requirement in future years. ASCs do not have to use a particular checklist in order to meet the requirement; however, CMS does require the use of a checklist that focuses on communication and safe surgery practices in each of three perioperative periods (where applicable):

(1) The period prior to the administration of anesthesia
(2) The period prior to skin incision
(3) the period of closure of incision and prior to the patient leaving the operating room

Implementation strategies for ensuring consistent use of the safe surgical checklist are provided on the following page.

Implementation Strategies for

Ensuring Consistent Use of the Safe Surgical Checklist

Review your ASC's use of the safe surgical checklist with a particular focus on implementation of Time-outs, including surgical site markings

Review the Comprehensive Surgical Checklist available on the Association of periOperative Registered Nurses' (AORN) website, which includes recommended key elements from both WHO and the Joint Commission.

Perform a "spot check" to ensure consistent, systematic use of the safe surgical checklist

Conduct random evaluations to ensure consistent use of the checklist. For example, print out a simple form with one question, "Was the surgical checklist followed completely during this surgery?" and attach it to the surgical documentation for each surgery for one week. Designate an individual for each surgery to mark "yes" or "no" at the end of surgery.

- Perform spot checks at least annually to monitor continued use
- Spot checks should gather data for at least a week to avoid a one-day Hawthorne effect[13], and to expose as many staff as possible to the question

Implementation of a checklist may not be sufficient if a strong culture of safety and effective communication are not in place. The power difference between providers and other staff can inhibit staff from speaking up about patient safety lapses specifically addressed in a checklist. If staff are not comfortable speaking up about these types of lapses, the impact of the safe surgical checklist will remain limited.

[13] A Hawthorn effect is the alteration of behavior by the subjects of a study because they are being observed.

Recommendation: Eliminate "Known Complication" from Your Vocabulary

Post-operative bleeding, Unanticipated blood transfusion, *Lacerations, perforations, punctures, or nicks* (for the purposes of this report, we refer to these four items collectively as "perforations") are common adverse event types occurring predominantly during surgical or other invasive procedures.

An identified trend following these event types is the acceptance on the part of ASCs that the event was unavoidable. In most of these events, related follow-up was dedicated solely to responding to the harm caused by the bleed, need for a blood transfusion, or perforation, rather than identifying the event's cause (see *Root Cause Identification* on page 26). Reports noted that the bleed or the perforation was a "known risk," suggesting that the event was not preventable and an investigation of the events cause(s) would be unnecessary. Although an examination of the response to injuries associated to an event is important and necessary, it is not a substitute for exploring the precipitating event.

Current thinking in patient safety challenges the concept of attributing adverse events to an unavoidable, yet known, risk (Wachter, 2008). Historically, catheter-related bloodstream infections and ventilator-associated pneumonias were considered known risks but have now been deemed preventable. No adverse event or potential adverse event should be exempt from investigation. If events that appear to be unavoidable are not examined, an organization's ability to assess opportunities for prevention becomes impaired. So-called "unavoidable" events should be used as opportunities to identify prevention strategies, improve practice, and strengthen the culture of safety.

Implementation Strategies for

Eliminating "Known Complication" from Your Vocabulary

Conduct investigations for events that your facility feels are "known complications" or "unavoidable," to identify root causes.

For example: perforations during colonoscopy or unanticipated visits to the hospital for dehydration or pain control

Track occurrence rates and look for patterns among those cases and identified causes

For example:

- Do the patients have similar health histories?
- Was a specific piece of equipment used each time?
- Was the safe surgical checklist complete?
- What method was used to communicate patient self-care instructions?

Identify and implement system-level prevention strategies based on identified trends and causes

For more information on the development and implementation of prevention strategies, see *Effective Action Plan Development* on page 27.

Recommendation: Eliminate Unintended Retained Foreign Objects

While ASCs have very few retained objects, they do occur; the Commission has received more reports of UROs from ASCs each year of the program (see Table 10). It is possible to eliminate this type of adverse event and we are calling on Oregon's ASCs to lead the way and eliminate unintentionally retained foreign objects.

Table 10. Number of Reported Retained Objects, 2007-2011

Year	Reported Retained Objects
2007	0
2008	1
2009	1
2010	2
2011	3

Of the three unintended retained objects reported in 2011, one involved a saline lock left in a patient; the other two involved defective medical supplies that broke off inside the patient (a needle tip and a knife blade). In the case of the retained saline lock, the nurse was interrupted during her workflow and even though the facility had a checklist to ensure removal, there was no process in place for follow-up to ensure completion. In one of the cases involving a defective medical supply, the facility was able to implement system-level action plans to ensure no additional patients were impacted, at both their facility and others. Their action plans included replacing the defective custom surgical pack with a new brand, notifying the manufacturer of the defective surgical pack, and notifying the Food and Drug Administration (FDA). For additional information on action plans see *Effective Action Plan Development* on page 27.

In 2007, the Commission convened a workgroup to examine what was known regarding prevention of retained objects and to make recommendations that would decrease the possibility of a retained object after surgery for Oregon patients. The workgroup organized its recommendations into practices essential for the prevention of retained objects, preferred practices, and practices that deserve further discussion and consideration. [14] Table 11 lists these recommendations, which continue to align with current standards set by the Association of Perioperative Registered Nurses.[15]

There are many opportunities to strengthen prevention efforts and work towards elimination of unintended retained foreign objects. ASCs have the potential to identify these opportunities each time they conduct a root cause analysis of an event and submit an adverse event report. ASCs should particularly explore the possibility of retained object events occurring in locations

[14] The Oregon Patient Safety Commission's *Preventing Unintentionally Retained Objects* (2007) is available at http://oregonpatientsafety.org/healthcare-professionals/hospitals/

[15] Standards set by the Association of Registered Nurses are available in the book *Recommended Practices for Prevention of Retained Surgical Items* (Conner, et al. (2012)). See the *References* for a complete citation.

other than the operating or procedure room (e.g., retained saline lock). In addition, special attention should also be given to the use of safety briefings (see page 15).

Implementation Strategies for

Eliminating Unintended Retained Foreign Objects

Evaluate and revise your ASC's current policies and procedures related to the prevention of unintended retained foreign objects to reflect the Commission's 2007 recommendations

Use the Commission's 2007 *Recommendations for Preventing Unintended Retained Foreign Objects* (see Table 11) to assess your current practices and identify areas for improvement

Evaluate your ASC's safe surgical checklist

Ensure it includes counts and that it is used on every patient every time

- Evaluate and update your count policies to count everything (regardless of inclusion in a surgical kit)
- Conduct "safety briefings" with surgical teams about counts, as an opportunity to raise awareness about the importance of counts and ensure everyone is on the same page about how counts are done (see page 15)

Table 11. Oregon Patient Safety Commission Recommendations for Preventing Unintended Retained Foreign Objects

Level of Recommendation	Recommendation
Essential	Adopt AORN recommended practices for counting surgical items and actions when there is an incorrect count
	Perform methodical wound exploration prior to closing the surgical wound
	Identify non-radio opaque items (e.g., telfa, rubber dams, plasma tubing) on the sterile field and identify those to count
	Develop work practices that allow for distraction/interruption-free opening and closing counts
	Reconcile counts before an additional procedure is begun or permanent change in personnel occurs
	Perform a Pause/Time-out before additional procedure or new surgical team
	Strengthen communication among the surgical team by a pre-procedure briefing from the surgeon. This briefing should: • Occur during the Pause/Time-out before start of case or second procedure, or different surgical team • Include presence of risks for retained object (e.g., emergency surgery, patient with high body-mass index, multiple procedures) and note any possibility for unplanned changes or portions of the surgery that are particularly critical
	Establish policies to limit distractions and interruptions related to use of cell phones, pagers, non case-related discussion, music, and non-essential personnel in the operating room
Preferred	Agree upon a consistent set-up of the back table so that relief staff have a clear sense of sponge and instrument locations
	Simplify instrument trays: type and number for each type of surgery, with peel packs for special requests to decrease the number of unused items that need to be counted
	Develop reliable process to assure accurate surgeon-specific preference cards so that simplified instrument trays are sufficient
	Develop policy to restrict staff changes during critical times during a surgery
	Use clear bags in kick buckets to facilitate identification of sponges
	Trouble-shoot any equipment prior to start of surgery and have backups available to avoid surgical delays and time pressures that impact counts
Work Toward	Implementing technological advances that allow bar coding and radiofrequency identification of sponges and instruments
	Improving teamwork by development of surgical teams – physicians, nurses, and technicians -- that routinely work together

Recommendation: Strengthen Healthcare-Associated Infection Prevention and Control Programs

As the second most frequently reported event type (25), *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 a 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" (CMS, 2011).

The Commission is working to support all Oregon ASCs with effective management of infection control processes and to meet infection control standards outlined in Medicare's Conditions of Coverage and State of Oregon administrative rules. The *Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit* [16], designed specifically for the ASC setting, is now available on the Commission's website to help Oregon's ASCs implement infection prevention quality improvement projects, reduce infection risks, and better protect patients. Table 12 outlines the components of an infection prevention and control program presented in the toolkit, providing tools and resources for each area. The Commission will also be offering statewide trainings for Oregon ASC staff to introduce concepts and strategies from the toolkit.[17]

Implementation Strategies for

Strengthening an Infection Prevention and Control Program

Evaluate your ASC's current infection prevention and control program
Use the tools and resources provided in the *Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit* to assess your current practices and identify areas for improvement (see Table 12 for an overview of toolkit components)
Resource: Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit

Educate staff on 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
Resource: The Commission's Educational Offerings

Track and trend your infection rates
Actively engage in National Healthcare Safety Network (NHSN) reporting
Resource: NHSN (CDC)

[16] The Oregon Ambulatory Surgery Center Infection Prevention & Control Toolkit is available at http://oregonpatientsafety.org/healthcare-professionals/infection-prevention-toolkit/
[17] Visit the Commission's website to learn more about the trainings and other education offerings at http://oregonpatientsafety.org/news-events/events/

Table 12. Oregon Patient Safety Commission Infection Prevention and Control Program Components

Infection Prevention and Control Program Components	Content Description
Infection Prevention Program Development	The Centers for Medicare and Medicaid Services and the State of Oregon mandate that ASCs have an infection prevention program (IPP). Tools in this section support the development of an effective infection prevention program and maintenance of quality improvement efforts. Provided resources build upon one another and can be used to: • Assess compliance with infection control practices • Document assessment findings • Use identified deficiencies to select areas for improvement • Organize and analyze survey findings and surveillance data • Establish and evaluate goals • Conduct a complete infection prevention program evaluation and planning process
General Infection Prevention Practice	ASCs can use resources to help comply with basic infection practices such as hand hygiene, surgical hand antisepsis, standard precautions, management of patients with potentially transmissible infectious diseases, Oregon's reporting requirements for infectious diseases, and waste management.
Sterilization and Disinfection Practice	Resources incorporate current regulatory standards and best practices for processing re-usable surgical instruments and equipment. Sample policies, procedures, competency checklists, guidelines, and documentation forms for instrument/equipment cleaning, disinfection and preparation are available.
Environmental Hygiene	Policies, procedures, and tools provide information on appropriate cleaning and disinfection requirements, which can be adapted for an individual ASC. ASCs can use the checklists for training purposes as well as to assure environmental hygiene quality.
Safe Injection Practices	Available resources support the safe handling and use of needles and syringes, cannulae that replace needles, single-dose and multi-dose vials, and intravenous delivery systems and eye drops (where applicable). In addition, materials and references are available that address recommended practices for the safe handling and disinfection of blood glucose monitoring devices and medications.
Employee Health Program	An ASC's employee health program is an essential component of the infection prevention program. Sample policies and documentation forms are provided which include: healthcare worker communicable disease screening and immunization requirements, occupational exposure to communicable diseases, and blood and body fluid exposures. In addition, sample declination forms for Hepatitis B and Influenza immunizations are available.
Quality Improvement	Tools support implementation of change and contain an example of a safe surgery checklist (based on one published by the World Health Organization) that was developed by an Oregon-based group representing multiple state professional organizations and agencies.

Recommendation: Improve Patient Understanding

The majority of surgical events (75%) submitted in 2011 by ASCs were related to unplanned emergency department visits or hospital admissions. In the ambulatory surgery setting, there is heavy reliance on individuals to actively manage their own, often complex, care. It is not uncommon for people to struggle with understanding medications, instructions and consents, self-care pre/post-surgery, and follow-up plans. This often leads to unplanned emergency department visits or hospital admissions.

In the United States, more than 36% of the adult population (approximately 80 million people) have poor health literacy. Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information to make informed decisions about healthcare. 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 will 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)). ASC should ensure systems are in place to promote better understanding for all patients, not simply those with low health literacy.

ASCs can adopt health literacy approaches to support clear communication with all patients. Use of the following strategies will help ensure patients can easily understand and act on the health information they receive. Implementation strategies for improving patient understanding are provided on the following page.

Implementation Strategies for

Improving Patient Understanding

Evaluate health information materials to ensure they are easy to understand and act upon

Health care providers rely heavily on print materials to communicate with patients. Many health-related documents are complex and difficult for patients to understand.
Resource: Health Literacy: Checklist for Creating or Evaluating Materials (The ECRI Institute)

Use plain, non-medical language

Most patients don't understand the medical jargon used by providers. Incorporate the use of plain language into communication so patients are more likely to understand.
Resource: Plain Language Thesaurus for Health Communications (The Centers for Disease Control and Prevention)

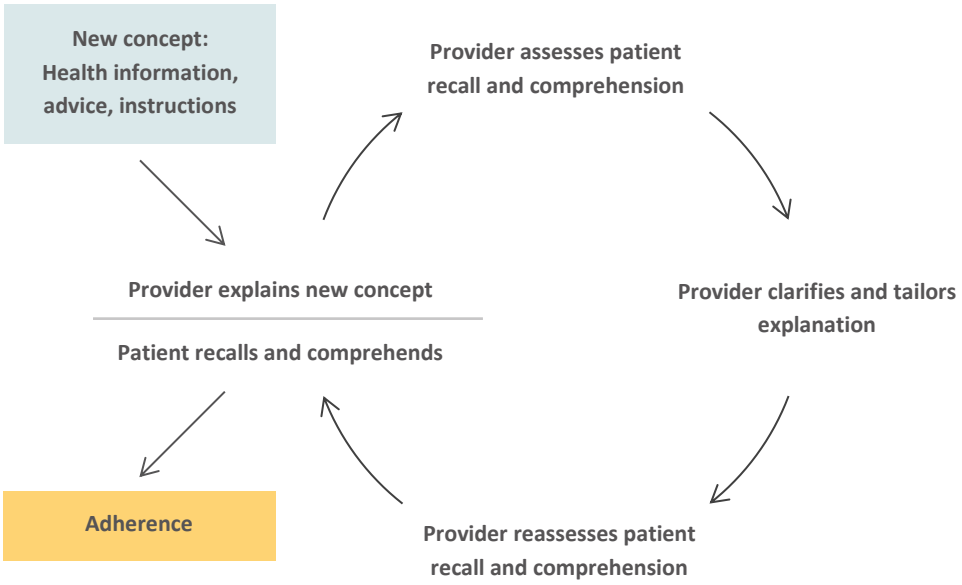
Determine readability of heath information material

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.
Resource: Text Readability Consensus Calculator (Readability Formulas)

Confirm patient understanding

Use methods such as "teach-back" to confirm that the patient easily understands what they need to know from the health information material. Patient understanding is confirmed when they explain it back to you (see Figure 5).
Resource: The Teach-Back Method (Agency for Healthcare Research and Quality)

Figure 5. Teach-Back: Closing the Loop



Schillinger, et al. (2003)

Recommendation: Conduct Deeper Investigations

The information in reports submitted by ASCs reflected superficial analyses— only uncovering surface-level causes to adverse events and a failure to ask "why" questions, leading to action plans that did not reflect an in-depth level of analysis. Identifying and reporting adverse events are only first steps in improving patient safety. Understanding why adverse events occur and identifying root causes are critical to the development of action plans to prevent similar events. Conducting more in-depth analyses using RCA methodology will allow ASCs to identify root causes and develop system-level action plans to prevent recurrence. The following section provides information to help conduct deeper investigations and sustain change over time using continuous improvement processes.

Root Cause Identification

Root causes, the most basic reason(s) for the event, are those that, if corrected on a system-level, can prevent or significantly reduce the likelihood of similar events. Root causes often stem from contributing factors that have undergone deeper investigation. Event reports submitted in 2011 did not show evidence of this deeper level of investigation to identify root causes. Health care team members can use the following tips to guide their investigation process to identify the root cause of an event.

Implementation Strategies for

Root Cause Identification

Use the 5 Whys
Continue to ask "why" - until it is no longer reasonable- to uncover the underlying causes of an event.

Clearly show a cause and effect relationship
Ask, if you eliminate this cause/contributing factor, will you minimize/prevent future events?

Identify the preceding causes, NOT the "human error"
Ask, could a peer with comparable qualifications and experience, behave in a similar way in similar circumstances? If the answer is 'yes,' then the event was likely caused by system-level factors.

Identify the preceding causes of procedure violations
Seek to understand why a policy/procedure was not followed. For example: Policy unclear, staff unfamiliar, too cumbersome, workaround was/is more efficient, etc.

Effective Action Plan Development

Action plans are the critical component of the root cause analysis. Strong and well-crafted action plans have a clear link to the root causes or contributing factors, are easily understood, and are more likely to be successful in accomplishing system changes. Through improved root cause identification, surgery centers will be better prepared to develop effective action plans.

Implementation Strategies for

Developing Effective Action Plans

Effective action plans:

- Address the root cause(s)/contributing factors
- Focus on systems, not on individuals
- Are specific and concrete
- Are understandable and can be implemented by a "cold reader"
- Consult process owners (those who will be implementing the action plan)
- Are tested prior to full implementation (*Plan-Do-Study-Act)

*See the next section, *Testing an Action Plan*, for more information on Plan-Do-Study-Act.

Additionally, some action plans are stronger than others. The stronger the action plan, the more likely it is to be successful in accomplishing system-level changes. The strongest, most effective actions plans re-design processes, devices, software, and workspaces, rather than trying to change individual memory or vigilance. Table 13 presents categories and types of actions for ASCs to consider. Because training and education are often a part of action plans, Table 14 provides examples of action plans by efficacy.

Table 13. Categories and Types of Actions in Strong Action Plans

Weak Action Plans	Intermediate Action Plans	Strong Action Plans
• Double checks • Warnings and labels • New policy/procedure • Training/education • Additional study/analysis	• Increase in staffing/decrease workload • Software enhancements/modifications • Eliminate/reduce distractions • Checklist/cognitive aid • Eliminate look/sound-alikes • Read back • Enhanced documentation/ communication • Redundancy	• Simplify the process and remove unnecessary steps • Standardize equipment or process • Tangible involvement and action by leadership in support of patient safety • New device with usability testing before purchasing • Architectural/physical plant changes

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

Table 14. Examples of Education and Training Action Plans by Efficacy

Less Effective	One-on-one counseling; onetime presentation; telling the patient's story
More Effective	Unit-level communication; integrating into orientation training; 30-day orientation training follow-up
Most Effective	Integrate education and training into staff competencies with follow-up; routine evaluation strategies

The most effective education and training action plans are ones that integrate preventive practices into staff competency requirements, and which provide routine follow-up and evaluation of staff performance. This level of integration will help to ensure that staff understand what is expected of them, in addition to making sure that they are equipped and consistently reminded of prevention expectations.

For additional information on developing an action plan that meets the "Quality" criteria for the Patient Safety Reporting Targets for 2012, see Appendix II.

Testing an Action Plan

Once the decision has been made to implement an action plan, purposeful planning will help guide effective implementation. Organizations can use the Model for Improvement, a simple tool that serves as a roadmap for improvement, to structure this process. The Model for Improvement is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. Hundreds of health care organizations have used this model to improve many different health care processes and outcomes (Langley, et al. (2009)). As shown in Figure 7, the Model for Improvement has two parts:

(1) Three fundamental questions

(2) The Plan-Do-Study-Act (PDSA) cycle to test and implement change. The PDSA cycle helps guide the test to determine if the change is an improvement.

Figure 6. Model for Improvement

Model for Improvement

What are we trying to accomplish?

Setting Aims: The aim should be time-specific and measurable.

How will we know that a change is an improvement?

Establish Measures: Quantitative measures will enable you to determine if a specific change leads to an improvement.

What change can we make that will result in improvement?

Selecting Changes: Organizations must identify the changes that are most likely to result in improvement.

Testing the Changes: The Plan-Do-Study-Act (PDSA) cycle is shorthand for testing a change in the real work setting — by planning it (Plan), trying it (Do), observing the results (Study), and acting on what is learned (Act). Use the PDSA to test change on a small scale multiple times, in order to learn and make modification before implementing changes on a large scale (i.e., facility-wide).

Langley, et al. (2009)

Recognition Targets

The Oregon Patient Safety Commission has established recognition targets in 2012 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). Recognition targets are also designed to encourage high-quality investigations and to ensure that the Commission receives sufficient 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 top performers based on established recognition targets. The Commission's website will identify all ASCs that meet or exceed recognition targets. Recognition targets for 2012 focus on the *quantity*, *quality*, and *timeliness* of reports submitted. For more information about the 2012 targets and the criteria for meeting or exceeding those targets, see *Patient Safety Reporting Program Recognition Targets for 2012* at http://oregonpatientsafety.org/reporting-programs/asc/.

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 and commitment to patient safety.[18] The Commission measures quantity as the number of reports submitted by a reporting program participant. The quantity target for 2011 was one report per participating ASC.

Oregon ASCs submitted 117 reports of adverse events that occurred in 2011. For the 47% of ASC program participants that reported 2011 events, the average number of reports per facility was 5.6 and with a range of 1-28. These numbers illustrate that, while adverse events are occurring in ASCs, many organizations are not identifying and reporting those events.

Quality

Reports are evaluated for quality by program consultants. When reviewing submitted adverse event reports, the Commission uses four criteria to determine if reports are of acceptable quality: reports should be complete, thorough, and credible, and have a meaningful action plan. Reports exceeding the standard for acceptability are considered to be of high quality.[19] In 2012, report quality will be incorporated into the annual recognition targets. For guidance on meeting the 2012 quality recognition target, see *Appendix II*.

[18] Oregon Patient Safety Commission. (2012). Patient Safety Reporting Program Recognition Targets for 2012. http://oregonpatientsafety.org/reporting-programs/asc/

[19] The high quality measurement aligns with criteria used by the Oregon Public Health Officer who certifies the reporting program and provides an assessment of the quality and quantity of adverse event reports submitted by participants.

Timeliness

After an adverse event, an immediate response is needed to collect full and reliable information on the circumstances surrounding the event. The Commission collects four pieces of time-related data for adverse events regardless of harm category (date event occurred, date event was discovered, date report was submitted, date facility completed their review and analysis of analysis of 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 (OAR) § 325-025-0025(3), 2007).

For events that occurred in 2011, the average time between event discovery and report submission for all reports was 63 days. The median time between discovery of an event and submission of a report for events that occurred in 2011 was 35 days. Although the median does not reflect the wide range of discovery-to-submission time (0-346 days, including several outliers that were not submitted for more than nine months after the event was discovered), it does reflect the majority of reports submitted.

Of the 92 serious harm reports submitted in 2011[20], 44 (48%) did not meet the state's timeliness standard specified in the OARs (see Table 15). Those that met the state's timeliness standard took an average of 17 days from event discovery to submission – just over two weeks of the roughly six week (specifically 45 days) requirement. Those that did not meet the timeliness standard, however, took an average of 120 days – more than twice as long as the 45 days indicated.

Table 15. Number and Percent of Reports by Compliance with State Timeliness Standard, with Average Number of Days between Discovery of Event and Submission, 2011

	Number	Percent	Average Number of Days
Met State Standard (submitted report within 45 days of event discovery)	44	48%	17 days
Did Not Meet State Standard (submitted report more than 45 days after event discovery)	48	52%	120 days

To help ASCs incrementally move toward achieving the State of Oregon's timeliness standard, the Commission has established annual recognition targets for timeliness, which change each year as organizations build their reporting programs. In 2011, the Commission's recognition targets did not include timeliness. However, in 2012, report timeliness will be incorporated into the annual recognition targets.

[20] Serious harm reports are those with a harm category of F, G, H or I, or include one of the 13 event types that are reportable regardless of harm level (see *Appendix I* for a complete list of these event types).

Information presented in this report 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.) it 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.

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Appendix I

Reportable Adverse Events for Ambulatory Surgery Centers

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,[21] and
(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)

[21] "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

Acceptable Quality Reports – Meeting the 2012 Recognition Targets

The Oregon Patient Safety Commission has established recognition targets in 2012 to guide healthcare organizations participating in the Patient Safety Reporting Program. Recognition targets are designed to encourage high-quality investigations and to ensure that the Commission receives sufficient 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 will identify all ASCs that meet or exceed recognition targets. Recognition targets for 2012 focus on the *quantity*, *quality*, and *timeliness* of reports submitted.[22] While *quantity* and *timeliness* targets are quantifiable and easily understood, the *quality* target can be more challenging to interpret.

A Closer Look at the Quality Target

Reports should contain information about the event that occurred as well as reflect an in-depth investigation (i.e., using root cause analysis). The quality target serves to provide some structure to participants for submitting reports with consistent and meaningful information. Reports are evaluated for acceptable quality by program consultants.

Acceptable Quality Criteria

Complete
All information in required fields is provided; the event description includes information pertinent to understanding what happened

Thorough
Report considers system-level contributing factors and identifies the root cause(s)

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

Action Oriented
Report includes system-level plans that are likely to prevent future occurrence; those plans address identified causes

[22] For more information about the 2012 targets and the criteria for meeting or exceeding those targets, see *Patient Safety Reporting Program Recognition Targets for 2012* at http://oregonpatientsafety.org/reporting-programs/asc/.

Guidance for Meeting Acceptable Quality Criteria

There are several areas on the reporting form that require text entry allowing participants to describe information specific to the event they are reporting; namely, the *complete account*, the *causes* and the *action plans*. Each of these sections provides critical information and summarizes the root cause analysis – what happened, why it happened, and how similar events will be prevented in the future. The following provides a description of each of these areas as it relates to the acceptable quality criteria.

Complete Account

A complete, narrative account of the event

An acceptable quality complete account briefly summarizes the sequence of activities and circumstances leading up to the event, in a way that someone unfamiliar with the event could easily understand. It also includes any relevant environmental conditions or clinical information. The summary should not be solely a description of the patient's clinical progress, although that may be included as appropriate.

Causes

The causes identified during the event review and analysis

Acceptable quality causes or findings show a clear link to the adverse event /near miss, including at least one root cause. Due to the complex nature of healthcare, there are typically multiple causes or findings for an event. The reporting form allows up to five findings.

Action Plan

The action plan that addresses each cause and is designed to prevent occurrence of similar events

An acceptable quality action plan directly addresses the identified root causes and other relevant findings. Action plans should be strong, system-level actions your organization will take to prevent or minimize the occurrence of similar events.

Appendix III

Comparison of Patient Safety Reporting Program (PSRP) Events, Administrative Rules Appendix A, Original Reporting Form, and NQF 2011 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.	*Air embolism* is considered a Medicare Healthcare-Acquired Condition (HAC)
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	*Blood incompatibility* is considered a Medicare HAC Appendix A defines this event as *Hemolytic reaction*; however, the PSRP accepts reports associated with any unsafe administration of blood products.

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
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	*Falls and trauma* is considered a Medicare HAC 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
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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
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	*Falls and trauma* is considered a Medicare HAC
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	*Falls and trauma* is considered a Medicare HAC Addressed in NQF's list of recommended safe practices (see *References* for link)
Healthcare-associated infection (HAI)	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 *References* 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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
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 *References* 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*. *Manifestations of poor glycemic control* is considered a Medicare HAC *Glycemic control* is also addressed in NQF's list of recommended safe practices (see *References* for link)
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 incorrect site, incorrect patient and, incorrect procedure)	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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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 incorrect site, incorrect patient and, incorrect procedure)	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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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
Surgical or other invasive procedure (including incorrect site, incorrect patient and, incorrect procedure)	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

PSRP	Admin. Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
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 *Foreign object retained after surgery* is considered a Medicare HAC
Other	6A) Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	--

Appendix IV

Converting Harm from the Old to New System

ASCs that submitted reports in 2011 assigned a harm level using the Commission's original system (nine numerical categories, 1through 9). In late 2011, the Commission adopted formally-validated national harm categories established by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (nine alphabetical categories, A-I).

The two systems of categorizing harm do not correspond on a one-to-one basis. Table 16 provides an overview of how the original harm level system corresponds to the new NCC MERP harm categories. While the Commission's original, numerical harm level scale reflects two dimensions (the degree of harm and whether the harm is permanent or temporary), the NCC MERP system categorizes events based on the degree of intervention required. No categorization fits all situations and the determination of harm will always reside with the clinicians involved; however, the NCC MERP categories provide a helpful degree of precision.

Table 16. Comparison of Original Harm Levels and New NCC MERP Harm Categories

NCC MERP Category	Definition	Original Level	Definition
A	Circumstances or events that have the capacity to cause harm	–	—
B	An event occurred but it did not reach the patient	1	Did not reach the patient
C	An event occurred that reached the patient, but did not cause patient harm	2	No detectable harm
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	2	No detectable harm
		3	Minimal temporary harm
E	An event occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	5	Moderate temporary harm
		7	Serious temporary harm
F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	7	Serious temporary harm
G	An event occurred that may have contributed to or resulted in permanent patient harm	4	Minimal permanent harm
		6	Moderate permanent harm
		8	Serious permanent harm
H	An event occurred that required intervention necessary to sustain life	7	Serious temporary harm
		8	Serious permanent harm
I	An event occurred that may have contributed to or resulted in the patient's death.	9	Death

To transition from one system to another, the Commission used the NCC MERP algorithm to assign a new harm category to each event reported in 2011. For serious harm events, conversion to the NCC MERP categories is fairly consistent. Reports originally assigned a harm level of 7 generally were assigned to the NCC MERP category F, although some fell into categories H or E depending on the degree of intervention; reports originally assigned a harm level of 8 or 9 were almost entirely assigned to the NCC MERP categories G and I, respectively.

For less serious harm levels, the conversion of harm from one system to the other was more variable. Harm levels 3, 4, 5, and 6 (minimal and moderate harm events) corresponded to categories D and E. Upon review, several of these less serious events fell into category F and likely should have originally been submitted as harm level 7. Table 17 outlines the conversion of harm from original level to new harm category for all reports submitted in 2011.

Table 17. Original Harm Level by New Harm Category, 2011

NCC MERP Harm Category	Harm Level 1	Harm Level 2	Harm Level 3	Harm Level 5	Harm Level 7	Harm Level 8	Harm Level 9	No Harm Level	Total Reports
A	3	5	3	2					**13**
B		1							**1**
C		11	4						**15**
D		7	10	2	3				**22**
E		2	11	11					**24**
F		1	10	21	6		1	1	**39**
H				2					**2**
I							1		**1**
Total Reports	**3**	**27**	**38**	**38**	**9**	**1**	**1**	**1**	**117**

Appendix V

Harm Categories in Reported Adverse Events

The following table presents all harms by event type reported in 2011 (n=124) according to newly adopted harm categories from the National Coordinating Council for Medication Error Reporting and Prevention.

Table 18. Events by serious harm

						Serious Harm				
Event Type	Harm A	Harm B	Harm C	Harm D	Harm E	Harm F	Harm G	Harm H	Harm I	TOTAL
Anesthesia					1	1				**2**
Contaminated drugs, device or biologics	1			2						**3**
Deep vein thrombosis with or without pulmonary embolism					1	2				**3**
Device or medical/surgical supply	2	1	2			2				**7**
Fall						1				**1**
Healthcare-associated infection				3	10	12				**25**
Medication or other substance			7	5	1			1		**14**
Other event	1		1	3						**5**
Surgical or other invasive procedure	9		4	10	12	24		1	1	**61**
Unintended retained foreign object			2			1				**3**
Total	**13**	**1**	**16**	**23**	**25**	**43**	**0**	**2**	**1**	**124**