Patient Safety Reporting Program

2011 Hospital Annual Summary

Report. Learn. Improve Patient Safety.

Bethany Higgins
Executive Director

Leslie Ray PhD, RN
Patient Safety Consultant

Carrie Parrish
Project Manager

Sydney Edlund
Data Analyst

August 2012

OREGON
PATIENT SAFETY
COMMISSION

Page intentionally left blank

Table of Contents

Executive Summary

In 2011, Oregon hospitals submitted more adverse event reports to the Oregon Patient Safety Commission than ever before. This increase in reports is not an indication that more adverse events are occurring, but rather, that Oregon hospitals are improving their ability to identify adverse events. Not only did the quantity of reports improve, but the quality and timeliness of the reports submitted also improved.

This annual summary provides an aggregate look at the adverse events reported by Oregon hospitals in 2011. Based on an analysis of these reports, this summary provides information regarding the volume and type of adverse events reported, as well as a clear set of recommendations to promote awareness and prevent recurrence of similar problems.

As hospitals are aware, the voluntary, confidential nature of the Patient Safety Reporting Program is unique. In 2011, Oregon hospitals reached a huge milestone by achieving 100% participation! Oregonians can be proud of our hospitals' work in identifying, investigating, and reporting adverse events. Each year, the Commission strives to provide robust information on statewide trends and meaningful feedback for hospitals to learn and improve. Adverse event reports provide substantive proof of hospitals' commitment to patient safety and help to preserve the unique qualities of the program.

The Commission is dedicated to providing value to our Patient Safety Reporting Program participants. In addition to our work this year to enhance the Patient Safety Reporting Program, the Commission offers many other programs specifically designed to support hospitals with patient safety. Information regarding Commission programs is available online (http://oregonpatientsafety.org) and in a monthly newsletter that provides essential patient safety information to professionals across the healthcare continuum (subscribe at http://oregonpatientsafety.org/news-events/subscribe/).

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

Overview of Oregon's Hospital Patient Safety Reporting Program

Each year, hospitals participating in Oregon's Patient Safety Reporting Program submit adverse event reports about the unintended harm (or potential harm) to patients that occurs as a result of medical care. This annual summary provides a statewide, aggregate picture of the information reported by hospitals in 2011. The reporting program focuses more on learning from adverse events than simply measuring the number of events reported and aims to:

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

In 2012, the Commission enhanced the adverse event reporting system for hospitals to more efficiently and effectively collect information and provide feedback to reporting program participants. Changes to the reporting system enable participants to more easily report the events that result in patient harm or have the potential to cause harm.[1] System enhancements also improve the Commission's ability to analyze reports and provide feedback that can help participants learn from adverse events and improve patient safety in Oregon.

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

Reporting History

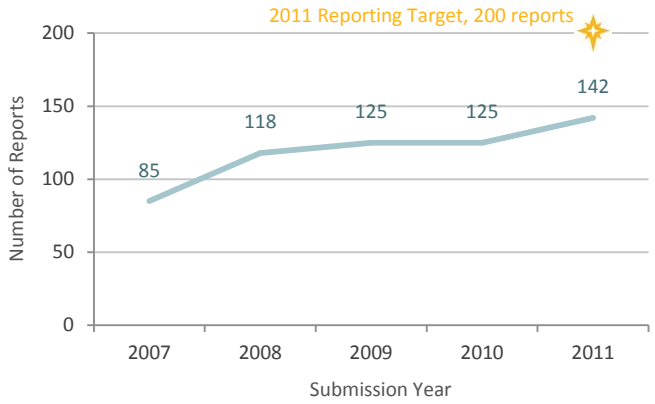
The Commission has seen incremental increases in the number of reports submitted each year since the reporting program began in 2006 (see Figure 1). Hospitals submitted 142 reports in 2011, the highest annual number of reports submitted to date. The number of reports submitted in 2011 falls short of the Commission's recognition targets for quantity, which are designed to ensure that the Commission has enough adverse event reports to build a strong database for learning (see Reporting Targets section for further discussion); however, 142 reports does align with what the Commission anticipated receiving based on prior reporting patterns.

In 2010, the Commission estimated the number of reports that hospitals would likely submit in future years based on prior Oregon reporting trends. We estimated that hospitals would submit

[1] More information on these enhancements can be found throughout this report and in the Commission's *Hospital Patient Safety Reporting Program System Enhancement Summary*, http://oregonpatientsafety.org/reporting-programs/.

145 reports in 2011. The actual number of reports submitted in 2011 was 142. While reporting levels continue to grow slowly from year to year, the number of reports submitted annually falls short of the actual number of adverse events that may be occurring in Oregon each year.[1]

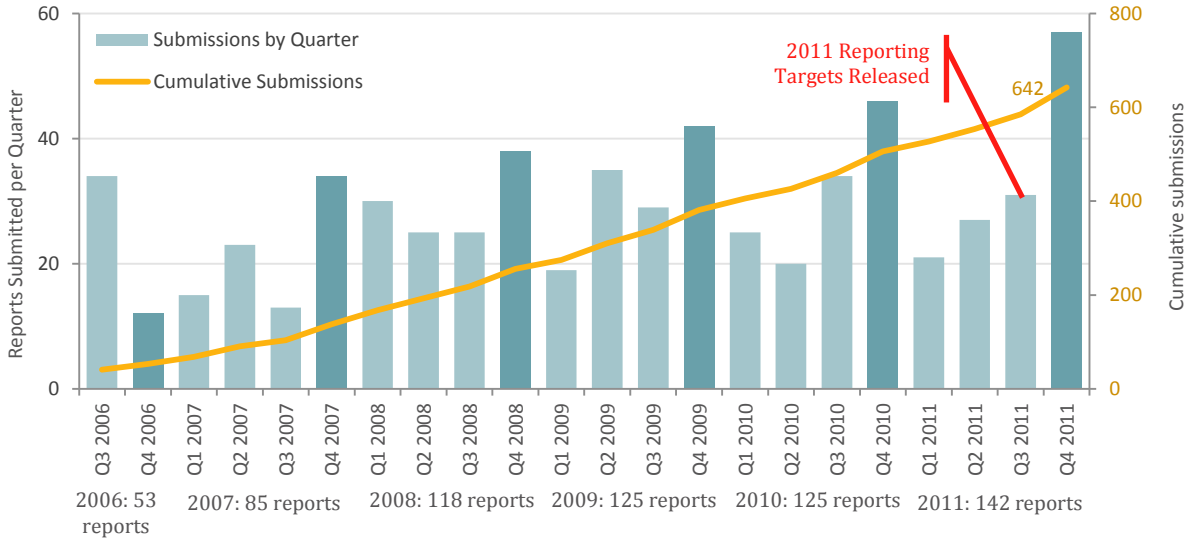
Figure 1. Reports Submitted by Year, 2007-2011*



** 2006 includes only seven months of data and is not included in this chart.*

Hospital reporting has historically fluctuated throughout the year (see Figure 2). In 2011, the number of reports submitted increased gradually throughout the year. The fourth quarter of the year continues to be the time when hospitals submit the most reports. This does not necessarily imply that more adverse events are occurring in the last quarter of each year as reports submitted in the fourth quarter are often for adverse events that occurred earlier in the year.

Figure 2. Reports Submitted 2006-2011 by Quarter and Cumulatively*



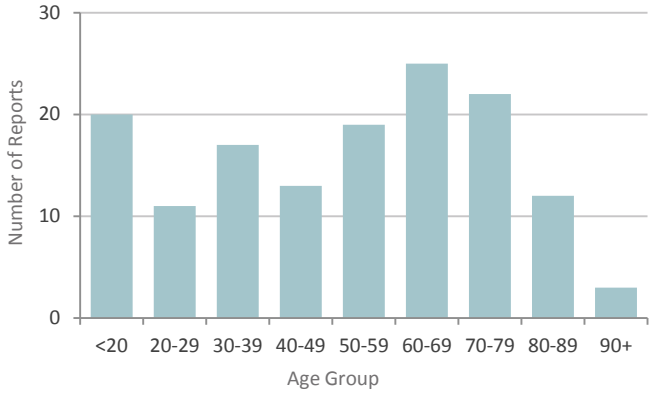
** Graph does not include five 2011 reports for which the submission date was unavailable*

[1] Using adverse event frequency estimates from Classen et al. (2011) and assuming that patient days per year stay largely similar to the 2010 figures from the Oregon Office of Health Policy and Research's publicly available databank data, reaching the Commission's current goal of 500 adverse event reports in 2015 will capture approximately 0.4% of the adverse events that result in some level of patient harm that are likely to occur in Oregon hospitals.

2011 Reporting

This report provides an aggregate overview of adverse event reports submitted to the Oregon Patient Safety Commission by hospitals in 2011 and focuses on the types of adverse events reported, the harms associated with those events, and the factors that contributed to the events. The patients impacted by these adverse events ranged in age from zero to 92. While reported adverse events were experienced by patients in every age group, the group experiencing the highest number of events were those ages 60 to 69 (see Figure 3).

Figure 3. Number of Reports by Patient Age, 2011



Types of Adverse Events

When reporting adverse events, hospitals must indicate the type of event that occurred. Hospitals select an event type from a list of 27 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 NQF's two new events—*Irretrievable loss of an irreplaceable biological specimen* and *Failure to follow up or communicate laboratory, pathology, or radiology test results.* Appendix I provides a comparison of the reporting program's original and revised event types.

In 2011, the Commission received 142 reports, which included 146 events from 21 of the 27 event types, including an *Other* category (see Table 1).[1] The four most frequently reported events were *Unintended retained foreign object*, *Fall, Medication or other substance,* and *Surgical or other invasive procedure*, which represent 53% of all reported adverse events. Together, two

[1] Four of the 142 reports identified an additional event type. These four reports consisted of a *Device or medical/surgical supply* event and a *Medication or other substance* event; a *Healthcare-associated infection* and *Pressure ulcer*; a *Healthcare-associated infection* and *Surgical or other invasive procedure* event; and a *Healthcare-associated infection* and *Care delay*.

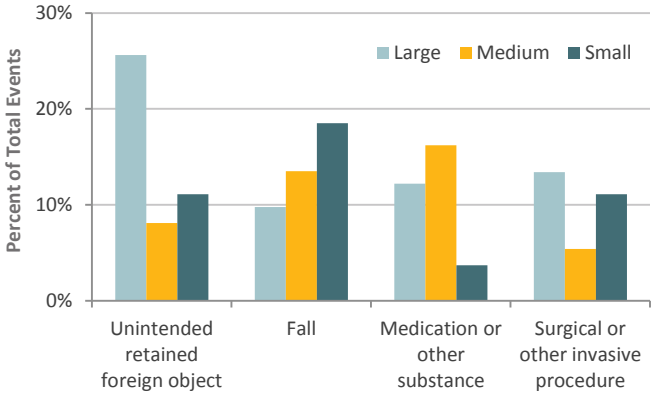
of the most frequently reported adverse events, *Unintended retained foreign object* and *Surgical or other invasive procedure,* account for 31% of all adverse events reported in 2011.

Table 1. Number and Percent of Events Reported by Type and by Hospital Size, 2011

	Large n=10		Medium n=10		Small n=13		All Hospitals N =33	
Event Type	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Unintended retained foreign object	21	26%	3	8%	3	11%	27	18%
Fall	8	10%	5	14%	5	19%	18	12%
Medication or other substance	10	12%	6	16%	1	4%	17	12%
Surgical or other invasive procedure	11	13%	2	5%	3	11%	16	11%
Care delay (including delay in treatment, diagnosis)	7	9%	0	0%	2	7%	9	6%
Healthcare-associated infection	1	1%	5	14%	3	11%	9	6%
Blood or blood product (including hemolytic reactions)	0	0%	1	3%	6	22%	7	5%
Device or medical/surgical supply (including use error)	6	7%	1	3%	0	0%	7	5%
Anesthesia	2	2%	2	5%	1	4%	5	3%
Perinatal	2	2%	2	5%	1	4%	5	3%
Pressure ulcer	4	5%	1	3%	0	0%	5	3%
Radiologic	5	6%	0	0%	0	0%	5	3%
Suicide or attempted suicide	1	1%	4	11%	0	0%	5	3%
Other event	1	1%	3	8%	0	0%	4	3%
Air embolism	0	0%	1	3%	0	0%	1	1%
Aspiration	1	1%	0	0%	0	0%	1	1%
Contaminated drugs, devices or biologics	0	0%	0	0%	1	4%	1	1%
Contaminated, wrong or no gas given to a patient	0	0%	0	0%	1	4%	1	1%
Failure to follow up lab, pathology, or radiology test results	0	0%	1	3%	0	0%	1	1%
Health information technology	1	1%	0	0%	0	0%	1	1%
Irretrievable loss of irreplaceable biological specimen	1	1%	0	0%	0	0%	1	1%
Total Events	**82**		**37**		**27**		**146**	
Total Reports	**81**		**34**		**27**		**142**	

The number of events reported differs slightly by hospital size (see Figure 4).[1] Small hospitals reported a greater proportion of *Falls* than medium or large hospitals, while medium hospitals reported a greater proportion of *Medication or other substance events* than other hospitals. Large hospitals reported a greater proportion of *Unintentionally retained foreign objects* than small or medium hospitals.

Figure 4. Top Four Most Frequently Reported Events by Hospital Size, 2011



Participants report on several different types of *Surgical or other invasive procedure* events. *Incorrect site or side* and *Laceration, perforation, puncture, or nick* events were the most common *Surgical or other invasive procedure* events reported in 2011 and comprised 81% of this event type. Table 2 summarizes the types of *Surgical or other invasive procedure* events reported in 2011. The report section, A Closer Look: How Data Informs Change, provides additional details on key surgery-related events.

Table 2. Number and Percent of *Surgical or Other Invasive Procedure* Events Reported by Type, 2011

Type of *Surgical or other invasive procedure* Event	Number	Percent
Incorrect site or side	7	44%
Laceration, perforation, puncture, or nick	6	38%
Incorrect procedure	2	13%
Expired implant	1	6%

Harm in Adverse Event Reports

When hospitals report adverse events, they assess harm related to the event. Historically, hospitals 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

[1] The Commission uses annual discharges to determine hospital size. A large hospital has over 10,000 discharges a year, a medium hospital has 3,001 to 10,000 discharges, and a small hospital has 3,000 or fewer discharges. Our current hospital sizes were determined using 2010 discharge data from the Office for Oregon Health Policy and Research and the Oregon DataBank Program (http://www.oregon.gov/OHA/OHPR/RSCH/databank.shtml).

harm (levels 7-9) and less serious harm (levels 2-6).[1] In 2011, 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).[2]

Table 3. NCC MERP Harm Categories

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

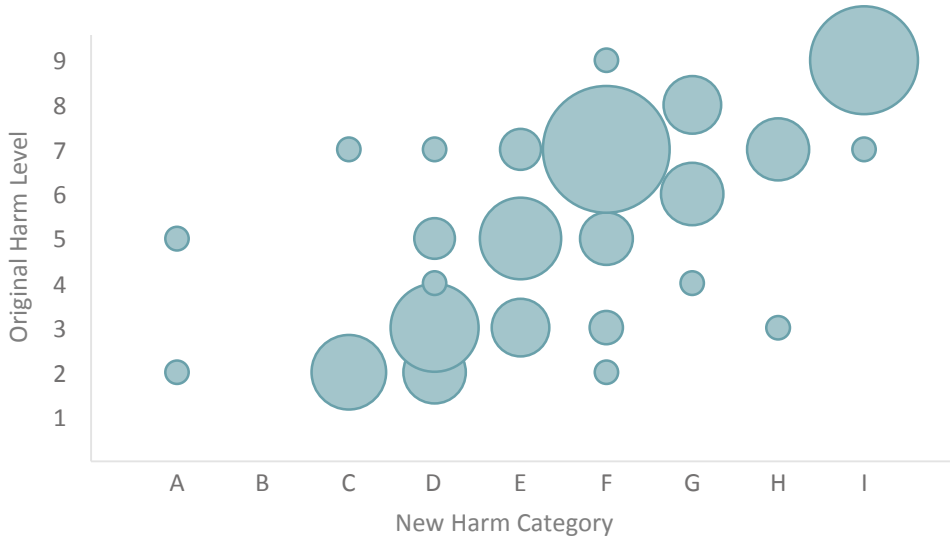
[1] Participants in the Patient Safety Reporting Program are only required to submit adverse event reports for serious harm (Oregon Patient Safety Commission, 325 Oregon Administrative Rules § 010-0025. 2006). Serious harm is defined as NCC MERP harm categories F through I (see table 3).

[2] 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.

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.[1] 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 to each event reported in 2011 using the NCC MERP algorithm. 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 II. 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. Figure 5 shows how the original harm levels recorded in 2011 converted to the new categorization system using the NCC MERP algorithm.

Figure 5. Conversion of Original Harm Levels to New Harm Categories, 2011*



** Each bubble represents the original harm level and the newly assigned harm category. The size of the bubble represents how many reports mapped in that particular pattern. Appendix II provides this information in a table format reflecting the actual number of reports in each level/category.*

In 2011, 84 reports (59%)—capturing 88 total adverse events (60%)—indicated that the event resulted in serious harm (categories F, G, H, and I). Table 4 shows the number of serious harm

[1] Algorithm available at http://oregonpatientsafety.org/reporting-programs/hospitals-submit-reports/

events by event type for 2011. The four events most frequently associated with serious harm were *Falls*, *Unintended retained foreign object*, *Medication or other substance*, and *Surgical or other invasive procedure*. Appendix III provides a table of all harms reported in 2011 by event type.

Table 4. Number and Percent of Serious Harm Events (F-I) by Event Type, 2011

Event Type	Number of Serious Harm Events	Percent of Total Events
Fall	14	10%
Unintended retained foreign object	13	9%
Medication or other substance	11	8%
Surgical or other invasive procedure	11	8%
Healthcare-associated infection	8	5%
Care delay (including delay in treatment, diagnosis)	7	5%
Perinatal	5	3%
Pressure ulcer	5	3%
Suicide or attempted suicide	5	3%
Device or medical/surgical supply (including use error)	4	3%
Other event	2	1%
Air embolism	1	1%
Anesthesia	1	1%
Aspiration	1	1%
Total Events Resulting in Serious Harm	88	60%
Total Events	146	

While hospitals are only required to report serious adverse events, the identification of less serious harm, no harm, and "near miss" events provides important opportunities to improve patient safety and prevent the likelihood for serious adverse events to occur in the future. In 2011, hospitals reported 21 (15%) less serious harm events (harm category E), 35 (25%) no harm events (categories C and D), and two (1%) near miss events (harm categories A and B). The two 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.

Hospitals reported fewer patient deaths in 2011 than in previous years (see Table 5). The reason for this apparent decrease is unclear. Possible explanations may range from under-

reporting of death events to improved identification of adverse events (or potential events) before they result in an outcome as severe as death. Hospitals may also be more effectively implementing strategies to reduce or prevent the potential for harm associated with an adverse event.

Table 5. Number of Reports Resulting in Death (Harm Category I) by Year

	2006*	2007	2008	2009	2010	2011
Number of Harm I Reports	17	26	27	29	33	22
Percent of Total Reports	32%	31%	23%	23%	26%	15%

** 2006 includes only seven months of data*

Contributing Factors

In reporting an adverse event (or potential event), hospitals identify the factors that contributed to the occurrence of the event. Contributing factors are grouped into eight categories (see box). The 142 reports submitted in 2011 identified 666 individual contributing factors across the eight categories. Facilities can select multiple contributing factors in any category.

When hospitals identify contributing factors, they are identifying opportunities to make improvements that create a more reliable system of care. On average, reports identified five contributing factors across the eight categories, with a range of 0-17 factors per report. Eight percent of reports did not indicate contributing factors. Small hospitals were more likely to submit reports without identified contributing factors than medium or large hospitals.

Contributing Factor Categories

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

The categories with the most frequently reported factors were *Communication* (66% of reports identified at least one factor), *Policy/procedure* (57%), and *Organizational* (54%) (see figure 6). These three categories have been the top most reported categories for several years running, with *Communication* consistently being the most reported. Interestingly, while *Communication* has been highly indicated since the beginning of the reporting program, hospitals are increasingly identifying factors in all other categories. This trend likely indicates that hospitals are improving their ability to identify contributing factors through investigation.

Large hospitals represent 57% of all reports submitted and largely determine the relative rankings of contributing factors. For example, while *Communication* was the most frequently reported category overall, it was the third most frequently identified category for small and medium hospitals. However, hospitals identified other categories such as *Policy/procedure* and *Organizational* more consistently, regardless of hospitals size (see Figure 7).

Over time, *Communication* has remained the top contributing factor category. In 2011, the most commonly reported factors within the *Communication* category were *Among hospital personnel* (40%), *Handoffs/shift reports* (29%), and *Available information* (17%). To aid hospitals that are working to address the communication issues that lead to adverse events, the Commission continues to highlight tools and resources that are known to help improve communication (see A Closer Look: How Data Informs Change section).

As part of the 2012 reporting system enhancements, the Commission updated the list of contributing factors to:[1]

- 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 overall was *Organizational – job orientation/training*. While hospitals have consistently identified training as a major

Figure 6. Contributing Factor Categories, 2011

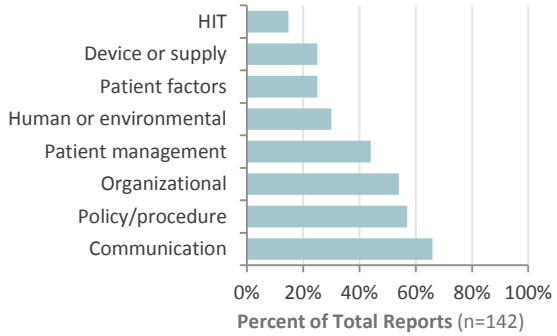
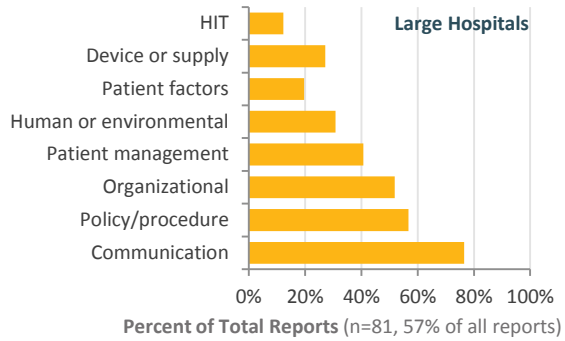
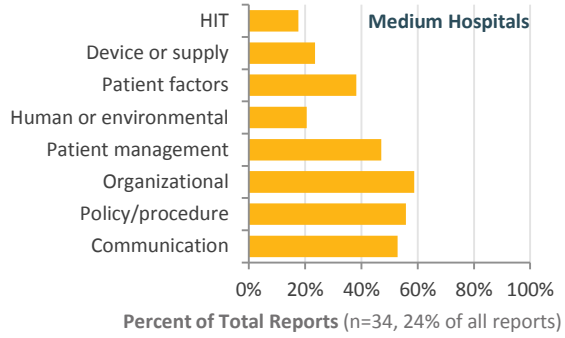
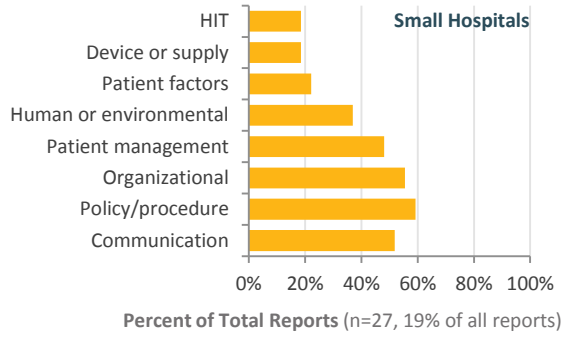


Figure 7. Contributing Factor Categories by Hospital Size, 2011







[1] More information on these enhancements is available in the *Hospital Patient Safety Reporting Program System Enhancement Summary*, http://oregonpatientsafety.org/reporting-programs/.

patient safety issue over time, some of the frequency with which hospitals selected this factor in 2011 may be due to reporting system enhancements that modified the scope of this factor.

As part of recent system enhancements, the Commission removed the second most commonly reported contributing factor in 2011—*Policy/procedure - not followed/compliant*. Although hospitals consistently identified the factor over time, the Commission found that the factor did not facilitate a closer look into why an adverse event occurred, nor did it aid hospitals or the Commission in developing effective solutions for preventing similar adverse events in the future. Instead, the Commission added four new factors to more clearly identify where breakdowns are occurring in the system: *Policy/procedure - clarity*, *Policy/procedure - provider/staff unfamiliar*, *Policy/procedure - too cumbersome*, *Policy/procedure - workaround is/was more efficient*.

A Closer Look: How Data Informs Change

A closer look into the most frequently reported adverse events reveals a detailed picture of what hospitals can learn from adverse event reports. The Commission's in-depth analysis highlights opportunities for hospitals to improve patient safety efforts for the following key event types reported in 2011: *Unintended retained foreign object*; *Surgical or other invasive procedure* and *Anesthesia*; *Laceration, perforation, puncture or nick*; *Medication or other substance*; *Fall*; and *Care delay*. While this report offers recommendations to improve patient safety efforts for each of these six event types, the common thread connecting all improvement efforts is the need to strengthen each organization's culture of safety.

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***

Establishing a "culture of safety" means creating a work environment where staff use teamwork effectively, communicate clearly, and are open about adverse events that 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 box).

Unintended Retained Foreign Object Events

The most common adverse event type reported in 2011 was *Unintended retained foreign object* (27 reports).[1] Not all retained object events took place in an operating or procedure room. Events also occurred in inpatient units (7%) as well as labor and delivery (22%). Of the 27 retained object events reported to the Commission, the most frequently reported objects were surgical sponges (see Table 6). Six reports noted sponge sizes—three of which were 4x4 sponges. Evidence indicates that using 4x4 sponges during many surgical procedures is risky given their small size. Furthermore, the sponges are difficult to identify on routine X-rays, difficult to palpate, and unreliable to identify despite the presence of radio-opaque markers (Brisson, 2009). Hospitals should pay attention to sponge size when conducting a root cause analysis in conjunction with an adverse event and should consider the risk.

[1] Some *Unintended retained foreign object* events were associated with an equipment malfunction or design flaw. Even if there has been an equipment malfunction or break, because equipment is not inherently retained, these events are solely considered retained object events.

According to discharge data provided by the Office for Oregon Health Policy and Research (OHPR), Oregon patients experienced 30 retained foreign objects in 2011.[1] Discharge data offers insight into how hospitals are doing in terms of reducing preventable adverse events related to retained objects and in terms of reporting those serious adverse events to the Oregon Patient Safety Commission. Most adverse events are not visible in hospital discharge data because events are not coded for billing purposes; however, retained objects are an exception. Since the Oregon Patient Safety Reporting Program began in 2006, hospitals have generally submitted increasing numbers of retained object reports each year to the Commission (see Table 7). Hospital discharge data allows us to see that this does not indicate an increase in retained objects but rather, an increase in the reporting of retained objects. In fact, hospital discharge data indicates that the frequency of unintentionally retained foreign objects remained fairly stable between 2002 and 2006, but since 2007, fewer and fewer retained object events have occurred (see Figure 8).

Table 6. Number and Percent of Retained Objects by Type of Object, 2011

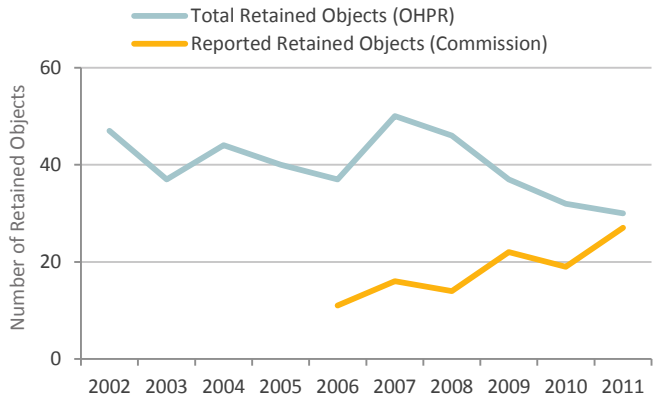
Type of Retained Object	Number	Percent
Sponge	15	56%
Whole instrument	2	7%
Instrument part or fragment	2	7%
Needle	2	7%
Guidewire	2	7%
Towel	1	4%
Other object	3	11%

Table 7. Number of Retained Objects, 2002-2011

Year	Reported Retained Objects (Commission)	Total Retained Objects (OHPR)	Percent of Total Retained Objects Reported
2002	*The Commission's hospital reporting program began in 2006*	47	
2003		37	
2004		44	
2005		40	
2006	11	37	30%
2007	16	50	32%
2008	14	46	30%
2009	22	37	59%
2010	19	32	59%
2011	27	30	90%

[1] "Foreign body accidentally left during a procedure not elsewhere classified" (ICD-9-CM 998.4). Office for Oregon Health Policy and Research, hospital discharge data, 2011.

Figure 8. Number of Retained Objects and Number of Reported Retained Objects, 2002-2011



The decline in retained object events is evidence that Oregon hospitals are taking patient safety seriously. At present, hospitals are finding widespread support and justification for improving their patient safety efforts through many national campaigns, including the Institute for Healthcare Improvement's (IHI) Triple Aim Initiative and the Federal government's Partnership for Patients (Institute for Healthcare Improvement, n.d.; U.S. Department of Health and Human Services, n.d.). Both of these campaigns encourage healthcare system improvements aimed at providing better care and lowering healthcare costs. Analysis of Oregon's 2011 *Unintended retained foreign object* events shows that retained objects cause serious harm to patients and often require additional follow-up (see Table 8). The amount of follow-up required after a retained object also means significant additional healthcare costs for hospitals, especially for Medicare patients as "Foreign Object Retained After Surgery" is on the Centers for Medicare and Medicaid Service's list of Hospital-Acquired Conditions (Centers for Medicare and Medicaid Services, 2012). When hospitals prevent retained objects, not only do patients experience better care, but the costs associated with that care are reduced.

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 to the prevention of retained objects, preferred practices, and practices that deserve further discussion and consideration.[1] Table 9 lists these recommendations, which continue to align with current standards set by the Association of Perioperative Registered Nurses (Association of Perioperative Registered Nurses, 2012).

Table 8. Most Common Actions Taken After Retained Object Was Identified, 2011

Action	Number
Additional surgery or invasive procedure	12
Removed by reopening incision or at an unrelated, previously scheduled surgery	9
Removed at doctor's office	3
Expelled at home	3

[1] Oregon Patient Safety Commission. (2007). *Preventing Unintentionally Retained Objects.* http://oregonpatientsafety.org/healthcare-professionals/hospitals/

Table 9. 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
	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 if 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 the sponges 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

Implementation of the Commission's recommendations may positively affect the potential for retained object-related adverse events to occur. The most common contributing factors

reported by hospitals for retained objects were communication among hospital personnel (52%), interruptions or distractions (44%), and handoffs or shift reports (33%). Additionally, in the narrative sections of the adverse event reporting form, hospitals identified other factors that may have contributed to the event, including:

- No wound sweep was performed (5)
- Surgical wound was closed despite an incorrect closing count (5)
- Surgical wound was closed before finishing the closing count (6)
- Lack of clarity existed regarding what should be included in the count (5)

RECOMMENDATION

Review hospital policies and procedures related to the prevention of *Unintended retained foreign objects* and revise policies and procedures as needed to reflect the Commission's 2007 recommendations. Oregon hospitals have succeeded in reducing the number of retained object events occurring each year and have made strides towards eliminating these events. Opportunities remain to strengthen prevention efforts and hospitals have the potential to identify these opportunities each time they conduct a root cause analysis of an event and submit an adverse event report. Hospitals should particularly explore the possibility for retained object events to occur in locations other than the operating or procedure room. In addition, special attention should also be given to the use of safety briefings (see page 12).

Surgical or Other Invasive Procedure and Anesthesia

The ten *Incorrect site or side* events reported in 2011 were associated with both *Surgical or other invasive procedure* events and *Anesthesia* events (see Table 10). Of the ten events, three were related to anesthesia (regional or femoral blocks), six were surgeries performed on the incorrect site or side (1 site; 5 side), and one was an incorrect site event related to an invasive procedure (fluoroscopically-guided joint injection).

Table 10. Number and Percent of *Incorrect Site or Side* Events by Event Type, 2011

Event Type	Incorrect Site/ Side Events	Total Events	Percent
Anesthesia	3	5	60%
Surgical or other invasive procedure	7	16	44%
Total	10	21	48%

The harm resulting from *Incorrect site or side* events varied from no harm to permanent harm. All three of the anesthesia-related *Incorrect site or side* events resulted in no harm (harm category C or D). Of the seven S*urgical or other invasive procedure* events, three resulted in permanent harm (harm category G), one resulted in a return to surgery (harm category F), one required no significant intervention (harm category E), and two resulted in no harm (harm category C or D).

Currently, using a safe surgery checklist is a best practice for the prevention of wrong site, wrong side, and wrong patient events. Both The Joint Commission and the World Health Organization recommend key checklist elements to address the continuing occurrence of wrong site, wrong procedure, and wrong person surgery (for more information, see Resources section). In addition, the Oregon Institute for Healthcare Improvement Network has recommended a best practice model of the safe surgical checklist (2010).

Of the *Incorrect site or side* events reported in 2011, hospitals may have been able to prevent or reduce the impact to the patient in 100% of anesthesia events and in 86% of surgical events by systematically using a safe surgical checklist.[1] In two of the three anesthesia-related *Incorrect site or side* events, the Time-out was omitted, and in the third case, a safe surgical/procedural checklist had yet to be implemented for anesthesia administration outside the operating room. Four of the seven surgical-related *Incorrect site or side* events stated that the surgeon selected the procedure site or side by relying on their memory, physical palpation, or other information that was not informed explicitly by documentation. Five reports also indicated that inadequate marking of the surgical site contributed to the event. Among these cases, surgical marking was either not performed (three cases), the mark was not visible after draping (one case), or the mark was removed prior to draping (one case). Additionally, in four of seven surgical cases, there was a limited field of vision making it difficult for staff to recognize that an adverse event was about to occur.

Using a safe surgery checklist is a best practice for the prevention of wrong site, wrong side, and wrong patient adverse events.

Time-outs are a key element of the safe surgical checklist and are specifically designed to address the types of issues that contributed to *Incorrect site or side* events in 2011.[2] However, implementation of the Time-out (and a checklist in general) 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 such as an inadequate Time-out. If staff are not comfortable speaking up about these types of lapses, the impact of the safe surgical checklist will remain limited.

---

[1] In one reported surgical *Incorrect site or side* event, the surgical checklist was properly used, but the initial documentation recorded in a pre-surgical office visit was incorrect.

[2] The Time-out is an opportunity for the entire surgical team to huddle and briefly discuss and agree upon the patient's name and intended procedure.

RECOMMENDATION

Review the use of the safe surgical checklist with a particular focus on implementation of Time-outs including surgical site markings. While accreditation standards require hospitals to comply with Universal Protocol, ongoing *Incorrect site or side* events indicate that systematic use of the protocol may decrease over time. Hospitals should review associated policies and procedures and examine how a facility's culture of safety can contribute to more effective implementation of a safe surgical checklist, with specific attention given to the use of Time-outs.

Laceration, Perforation, Puncture, or Nick

Lacerations, perforations, punctures, or nicks are a common types of adverse events that occur predominantly during surgical or other invasive procedures. For the purposes of this report, we refer to these four items collectively as "perforations." Depending on the nature of the event, perforations may be reported to the Oregon Patient Safety Commission as a *Surgical or other invasive procedure* event or as a *Device or medical/surgical supply* event. In the case of a *Device or medical/surgical supply* event, the device or supply issue is considered the adverse event and the perforation is considered the harm.

In 2011, eight reports involving perforations were submitted, two as *Device or medical/surgical supply* events that resulted in bowel perforations, and six as *Surgical or other invasive procedure* events. Perforations were one of the most frequently reported *Surgical or other invasive procedure* events (38%). All eight perforations resulted in serious harm and were the only type of *Surgical or other invasive procedure* event to result solely in serious harm. The instances of perforation include two deaths, one permanent harm, three temporarily life-threatening situations, and two temporary

Factors that Contribute to Perforations

Understanding perforations as patient safety events rather than as known risks requires the identification of contributing factors surrounding the event. Associated environmental factors may include:

- Operating room traffic
- Noise
- Distractions and interruptions
- Time pressures to turn over the room
- Team cohesion
- Use of new equipment
- Implementation of new procedure
- Patient factors such as: urgency of the surgery, American Society of Anesthesiologists physical status classification, fragility of the tissues, or unusual anatomical characteristics

harms requiring significant interventions. Neither of the two *Device or medical/surgical supply* perforation events occurred in an operating or procedure room. One event involved the misconnection of a nasogastric tube to oxygen and the other involved a failure to lower settings on a patient's personal continuous positive airway pressure (C-PAP) machine post-surgery.

What is striking about hospitals' responses to all six of the surgical perforation events is that the event was accepted as unavoidable. In most of these cases, all related follow-up was dedicated to responding to the harm caused by the perforation, rather than to identifying the original cause of the perforation (see box on page 18).[1] Three of the surgical perforation reports labeled the perforation as a "known risk," indicating that the perforation was not preventable and that investigating the perforation's cause was unnecessary. For example, one perforation resulted in post-operative bleeding and the investigation looked exclusively at the timeliness of recognition and response to the bleeding. While examining the response to subsequent injuries due to the original perforation is important and necessary, such an examination 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.[2] "Unavoidable" events should be used as opportunities to identify prevention strategies, improve practice, and strengthen the culture of safety.

RECOMMENDATION

Track occurrence rates and conduct investigations for events that may initially appear "unavoidable." When faced with an adverse event that appears to be "unavoidable," hospitals should investigate the root cause of the event and identify possible prevention strategies.

[1] By contrast, investigations into the *Device or medical/surgical supply* event perforations were able to identify the cause of the perforation and take steps to prevent future occurrence.

[2] Additionally, organizations that deem certain adverse events to be "unavoidable" may be missing an opportunity to provide written notification. Participation in the Oregon Patient Safety Commission's adverse event reporting program requires that hospitals provide notification in writing to patients involved in serious adverse events. Although the six surgical perforation events that occurred in 2011 involved serious harm (harm categories F, G, H or I), none of the patients involved received written notification of the event.

Medication or Other Substance

In 2011, hospitals submitted seventeen reports related to *Medication or other substance* events (see Table 11). The most frequently occurring medication-related events were *Incorrect medication or substance, Incorrect dose,* and *Medication or substance omitted*.

Table 11. Number and Percent of Reported *Medication or Other Substance* Events by Type, 2011

Type of *Medication or other substance* Event	Number	Percent
Incorrect medication or substance	4	24%
Incorrect dose	3	18%
Medication or substance omitted	3	18%
Incorrect strength	2	12%
Medication or substance contraindicated	2	12%
Incorrect rate	1	6%
Adverse reaction not due to allergy or known contraindication	1	6%
Drug interaction	1	6%

Building a strong culture of patient safety requires the creation of a robust medication safety program focused on the prevention of adverse events. Designing a safety program that supports the complexity of medication management is challenging given the variety of process steps where breakdowns can occur: purchasing, storing, prescribing/ordering, transcribing, preparing, dispensing, administering, and monitoring.

The *Medication or other substance* events reported in 2011 were associated with three stages of the medication management process: prescribing/ordering, administration, and transcribing. Hospitals indicated that the most common challenges associated with medication management included:

- Medication reconciliation in the form of both paper and health information technology
- Human factors involving work-arounds associated with feeling rushed or hurried, distractions, and interruptions

In addition to medication reconciliation and human factors, teamwork and communication continue to be a primary opportunity for improvement. Daily or weekly safety briefings are a tool that can be 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, see Resources section).

Medication Reconciliation

Preventing medication-related events requires the implementation of strong action plans that force reliability into the system. In many cases, hospitals can avoid prescribing/ordering errors

with strong medication reconciliation.[1] In July 2011, The Joint Commission incorporated medication reconciliation into their National Patient Safety Goal #3: Improving the safety of using medications, which requires that organizations "maintain and communicate accurate medication information" (Agency for Healthcare Research and Quality, n.d.). Hospitals can improve medication reconciliation through a variety of avenues. One useful tool for proactively evaluating medication management stages and identifying possible areas of risk is the Failure Mode and Effects analysis (FMEA). FMEA is carried out by a multidisciplinary team and involves examining the use of new products and the design of new services and processes to determine points of potential failure and the effect of those potential failures (Institute for Safe Medication Practices, 2001).

National Patient Safety Goal #3 also requires that organizations "compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies." None of the action plans submitted for *Medication or other substance* events in 2011 described improvements that include involving the patient in the medication reconciliation process. In addition to staff review of medications at admission, transfer, and discharge, the patient can be a valuable partner in many cases. At a minimum, engaging the patient and family at discharge to review the list of medications can prevent discrepancies and help reinforce any changes that occurred during their hospital stay.

Human Factors

In the 2011 reports of *Medication or other substance* events, hospitals frequently indicated human factors were an issue. In descriptions of what happened before a medication-related event occurred, some hospitals noted factors like staff rushing to turn over a room for the next patient or staff being distracted by another patient admission. Removing some of the chaos associated with healthcare delivery is often impossible; however, even in chaotic environments, hospitals can establish more reliable systems to help avoid an adverse event. Many of the action plans hospitals developed in response to medication-related adverse events demonstrated strong examples of how to establish more reliable systems, including:

- Remove expired medications and have a routine process to purge them
- Remove the opportunity for mix-ups during procedures by setting up only what is needed and double-checking the medications planned for administration during the Time-out process
- Implement a clear policy and procedure for high-alert medications (for more information, see Resources section); define the independent double-check process to follow when appropriate

[1] The Agency for Healthcare Research and Quality defines medication reconciliation as "the process of avoiding such inadvertent inconsistencies across transitions in care by reviewing the patient's complete medication regimen at the time of admission, transfer, and discharge and comparing it with the regimen being considered for the new setting of care (n.d.).

- Collaborate across pharmacy, nursing units, the emergency department, and other appropriate ancillary services like laboratory and radiology, to minimize the opportunity for miscommunication

RECOMMENDATION

Consider conducting a review process such as the Failure Mode and Effects Analysis to evaluate your hospital's medication reconciliation process. Given the speed with which new medications and services are adopted, hospitals should regularly conduct reviews of the medication reconciliation process to ensure that vulnerable areas or processes are identified before the occurrence of an adverse event.

Engage the patient and family at discharge to review their list of medications. Hospitals should consider ways to engage patients and families in medication reconciliation at the time of discharge to prevent discrepancies and help reinforce any changes that occurred during their hospital stay.

Falls

Falls are one of the most frequently reported adverse events both in 2011 and over the history of the adverse event reporting program. In 2011, 18 fall events were reported, representing 12% of all reported events. Five of the 18 patients had a history of previous falls, including four who were admitted following a fall at home. While the falls reported to the Commission occurred in adults from age 49 to 90, falls are a risk for patients of any age and in previous years we have received reports of newborn or pediatric drops or falls.

Most fall events reported in 2011 (78%) resulted in serious harm, the majority of which were temporary harm requiring significant intervention (harm category F, 61%). Ninety-four percent of fall events resulted in physical injury, most of which were fractures. In 72% of falls, the patient required a surgical repair. Table 12 details the patient harms that occurred after the reported falls.[1]

[1] For all reported falls, staff members were not near the patient to provide assistance once they began to fall. For two falls, hospitals noted that the fall was observed by a staff member who was in the room with the patient when the fall occurred.

Table 12. Number and Percent of Fall Reports by Resulting Physical Injury to Patient, 2011

Type of Physical Injury	Number	Percent
Fracture	12	67%
Hip	*6*	*33%*
Arm or wrist	*3*	*17%*
Leg	*2*	*11%*
Other	*1*	*6%*
Return to surgery	2	11%
Intracranial injury	1	6%
Cardiac arrest	1	6%
Minor abrasions	1	6%
No physical injury	1	6%

The variety of factors that may contribute to a fall add complexity to any prevention effort. Falls may be categorized according to whether they arise from factors related to the patient (intrinsic), the medical therapy, or the environment (extrinsic) (see Table 13). While many of these factors can be anticipated, others cannot. In 2011, 17 of the reported falls could be anticipated and only one fall was considered to be unanticipated (due to cardiac arrest). Of the 17 falls that could be anticipated, 16 were related to intrinsic conditions that included:

- Multiple comorbidities (13)
- Age 65 or older (10)
- Cognitive/psychological status (7)
- Recent history of falls (5)
- Mobility/balance/strength problems (4)

Table 13. Risk Factors for Falls*

	Related to the Person's Condition (Intrinsic)	Related to Medical Therapy	Related to the Environment (Extrinsic)
Anticipated	Recent history of falls (most significant risk factor) Incontinence Cognitive/psychological status Mobility/balance/strength problems Dizziness/vertigo Postural hypotension Age (over 65 years) Osteoporosis Overall poor health status	Medications: Analgesics Diuretics Hypnotics/sedatives Prolonged length of stay	Environment (wet floor, floor glare, cluttered room, poor lighting, inadequate handrail support, monochromatic color schemes, loose cords or wires) Inappropriate or lack of footwear Low toilet seat Wheels on beds or chairs Restraints (including side rails in the up position) Broken or unsafe equipment (unsteady IV poles) Beds left in high positions
Unanticipated	Seizures Cardiac arrhythmias CVA or TIA Syncope "Drop attacks"	Individual reactions to medications	

** Modified from Veterans Health Administration. (2004). National Center for Patient Safety 2004 Falls Toolkit. Retrieved from http://www.patientsafety.gov/SafetyTopics/fallstoolkit/index.html.*

Hospital implementation of fall precautions is essential; however, the falls reported in 2011 demonstrate that fall precautions alone do not create a sufficient fall prevention program. Of the falls reported to the Commission, 13 stated that a fall risk assessment had been done and in all 13 cases the patient was identified to be at some level of fall risk, many as high risk. These patients were put on fall precautions, which vary from facility to facility and may include any of the following (among other interventions):

- Some form of visible fall risk identification (a sticker or door magnet)
- Non-slip socks
- Bed or tab alarms
- Side rails on the bed
- Intentional hourly rounding
- Bed set in low position
- Being placed in a room visible from the nurses' station
- Making sure a call light is in easy reach

Basic fall precautions such as these may mitigate the risk of a fall if a caregiver is nearby but do not, in and of themselves, actually prevent a fall. Including such interventions in fall prevention programs can provide a false sense of security and keep hospitals from identifying and

implementing interventions that have the potential to actually prevent a fall. For example, in 62% of fall-related adverse event reports where patients were identified as being at risk for a fall, hospitals identified bed or tab alarms as part of the patient's program of care.[1] The alarm does not prevent the fall; rather, the alarm merely notifies caregivers that the patient is out of bed. Caregivers then have an opportunity to mitigate the risk of a fall if they can get to the patient quickly enough.[2]

While hospitals are familiar with the idea that bed and tab alarms cannot prevent falls, the use of alarms is frequently referred to in adverse event reports as being part of the fall prevention program. A variety of tools and resources are available to help hospitals create more effective fall prevention programs that incorporate stronger precautions, rather than simply implementing practices that may mitigate falls (for more information, see Resources section).

In addition to establishing more effective fall prevention plans, hospitals can positively impact fall-related patient safety through more effective education and training. Hospitals respond to falls with a variety of education and training plans for staff. In some cases, hospitals provide one-time education to individual staff. In other cases, hospitals integrate lessons learned into routine education and training opportunities. Table 14 provides examples of less, more, and most efficient action plans related to staff education and training.

Falls prevention resources are available in the References section at the end of this report.

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 unit based competencies with follow-up; routine evaluation strategies

The most effective education and training action plans are ones that integrate prevention practices into staff competency requirements and 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 fall prevention expectations.

---

[1] Bed alarms are pressure sensitive monitors that alert the nurses' station when a patient gets out of bed; tab alarms work similarly, only they are attached to the patient's clothes and signal when the patient is moving.

[2] In practice, bed and tab alarms frequently are turned off, improperly programmed, or cause alarm fatigue—a situation in which the frequency of alarms causes staff to disable, silence, or ignore alarms.

RECOMMENDATION

Establish a falls-related education and training plan that includes competency requirements and routine evaluation and follow-up of staff. The Commission acknowledges that a multifaceted approach to fall prevention is needed; however, 2011 reports indicate that hospitals will benefit immediately from implementing more effective strategies for ongoing education and training of staff.

Care Delays

In 2011, Oregon hospitals submitted nine adverse event reports related to care delays. These events were primarily related to delay in diagnosis, delay in test results, or equipment-related delays. Seventy-eight percent of the care delays reported in 2011 resulted in serious harm. In eight (89%) of the care delay events, communication was identified as a contributing factor. Hospitals most frequently identified handoffs as the specific communication element that contributed to the event.

Hospitals are well aware that communication continues to be one of the most common contributing factors associated with adverse events; however, while hospitals continue to improve communication strategies and monitoring systems, care delay events continue to occur. Extensive resources are available to help hospitals strengthen communication, particularly in the areas of handoffs and establishing structured systems of communication. The Commission encourages hospitals to explore and consider using communication strategies such as Situation-Background-Assessment-Recommendation (SBAR) (see box).

Care delays have not historically been included as a unique event type on the Commission's adverse event reporting form. Until recently, hospitals have reported adverse events related to care delays as an *Other* event. In response to hospitals ongoing identification of adverse events related to care delays, the Commission added *Care delay* as an event type on the adverse event reporting form in 2012.

SBAR

Situation-Background-Assessment-Recommendation (SBAR) is an effective communication tool for gaining appropriate awareness of a situation by creating a solid framework for communication. Transitions and handoffs in patient care are good opportunities to apply the SBAR tool and standardize language and communications, which can help to prevent accidental patient harm. For more information, see Resources section.

RECOMMENDATION

Continue to identify and report adverse events related to care delays. By providing hospitals with a more explicit opportunity to identify and report *Care delay* events in the adverse event reporting form, the Commission is in a better position to collect more information about the factors that contribute to care delays. Having more information, especially with regard to how hospitals are working to prevent care delays, the Commission can readily share the lessons learned throughout the state.

Use a structured communication tool. Hospitals should use structured communication tools to ensure that important messages are heard and acted upon.

Reporting Targets

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

Each year, the Commission identifies leading participants and issues awards to the top performers based on established recognition targets. The Commission's website will identify all hospitals that meet or exceed recognition targets. Recognition targets for 2012 focus on the **quantity**, **quality**, and **timeliness** of reports submitted. Additionally, the Commission considers hospital compliance with state written notification requirements when awarding leading participants. 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/hospitals/.

Quantity

The Commission measures quantity as the number of reports submitted by a reporting program participant. Oregon hospitals submitted 142 adverse event reports in 2011. This is the highest number of annual reports submitted to date and aligns with the estimated number of reports the Commission expected to see for the year (145). Fewer hospitals submitted reports in 2011 (33) than in 2010 (37). For the second consecutive year, all but one large hospital submitted at least one adverse event report in 2011. More than half of the medium hospitals (59%) and almost half of the small hospitals (46%) submitted adverse event reports in 2011. Table 15 provides a summary of reporting by hospital size.

Hospitals submitted slightly more reports in 2011 than in 2010; however, fewer hospitals submitted reports in 2011 than in 2010.

Table 15. Report Submissions by Hospital Size, 2011*

	Count of Hospitals			Count of Reports Submitted	
Hospital Size	Number that Reported	Participating Hospitals	Percent that Reported	Number	Percent
Large	10	11	91%	81	57%
Medium	10	17	59%	34	24%
Small	13	28	46%	27	19%
Total	**33**	**56***	**57%**	**142**	

** Table does not include two hospitals that became participants in late 2011.*

Altogether, hospitals that submitted a report in 2011 accounted for 80% of Oregon's hospital discharges.[1] Of the hospitals that reported in 2011, large facilities represented 59% of Oregon discharges, while medium and small facilities represented 15% and five percent, respectively.

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.[2] The quantity target for 2011 was 200 reports—a request for 58 more reports than what hospitals actually submitted.[3] If each hospital had submitted one additional report in 2011, the Commission would have achieved the 2011 quantity target. Although hospitals fell short of that target, the number of reports submitted in the second half of the year almost doubled after the Commission published reporting targets in July 2011.

If each facility had submitted one additional report in 2011, hospitals would have achieved the 2011 quantity target.

Although hospital report submission rates align with projected estimates and hospitals are working to meet the Commission's quantity targets, the number of reports submitted annually falls short of the actual number of adverse events that may be occurring in Oregon each year. Classen et al. (2011) estimate that internal hospital reporting programs that are focused on voluntary reporting of adverse events by hospital personnel only capture around one percent of actual adverse events, far below the 90% captured by the Institute for Healthcare Improvement's Global Trigger Tool.

Quality

When reviewing submitted adverse event reports, the Commission uses four criteria to determine if reports are of acceptable quality: complete, thorough, credible, and having a meaningful action plan (see box on page 30). In 2011, 94% of the reports submitted by hospitals were determined to be acceptable (see Table 16).

---

[1] Based on first to third quarter 2011 Grand Total Discharges data from the Office for Oregon Health Policy and Research and the Oregon DataBank Program, http://www.oregon.gov/OHA/OHPR/RSCH/databank.shtml

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

[3] The Commission aimed to have a minimum of 200 reports submitted in 2011 in order to work toward the goal of having a minimum of 500 hospital reports submitted by 2015. The Commission calculates the quantity target for hospitals using discharge data provided by the Office for Oregon Health Policy and Research and the Oregon DataBank Program.

Table 16. Acceptable/Not Acceptable Adverse Event Reports by Hospital Size, 2011

	Acceptable		Not Acceptable
	High Quality	Not High Quality	
Large	75	4	2
Medium	28	5	1
Small	18	3	6
All Hospitals	**121**	**12**	**9**

Only nine reports (6%) did not meet the criteria for acceptability. Most of these reports failed to identify a root cause of the adverse event or meet the criteria used to evaluate action plans. By and large, these nine reports were from hospitals with new staff who were completing and submitting reports for the first time.

The 2011 quality target for hospitals called for 95% of reports to be of acceptable quality and, of those reports that were acceptable quality, for 86% to be of high quality.[1] Hospitals did meet both of the quality targets set for 2011. In total, 94% of all reports were of acceptable quality and, of those reports, 90% were of high quality.

Quality Criteria

A report is **complete** if it contains all of the information requested in the event report form, or explains to the Commission's satisfaction why that information is not available or not necessary to provide.

A report is **thorough** if the root cause analysis includes an analysis of all relevant systems issues and shows evidence of an inquiry into all appropriate areas.

A report is **credible** if it shows evidence that the investigation included leadership participation and was internally consistent.

A meaningful **action plan** clearly describes improvement strategies designed to minimize risk.

The Commission will be providing more detailed information about how acceptable quality is evaluated as a part of ongoing 2012 reporting system enhancements.

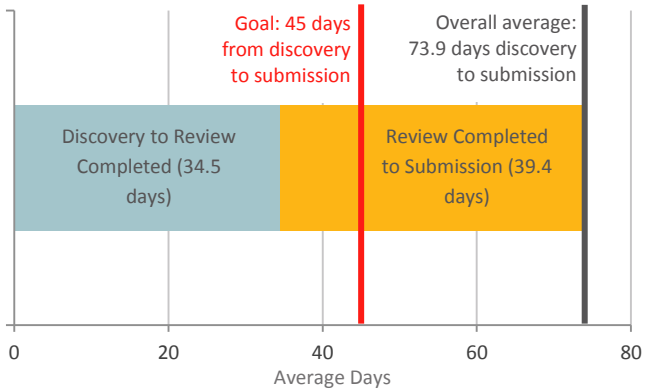
[1] Reports that exceed the standard for acceptability are considered to be of high quality. The high quality measurement aligns with criteria used by the Oregon Public Health Officer who certifies the reporting program and provides an assessment of the quality and quantity of adverse event reports submitted 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 three pieces of time-related data for adverse events regardless of harm category (date event occurred, date event was discovered, date report was submitted) and one additional date for serious harm events (date facility completed their review and 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 hospitals submit a completed adverse event report within 45 calendar days of discovery of a reportable serious adverse event (Oregon Administrative Rules, 325-010-0025(3) (2006)).

In 2011, the average time between event discovery and report submission for all reports was 80 days (an improvement of three weeks over the average time of 103 days in 2010).[1] The median time between discovery of an event and submission of a report in 2011 was 55 days. Although the median does not reflect the wide range of discovery to submission times (0-369 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. For the subset of reports that provided a completion date for their review and analysis process (n=84), that process took an average of 35 days to conduct and complete after the event was discovered. Once the review and analysis were complete, hospitals took an average of 39 days to submit those adverse event reports to the Commission (see Figure 9).

Figure 9. Breakdown of Average Days Spent from Event Discovery to Report Submission, 2011 (n=84*)



**Less serious harm reports are not required to provide the date the hospital completed a review and analysis of the event. Fifty-eight reports were either less serious harm reports or provided incomplete data and were not included in these averages.*

Of the 84 serious harm reports submitted in 2011, 49 (53%) did not meet the State's timeliness standard (see Table 17). Of those 49 reports, 12 indicated that the review was completed within the 45-day standard but averaged an additional 20 days until submission. The other 37 reports that did not meet the State standard averaged 51 days between review completion and submission. This indicates that once the 45-day standard has passed, reports are likely to sit on a desk or wait in a queue for internal approval for much longer than those reports still able to meet that standard. Hospitals who have historically not complied with the State's timeliness

[1] N=136; six event reports did not provide sufficient information to be included in the timeliness calculation.

standard may improve their compliance rates simply by increasing the speed with which they submit reports to the Commission after the event review and analysis is complete.

Table 17. Number and Percent of Reports by Compliance with State Timeliness Standard, with Average Number of Days between Completion of Review and Submission, 2011

	Number	Percent	Average Number of Days
Met State Standard (submitted report within 45 days of event discovery) (n=35)			
Completed review ≤45 days	35	100%	12 days
Did Not Meet State Standard (submitted report more than 45 days after event discovery) (n=49)			
Completed review ≤45 days	12	24%	20 days
Completed review in >45 days	37	47%	51 days

To help hospitals 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 target for timeliness was for hospitals to submit 80% of all reports within 70 days of discovery. Only 15 hospitals that submitted reports in 2011 met the timeliness target for 2011 (see Table 18), but an additional ten hospitals could have met the target had one more of their 2011 reports been submitted to the Commission within 70 days of event discovery.[1]

Hospitals that have historically not complied with the State's timeliness standard may improve their compliance rates simply by increasing the speed with which they submit reports to the Commission after the event review and analysis is complete.

Table 18. Number of Reports and Facilities that Achieved 2011 Timeliness Target

	Reports (n=136)		**Hospitals** (n=33)	
	Number	Percent	Number	Percent
Met 2011 Target	77	57%	15	45%
Did Not Meet 2011 Target	59	43%	18	55%

[1] In 2012, the Commission's timeliness target is for hospitals to submit 75% of all reports within 45 days of discovery. See *Patient Safety Reporting Program Recognition Targets for 2012*, http://oregonpatientsafety.org/reporting-programs/.

Original Harm Level Definitions

Harm Level 1
Did not reach the patient

Harm Level 2
No detectable harm

Harm Level 3
Minimal temporary harm

Harm Level 4
Minimal permanent harm

Harm Level 5
Moderate temporary harm

Harm Level 6
Moderate permanent harm

Harm Level 7
Serious temporary harm

Harm Level 8
Serious permanent harm

Harm Level 9
Death

Written Notification

Oregon Administrative Rules require that hospitals provide written notification of reportable serious adverse events to the patient or patient's personal representative (OAR 325-010-0045). Because 2011 reports were submitted using the Commission's original, numerical process for assigning harm levels, our analysis of written notification in Oregon is presented using the old system of assigning harm (see box).[1] According to original harm level definitions, hospitals were required to provide written notification for all events with a harm level of 7, 8, or 9. Written notification was also required for any *Unintended retained foreign object*, *Incorrect patient surgery*, *Incorrect procedure surgery*, or *Incorrect site or side surgery* events, regardless of level of harm.

In 2011, hospitals submitted 87 reports of serious adverse events requiring written notification. Of these events, 40 (46%) patients or their families received a letter from the hospital (see Table 19). Written notification practices varied depending on the degree of harm associated with the event. Hospitals completed written notification in 46% (19/41) of the serious *temporary* harm events (harm level 7) but only in 30% (6/20) of the death events (harm level 9).

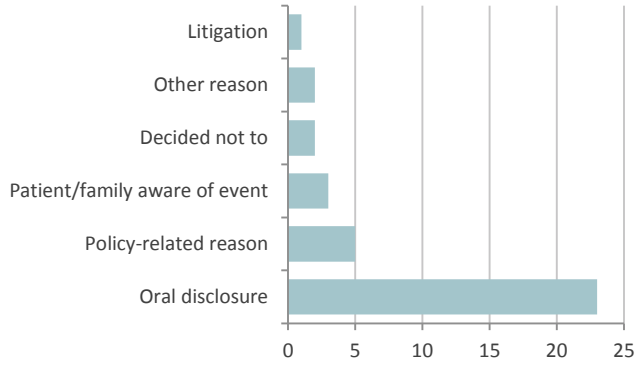
Table 19. Written Notification Completion When Required, 2011

	Number	Percent
Written Notification Provided	40	46%
Written Notification NOT Provided	47	54%
Total	87	

Of the adverse event reports where written notification was required but not provided (47/87), some reports provided reasons for not providing written notification (see Figure 10). The most common reason given for not providing written notification was that the hospital had provided oral disclosure, often through multiple conversations.

[1] Starting in 2012, the Commission will assess all written notification requirements according to the definition of reportable serious adverse event as defined by the newly adopted National Coordinating council for Medication Error Reporting and Prevention harm categories (see Appendix II).

Figure 10. Primary Reason for Not Providing Written Notification, 2011



Starting in 2012, the Commission is defining reportable serious adverse events based on newly adopted harm categories from the National Coordinating Council for Medication Error Reporting and Prevention. Reportable serious adverse events are those that fall into the following harm categories:

Category F	An event occurred that may have contributed to or resulted in temporary harm to the patient and required a significant intervention
Category G	An event occurred that may have contributed to or resulted in permanent patient harm
Category H	An event occurred that required intervention necessary to sustain life
Category I	An event occurred that may have contributed to or resulted in patient's death

Additionally, the Oregon Patient Safety Commission encourages facilities to strongly consider providing written notification for harm **Category E** events—events that may have contributed to or resulted in temporary harm to the patient but did not require a significant intervention. The State of Oregon requires that written notification be consistent with internal communication policies of the hospital and that it be timely. Recognizing the significant difficulty many hospitals have had in meeting this requirement, the Commission has published the *Oregon Adverse Event Disclosure Guide* to serve as a resource for physicians and healthcare organizations.[1]

[1] Oregon Patient Safety Commission. (2012). Oregon Adverse Event Disclosure Guide. http://oregonpatientsafety.org/healthcare-professionals/disclosure-guide/

References

Agency for Healthcare Research and Quality, Patient Safety Network. (n.d.). Patient Safety Primer: Medication Reconciliation. Retrieved from http://psnet.ahrq.gov/primer.aspx?primerID=1

Association of Perioperative Registered Nurses. (2012). Recommended Practices for Prevention of Retained Surgical Items. In R. Conner, J. Blanchard, B. Burlingame, B. Denholm, S. Giarrizzo-Wilson, M. Ogg & S. Van Wicklin (Eds.), Perioperative Standards and Recommended Practices (pp. 313-332). Denver, CO: AORN, Inc.

Brisson P. (2009). Prevention of Retained Foreign Objects. Bulletin of the American College of Surgeons.

Centers for Medicare & Medicaid Services. (2012, April 26). Hospital-Acquired Conditions. Retrieved from https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html

Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, James BC. (2011). 'Global Trigger Tool' Shows that Adverse Events in Hospitals May be Ten Times Greater than Previously Measured. Health Affairs, 30(4), 581-589.

Institute for Health Care Improvement. (n.d.). Triple Aim Initiative. Retrieved from http://www.ihi.org/offerings/Initiatives/TripleAim

Institute for Safe Medication Practices. (2001, October 17). Failure Mode and Effects Analysis (FMEA): A Tool to Help Guide Error Prevention Efforts. Retrieved from http://www.ismp.org/tools/FMEA.asp

National Quality Forum (NQF). Safe Practices for Better Healthcare–2010 Update: A Consensus Report. Washington, DC: NQF; 2010. Retrieved from http://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_2010_Update.aspx

Oregon Institute for Healthcare Improvement Network. (2010). Safer Surgeries: Implementation of the WHO Surgical Safety Checklist in Oregon. Retrieved from http://oregonpatientsafety.org/docs/reports/SSC_Report_July_2010_ORIHIN.pdf

U.S. Department of Health & Human Services. (n.d.). Partnership for Patients. Retrieved from http://www.healthcare.gov/compare/partnership-for-patients/

Wachter, R.M. (2008). Understanding Patient Safety. United States: McGraw Hill, p. 6.

Resources

Culture of Safety

Agency for Healthcare Research and Quality, Patient Safety Network. (n.d.). Patient Safety Primers: Safety Culture. Retrieved from http://psnet.ahrq.gov/primer.aspx?primerID=5

Falls

Veterans Health Administration, National Center for Patient Safety Fall Prevention and Management. (n.d.). Fall Prevention and Management Aid. Retrieved from http://www.patientsafety.gov/CogAids/FallPrevention

Morse JM. (2009). Preventing Patient Falls: Establishing a Fall Intervention Program (Second ed.). New York: Springer. Retrieved from http://www.springerpub.com/samples/9780826103895_chapter.pdf

Medication

Institute for Healthcare Improvement. (2011, April 28). Conduct Safety Briefings. Retrieved from http://www.ihi.org/knowledge/Pages/Changes/ConductSafetyBriefings.aspx

Institute for Safe Medication Practices. (2012). ISMP's List of High-Alert Medications. Retrieved from http://www.ismp.org/tools/highalertmedications.pdf

Retained Objects

The Joint Commission. (n.d.). Speak Up: The Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery. Retrieved from http://www.jointcommission.org/assets/1/18/UP_Poster1.PDF

Situation-Background-Assessment-Recommendation

Institute for Healthcare Improvement. (2011, June 30). SBAR Technique for Communication: A Situational Briefing Model. Retrieved from http://www.ihi.org/knowledge/Pages/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.aspx

Surgical and Other Invasive Procedure

Association of PeriOperative Registered Nurses. (n.d.). Comprehensive Checklist. Retrieved from 6http://www.aorn.org/Clinical_Practice/ToolKits/Correct_Site_Surgery_Tool_Kit/Comprehensive_checklist.aspx#axzz22E1UZ2tB

Appendix I: Comparison of Patient Safety Reporting Program (PSRP) Events, Administrative Rules Appendix A, Original Reporting Form, and NQF 2011 Update

PSRP	Administrative 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	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	1) GENERAL: 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	1) GENERAL: 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)	5B) Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products	Hemolytic reaction	4B) Care management: Patient death or serious injury associated with unsafe administration of blood products	"Blood incompatibility" is considered a Medicare HAC Appendix A's "General" category defines this event as “hemolytic reaction;” however, the PSRP accepts reports associated with any unsafe administration of blood products.

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Burn (unrelated to use or misuse of a device or medical/surgical supply)	6C) 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)	1) GENERAL: 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	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	6B) 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	Wrong or contaminated gas given to a 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's "General" category defines this event as wrong or contaminated gas only; however, the PSRP also accepts reports of no gas.
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	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

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Discharge or release of a patient of any age, who is unable to make decisions, to an unauthorized person	4A) Infant discharged to the wrong person	Infant discharged to the wrong person	3A) Patient protection: Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person	Appendix A limits this event to infants discharged to the wrong person. The PSRP definition has been broadened to include discharge or release of any person, both in keeping with NQF and to better align with the other PSRP reporting segments (ambulatory surgery centers and nursing homes). Appendix A's "General" category covers discharges of older people to unauthorized persons.
Electric shock	6A) 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
Elopement	4B) Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours	Patient elopement (disappearance) for more than four hours	3B) Patient protection: Patient death or serious injury associated with patient elopement (disappearance)	PSRP updated in 2012 to better align with other PSRP reporting segments Appendix A limits this to elopements for more than four hours; however, the PSRP accepts reports of elopements for less than four hours if the reporter feels they offer an important patient safety lesson.
Failure to follow up or communicate laboratory, pathology, or radiology test results	1) GENERAL: Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	4I) Care management: Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results	PSRP event type added in 2012 to reflect NQF 2011 Update The PSRP category includes hyperbilirubinemia (see note for NQF retired event 4I: Care Management at end of this table)

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Fall	6D) 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)	1) GENERAL: Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Hospital-acquired infection	--	CLABSI, CAUTI, SSIs, and "care of the ventilated patient" addressed in NQF's list of recommended safe practices (see references for link)
Health information technology (HIT)	1) GENERAL: Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Equipment	--	Appendix A's "General" category does not include HIT; however, the PSRP accepts reports of HIT in order to be more inclusive and align with AHRQ Common Formats.
Irretrievable loss of an irreplaceable biological specimen	1) GENERAL: 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
Maternal	5C) Maternal death or serious physical injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Maternal labor or delivery	4C) Care management: Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Appendix A defines this event as death or serious physical injury associated with low-risk pregnancy; however, the PSRP accepts reports of maternal events associated with any level of risk if the reporter feels they offer an important patient safety lesson.

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Medication or other substance	5A) 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)
Perinatal	5H) Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams	Perinatal	4D) Care management: Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy	Appendix A defines this event as death or serious physical injury associated with an infant weighing more than 2,500 grams; however, the PSRP accepts reports of perinatal events associated with any birth weight if the reporter feels they offer an important patient safety lesson.
Pressure ulcer	5F) Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Pressure ulcer – stage 3 or 4, acquired after admission	4F) Care management: Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ presentation to a healthcare setting	"Stage III and IV pressure ulcer" is considered a Medicare HAC Addressed in NQF's list of recommended safe practices (see references for link)
Radiologic	1) GENERAL: Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	6A) Radiologic: Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	NQF will likely add other radiation events to its list of serious reportable events in a future update Pediatric imaging is addressed in NQF's list of recommended safe practices (see references for link)
Restraint or bed rail related	6E) Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility	Restraints or bed rails	5D) Environmental: Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting	--

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Suicide or attempted suicide	4C) Patient suicide, or attempted suicide resulting in serious physical injury, while being cared for in a healthcare facility	Suicide	3C) Patient protection: Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting	--
Surgical or other invasive procedure (including incorrect site, incorrect patient, and incorrect procedure)	2A) Surgery performed on the wrong body part	Surgery or invasive procedure 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)
Surgical or other invasive procedure (including incorrect site, incorrect patient, and incorrect procedure)	2B) Surgery performed on the wrong patient	Surgery or invasive procedure 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)

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Surgical or other invasive procedure (including incorrect site, incorrect patient, and incorrect procedure)	2C) Wrong surgical procedure performed on a patient	Wrong surgical or invasive procedure performed on a 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 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)
Surgical or other invasive procedure (including incorrect site, incorrect patient, and incorrect procedure)	2E) Intraoperative or immediately postoperative death in an ASA Class I patient (ASA is the American Society of Anesthesiologists; Class I is a healthy patient with no medical problems)	Intraoperative or immediate post-operative death in ASA Class 1 patient	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;" 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"
Unintended retained foreign object	2D) Retention of a foreign object in a patient after surgery or other procedure	Retention (unintended) of a foreign object	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 "General" category "Foreign object retained after surgery" is considered a Medicare HAC

PSRP	Administrative Rules Appendix A	Original Reporting Form	NQF 2011 Update	Note
Other	1) GENERAL: Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury	Other	--	--
Retired Event Types				
--	5G) Patient death or serious physical injury due to spinal manipulative therapy	Spinal manipulative therapy	*Retired*	Related events can still be reported to the PSRP as an *Other* event
--	5E) Death or serious physical injury (kernicterus) associated with failure to identify and treat hyperbilirubinimia [sic] in neonates	Neonatal hyperbilirubinemia	4I) Care management: Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results	As of 2011, NQF considers hyperbilirubinemia to be the result of a failure to communicate test results; related events should be reported to the PSRP as a *Failure to follow up lab, pathology, or radiology test results* event
--	5D) 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 Also addressed (glycemic control) in NQF's list of recommended safe practices (see references for link)

Appendix II: Converting Harm from the Old to New System

Hospitals that submitted reports in 2011 assigned a harm level using the Commission's original system (nine numerical categories, 1-9). 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 20 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 20. 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 error	–	—
B	An error occurred but the error did not reach the patient	1	Did not reach the patient
C	An error occurred that reached the patient, but did not cause patient harm	2	No detectable harm
D	An error 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 3	No detectable harm Minimal temporary harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	5 7	Moderate temporary harm Serious temporary harm
F	An error 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 error occurred that may have contributed to or resulted in permanent patient harm	4 6 8	Minimal permanent harm Moderate permanent harm Serious permanent harm
H	An error occurred that required intervention necessary to sustain life	7 8	Serious temporary harm Serious permanent harm
I	An error 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, and 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. Another difference was classification of all stages 3, 4, or unstageable pressure ulcers into Category G as there is no distinction for degree of permanent harm based on the size or location of the pressure ulcer. Table 21 outlines the conversion of harm from original level to new harm category for all reports submitted in 2011.

Table 21. Original Harm Level by New Harm Category, 2011

NCC MERP Harm Category	Harm Level 1	Harm Level 2	Harm Level 3	Harm Level 4	Harm Level 5	Harm Level 6	Harm Level 7	Harm Level 8	Harm Level 9	Total Reports
A		1			1					**2**
C		10					1			**10**
D		7	14	1	3		1			**25**
E			6		12		3			**21**
F		1	2		5		29		1	**40**
G				1		7		6		**14**
H			1				7			**8**
I							1		21	**22**
Total Reports	**0**	**19**	**23**	**2**	**21**	**7**	**42**	**6**	**22**	**142**

Appendix III: Harm Categories in Reported Adverse Events

The following table presents all harms reported in 2011 (n=146) by event type according to newly adopted harm categories from the National Coordinating Council for Medication Error Reporting and Prevention.

						Serious Harm				
Event Type	Harm A	Harm B	Harm C	Harm D	Harm E	Harm F	Harm G	Harm H	Harm I	TOTAL
Air embolism								1		**1**
Anesthesia			2	2				1		**5**
Aspiration									1	**1**
Blood or blood product				2	5					**7**
Care delay			1	1		2	2		3	**9**
Contaminated drugs, device or biologics				1						**1**
Contaminated, wrong or no gas				1						**1**
Device or medical/surgical supply	2				1	4			1	**7**
Failure to follow up lab, pathology, or radiology test results				1						**1**
Fall			1		3	11	2		1	**18**
Healthcare-associated infection					1	5	2		1	**9**
Health information technology				1						**1**
Irretrievable loss of irreplaceable biological specimen			1							**1**
Medication or other substance			1	2	3	4		2	5	**17**
Other event					2				2	**4**
Perinatal									5	**5**
Pressure ulcer							5			**5**
Radiologic				2	3					**5**
Suicide or attempted suicide						1		1	3	**5**
Surgical or other invasive procedure			2	1	2	2	5	3	1	**17**
Unintended retained foreign object			2	7	5	13				**27**
Total	**2**	**0**	**10**	**25**	**21**	**40**	**16**	**9**	**23**	**146**