Oregon patient safety Commission

# 2010 Summary

## Hospital Adverse Event Reporting

**Bethany Higgins**
Administrator

**Leslie Ray PhD, RN**
Patient Safety Consultant

**Sydney Edlund**
Data Analyst

*April 2011*

## *Message from the Administrator*

This year, Oregon hospitals began their sixth year of adverse event reporting. Oregonians can be proud of our hospitals' work in identifying, investigating and reporting adverse events. In particular, your hospital's willingness to participate in this reporting program underlines your commitment to patient safety and demonstrates to the public that your organization is committed to safe care.

To create lasting improvements, however, we must commit to transparency in reducing preventable injury and harm. To build a true safety culture, we must learn from -- and capitalize on -- opportunities to identify and correct underlying system issues that lead to adverse events. Oregon is unique in its voluntary reporting system; this strength can be preserved by your full participation in transparency and reporting.

Please consider the Commission as your partner in patient safety; we are committed to providing resources and support so you can give your patients the high-quality, reliable and safe care they depend upon. Support that we offer includes:

1. Guidance through the adverse event reporting process, supporting and strengthening your root cause analyses;

2. Recommendations and access to quality improvement tools, based on needs identified through the reporting program;

3. Meaningful feedback – individualized to your hospital, and in aggregate to all Oregon hospitals -- helping promote awareness and prevent recurrence of similar problems;

4. A monthly newsletter that offers evidence-based resources and references to the latest patient safety news.

The following summary of adverse event reports submitted in 2010 serves two purposes. First, it provides statewide information on the adverse events themselves. Second, and perhaps more importantly, the 2010 data suggest a method to judge overall progress toward robust reporting. At the same time, we are committed to decreasing the administrative burden of reporting and are embarking upon a redesign process over the summer to optimize the reporting tool.

We are setting annual reporting goals for 2011 through 2015. These goals outline incremental targets and standards for quantity, quality and timeliness for both submissions and written notification. To develop these standards, we reviewed previous reporting trends and utilized some of the latest evidence related to volume of adverse events in hospitals. We then set achievable annual targets customized to your hospital, based on volume of discharges. For a more complete description of this

effort, please see the document entitled *Progress toward Robust Reporting*, which describes these goals in more detail.

Leslie Ray is your contact at the Commission for the hospital adverse event reporting program (503.224.9227 or leslie.ray@oregonpatientsafety.org). Please call or email Leslie with any questions regarding this report or comments regarding our new reporting standards for 2011-2015. Together, we can achieve Oregon's North Star Goal, creating the safest healthcare delivery system in the country. We welcome your thoughts as to how we can best support you in the coming year.

Sincerely,

Bethany A. Higgins
Administrator

*Alone we can do so little; together we can do so much.*
*– Helen Keller*

# Table of Contents

*Executive Summary* _____ *v*

*Characteristics of Adverse Events* _____ *1*

Event Types _____ 1

Infections _____ 3

Contributing Factors Identified in Reported Events _____ 3

Levels of Harm in Reported Events _____ 5

*Characteristics of the Reports* _____ *6*

Number of Reports Submitted _____ 6

Timeliness of Report Submission _____ 7

Quality of Adverse Event Reports _____ 8

Written Notification _____ 9

*Conclusion* _____ *10*

*Appendix I List of Reportable Events* _____ *11*

*Appendix II Contributing Factors* _____ *12*

*Appendix III Criteria for Evaluation of Adverse Event Report Quality* _____ *13*

# List of Figures and Tables

Figure 1. Over 98% of Oregon discharges are covered by hospitals participating in adverse event reporting. _____ v

Figure 2. Top Three Most Frequently Reported Events by Large, Medium, and Small Hospitals _____ 1

Figure 3. Reporting Trend by All Hospitals 2007-2010 _____ 7

Table 1. Events Reported Events 2010 – All Hospitals _____ 2

Table 2. Number and Percent of Infections Reported by Participating Hospitals _____ 3

Table 3. Proportion of Contributing Factors in Adverse Event Reports _____ 4

Table 4. Ten Most Common Specific Factors Noted in Adverse Event Reports _____ 4

Table 5. Event Type by Harm Level, for All Hospitals _____ 5

Table 6. Level of Harm in Adverse Event Reports by Hospital Size _____ 6

Table 7. Number of Reports Submitted 2006-2010 _____ 7

Table 8. Timeliness of Report Submission _____ 8

Table 9. Hospitals with Most Timely Submissions _____ 8

Table 10. Comparison of Acceptability and Quality of Reports by Hospital Size _____ 9

Table 11. Written Notification Rates by Hospital Size _____ 9

Table 12. Most Common Reasons for No Written Notification _____ 10

# Executive Summary

The Oregon Patient Safety Commission is charged with fostering a culture of patient safety and decreasing the risk of adverse events in Oregon. As part of that charge, the Commission conducts a voluntary and confidential adverse event reporting program for hospitals, nursing homes, ambulatory surgery centers, and community/retail pharmacies.

Figure 1. Over 98% of Oregon discharges are covered by hospitals participating in adverse event reporting.

The Commission promotes reporting as an act of transparency, and supports safer care by collating information on events across the state to identify risks and offer prevention strategies through a non-regulatory external review process. The act of reporting demonstrates to Oregon patients and their families that your organization is making a commitment to safe care.

Oregon has 58 general acute care hospitals; 56 of those hospitals are signed participants in adverse event reporting and cover over 98% of patient discharges in the state. These participating hospitals have agreed to submit reports of serious adverse events in order to share information across the state and prevent harm to other Oregon patients. The reporting program represents two key aspects in Oregon's North Star efforts: Learning from Experience and Patient/Family Engagement.

As the hospital arm of the program enters its sixth year, it has received 503 reports from hospitals covering a range of event types and levels of harm. This summary of adverse events for calendar year 2010 includes information on characteristics of adverse events reported by hospitals (types, frequencies, harm levels, and contributing factors). We also describe characteristics of submitted reports, (quantity, quality, and timeliness) as well as the extent to which hospitals provided written notification to patients.

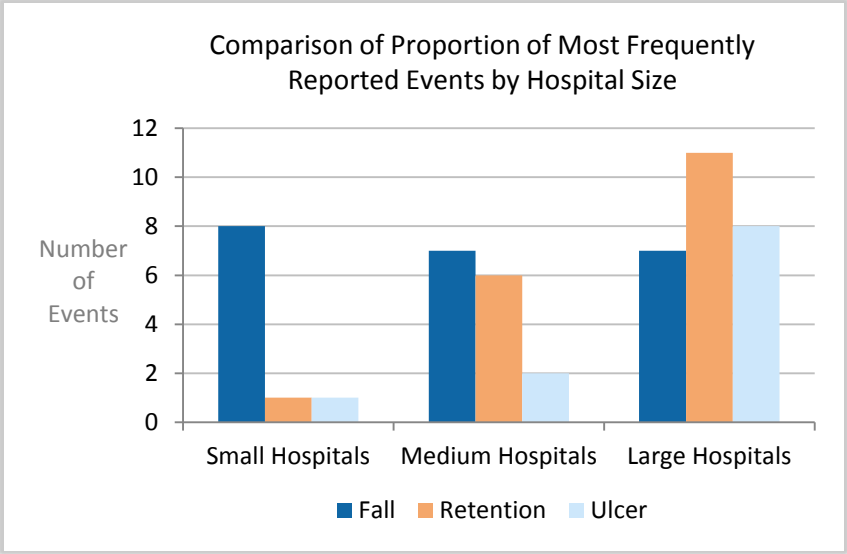
In 2010, the most frequently reported events overall were falls, unintentionally retained objects, and pressure ulcers. We also received reports of unexpected deaths and delays in care, which may indicate an increasing focus and attention on adverse events on the part of some hospitals. In reporting events that are not as readily apparent as falls, for example, hospitals are demonstrating an ability to identify more subtle adverse events.

# Characteristics of Adverse Events

## Event Types

The 136 events reported in 2010 fall into 30 event 'types': 18 were Never Events chosen from the list on the form, and 12 were Other Events, defined by facilities themselves upon reporting. Table 1 lists the types of events reported and their frequency.

Figure 2. Top Three Most Frequently Reported Events by Large, Medium, and Small Hospitals




The three most frequently reported events regardless of hospital size[1] were falls, unintentionally retained objects, and pressure ulcers. Within the Other category were varied events related to surgery, such as improper implants or lack of required equipment. Together, surgical and procedural events account for nearly one-third of the adverse events reported in 2010.

While large, medium, and small hospitals reported falls most frequently, the next most frequent events differed by hospital size. For large hospitals, retained objects and pressure ulcers were second and third in frequency. In medium hospitals retained objects and medication events were noted most frequently. For small hospitals, injuries and unexpected death were the next most frequent after falls. That smaller facilities perform fewer surgeries is a likely explanation for this difference.

Medication events were the fifth most frequent events, along with injuries, reported by hospitals of all sizes. Nationally, reports have identified medication-related events as a common type of adverse event. The Institute of Medicine (IOM) says that two of every 100 admissions result in "preventable adverse drug event[2]." Further, a study reported in the March 2011 issue of Health Affairs indicated that 38% of identified events were medication related[3]. An explanation for the difference seen in Oregon reports is

[1] The Commission uses annual discharges to determine hospital size. A large hospital has over 10,000 discharges a year, a medium hospital has between 3,001 and 10,000 discharges, and a small hospital has 3,000 or fewer discharges.

[2] Kohn LT, Corrigan JM, Donaldson MS, editors. To Err Is Human: Building a Safer Health System. Washington (DC): National Academies Press; 2000.

[3] Classen DC, Resar R, Griffin R, Federico Frankel T, Kimmel N, et al. 'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured. Health Affairs, 2011; 30(4):581-89.

less clear, though it may be related to an increased focus on adverse events that are more easily identified or those for which reimbursement may be denied.

## Table 1. Events Reported Events 2010 – All Hospitals

| Type of Event | Large | | Medium | | Small | | All Hospitals | |
|---|---|---|---|---|---|---|---|---|
| | # of Events | % of Events | # of Events | % of Events | # of Events | % of Events | # of Events | % of Events |
| **Fall** | **7** | **10%** | **7** | **18%** | **8** | **31%** | **22** | **16%** |
| **Retained Object** | **11** | **15%** | **6** | **16%** | **1** | **4%** | **18** | **13%** |
| **Pressure Ulcer** | **8** | **11%** | **2** | **5%** | **1** | **4%** | **11** | **8%** |
| Unexpected Death | 5 | 7% | 1 | 3% | 3 | 12% | 9 | 7% |
| Injury | 2 | 3% | 3 | 8% | 3 | 12% | 8 | 6% |
| Medication Event | 2 | 3% | 6 | 16% | | | 8 | 6% |
| Healthcare Associated Infection | 3 | 4% | 4 | 11% | | | 7 | 5% |
| Perinatal | 6 | 8% | | | 1 | 4% | 7 | 5% |
| Equipment | 2 | 3% | 2 | 5% | 2 | 8% | 6 | 4% |
| Suicide | 6 | 8% | | | | | 6 | 4% |
| Care Delay | 3 | 4% | | | 2 | 8% | 5 | 4% |
| Wrong Site Surgery | 3 | 4% | 2 | 5% | | | 5 | 4% |
| Wrong Procedure | 2 | 3% | 1 | 3% | | | 3 | 2% |
| Burn | 2 | 3% | | | | | 2 | 2% |
| Hypoglycemia | 2 | 3% | | | | | 2 | 2% |
| Perforation | 1 | 1% | | | 1 | 4% | 2 | 2% |
| Wrong Patient | 1 | 1% | 1 | 3% | | | 2 | 2% |
| Labor | 1 | 1% | | | | | 1 | 1% |
| Other | 5 | 7% | 3 | 8% | 4 | 15% | 12 | 9% |
| Total Events | 72 | | 38 | | 26 | | 136 | |
| Total Reports | 66 | | 35 | | 24 | | 125 | |

### Infections

The Commission has received few reports (n=7) of healthcare-associated infections (HAI) – 5% of all events -- despite state infection reporting data[1] that shows 86 infections reported during the first half of 2010. The 37 hospitals submitting HAI adverse event reports in 2010 represent 86% of central line associated bloodstream infections (CLABSI), and 73% of knee prosthesis surgical site infections (KPRO SSIs).

### Table 2. Number and Percent of Infections Reported by Participating Hospitals

| Year | Infection | All Large Hospitals n=11 | All Medium Hospitals n=16 | All Small Hospitals* n=29 | All Hospitals n=56 |
|---|---|---|---|---|---|
| 2009 | CLABSI | 60 (77%) | 17 (22%) | 1 (1%) | 78 |
| | KPRO SSI | 34 (52%) | 20 (30%) | 12 (18%) | 66 |
| | CBG SSI | 52 (84%) | 10 (16%) | 0 (0%) | 62 |
| Jan-Jun 2010 | CLABSI | 23 (82%) | 5 (18%) | 0 (0%) | 28 |
| | KPRO SSI | 6 (27%) | 13 (59%) | 3 (14%) | 22 |
| | CBG SSI | 28 (78%) | 8 (22%) | 0 (0%) | 36 |

*Excludes two small hospitals not participating in Oregon Patient Safety Commission

## Contributing Factors Identified in Reported Events

Of the nine categories of contributing factors, two were seen the most frequently across hospitals of all sizes: Communication and Policies & Procedures (see Table 3). Communication-related contributing factors were the most frequent, with 82 of the 125 reports (66%) noting some type of communication difficulty as contributing to the adverse event. Policies & Procedures were the next most frequent contributing factor category overall, cited in 60% of reports. It was seen in the highest proportion of reports from small hospitals (75%).

Communication and Policy/Procedure were the most common types of contributing factors identified in adverse event reports

[1] Data on infection rates from Oregon Health Policy and Research HAI Program 2009 and January – June 2010 (latest available) See http://www.oregon.gov/OHPPR/HAI_Report.shtml

## Table 3. Proportion of Contributing Factors in Adverse Event Reports*

| Contributing Factor | Large Hospitals n = 66 | Medium Hospitals n = 35 | Small Hospitals n = 24 | All Reports n = 125 |
|---|---|---|---|---|
| Communication | 65.2% | 65.7% | 66.7% | 65.6% |
| Policies Procedures | 57.6% | 57.1% | 75.0% | 60.8% |
| Patient Management | 54.5% | 45.7% | 41.7% | 49.6% |
| Training and Supervision | 45.5% | 34.3% | 50.0% | 44.8% |
| Equipment, Software, or Material Defects | 40.9% | 34.3% | 33.3% | 37.6% |
| Patient Factors | 40.9% | 34.3% | 41.7% | 39.2% |
| Work Area/Environment | 37.9% | 45.7% | 37.5% | 40.0% |
| Organizational Factors | 34.8% | 31.4% | 45.8% | 36.0% |

*Percentages do not total 100% because multiple categories can be selected in each event report.

Each of the main Contributing Factor categories includes a number of specific sub-factors. The ten most commonly indicated sub-factors are given in Table 4. In the top ten factors are two from the Communication, Patient Factors, and Patient Management categories, and one each from the Equipment, Policies & Procedures, and Training and Supervision categories. For a complete listing of each Category with sub-factors, see Appendix II.

## Table 4. Ten Most Common Specific Factors Noted in Adverse Event Reports

| | Large Hospitals n = 66 | Medium Hospitals n = 35 | Small Hospitals n = 24 | All Reports n = 125 |
|---|---|---|---|---|
| Communication — Among Hospital Personnel | 29 | 13 | 13 | 55 |
| Policies Procedures — Not Followed/Compliant | 18 | 13 | 12 | 43 |
| Communication — Hand-Offs/Shift Reports | 23 | 5 | 9 | 37 |
| Training And Supervision — In-Service Education/Competency | 18 | 9 | 8 | 35 |
| Patient Factors — Other | 17 | 4 | 8 | 29 |
| Patient Management — Response To Changing Condition | 14 | 7 | 5 | 26 |
| Equipment, Software, Or Material Defects — Other | 15 | 6 | 4 | 25 |
| Patient Factors — Mental Status | 11 | 6 | 4 | 21 |
| Work Area/Environment — Distractions | 6 | 10 | 5 | 21 |
| Patient Management — Care Plan | 12 | 4 | 3 | 19 |

## Levels of Harm in Reported Events

Hospitals overall reported more serious[1] harm events (81) than less serious harm events (41). The most frequently reported serious harm event were falls, followed by retained objects (see Table 5). Falls and retained objects were the most frequently reported serious events, followed by unexpected death and injury. Pressure ulcers, the third most frequently reported event, more often resulted in moderate harm.

Perinatal events were the most frequently reported event resulting in death

### Table 5. Event Type by Harm Level, for All Hospitals

| Type of Event | No Harm (1-2) | Low Harm (3-4) | Moderate Harm (5-6) | Serious Harm (7-9) |
|---|---|---|---|---|
| Fall | 3 | 1 | 2 | 16 |
| Retained Object | 1 | 3 | 3 | 11 |
| Pressure Ulcer | | | 7 | 4 |
| Unexpected Death | | | | 9 |
| Medication Event | 1 | | 1 | 6 |
| Healthcare Associated Infection | | 1 | | 6 |
| Perinatal | | | | 7 |
| Equipment | 3 | | 1 | 2 |
| Suicide | | | | 6 |
| Wrong site surgery | 1 | 1 | 3 | |
| Injury | | | | 8 |
| Care Delay | | | 1 | 4 |
| Wrong procedure | 1 | 1 | 1 | |
| Burn | | | 1 | 1 |
| Hypoglycemia | | | | 2 |
| Perforation | | | | 2 |
| Labor | | | | 1 |
| Wrong patient | | | 1 | 1 |
| Other | 2 | | | 6 |
| Total Events | 15 | 7 | 21 | 93 |
| Total Reports | 15 | 6 | 20 | 84 |

[1] Serious events are those resulting in harm levels of 7, 8, or 9 and six specific types of events that are considered serious, regardless of harm. (Infant discharged to the wrong person, wrong gas given to a person, wrong procedure performed, wrong site surgery/procedure, procedure on wrong person, and retained object.) See Appendix 1 for listing of reportable events.

Serious events are required reports; however, the Commission encourages reporting of less serious events (both required and non-required or "additional" reports) in order to develop deeper understandings. As noted in Table 6, large facilities reported the largest number of less serious harm events. Overall, medium and small facility groups each submitted 12 such reports; however, small hospitals submitted a higher proportion of "additional" lower harm events (as compared to required lower harm events) than did medium facilities. Small facilities reported the smallest number of required events, and the smallest number of serious harm events.

### Table 6. Level of Harm in Adverse Event Reports by Hospital Size

| | Large | Medium | Small | ALL |
|---|---|---|---|---|
| Less Serious Harm | 17 | 12 | 12 | 41 |
| Required | **9** | 6 | 1 | 16 |
| Additional | 8 | 6 | 11 | 25 |
| Serious Harm | 49 | 23 | 12 | 84 |
| TOTAL | 66 | 35 | 24 | 125 |

## Characteristics of the Reports

### Number of Reports Submitted

Oregon hospitals submitted 125 adverse event reports in 2010, the same number as were submitted in 2009.

The 37 hospitals that submitted adverse event reports in 2010 represent 86% of OR discharges and 85% of inpatient surgeries. The large facilities that reported in 2010 represent 60% of Oregon discharges; medium facilities represent 21% and small facilities 4.8%. They account for 53%, 28%, and 19% of all reported events, respectively.

**REPORTING ACTIVITY DROPS**

The 125 reports submitted in 2010 represent a leveling off in reporting from 2009 and a significant decline in the rate of increase from the 2007 to 2009 rates. The number of hospitals reporting events also declined in 2010.

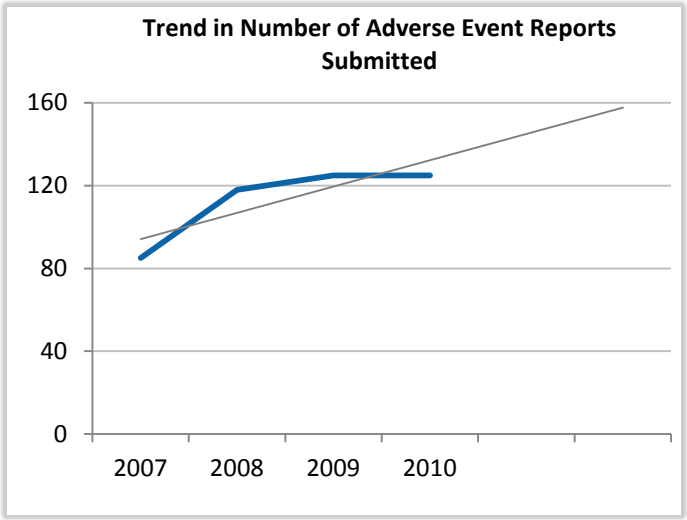
While the number of hospitals submitting reports in 2010 increased slightly, the overall number of submissions remained static from 2009. Table 7 gives the number of reports submitted each year of the program.

## Table 7. Number of Reports Submitted 2006-2010

| | 2006 | 2007 | 2008 | 2009 | 2010 | Total |
|---|---|---|---|---|---|---|
| Large | 23 | 55 | 67 | 72 | 66 | 283 |
| Medium | 12 | 19 | 28 | 28 | 35 | 122 |
| Small | 18 | 11 | 23 | 25 | 24 | 101 |
| Total | 53 | 85 | 118 | 125 | 125 | 506 |

Reporting activity, as noted in the chart below, shows a marked increase from 2007 to 2008 with a slight increase in 2009 and no increase in 2010. Based on the 2008 to 2009 increase, we expected to see 136 reports in 2010. The more recent trend line, based on the annual number of reports since 2007, projects 145 reports for 2011 and 156 for 2012. This is still well below what might be expected based on literature published in the past several years.

Figure 3. Reporting Trend by All Hospitals 2007-2010




## Timeliness of Report Submission

Memories fade quickly after an adverse event, requiring an immediate response to collect full and reliable information on the circumstances surrounding the event. The goal for submission of an adverse event report is 45 days following discovery of the event.

**MILESTONES IN ADVERSE EVENT INVESTIGATION**

*Discovery of the Event

*Event Investigation

*Investigation & Review Completed

*Submission of Report

The average event to submission time for all facilities in 2010 was 103 days (over three months). The median days from event to submission was 62 days in 2009 (about two months) and 79 days in 2010 (about two and a half months). While hospitals reduced their previous average event to QM notification time in 2010, they increased their review completion to submission time. In Table 8, three significant time periods are shown: days between occurrence of the adverse event and notification of Quality Management; days between notification and completion of the event review; and days between completion of the review and submission to the Commission.

### Table 8. Timeliness of Report Submission

| (all values in days) | Event to Quality Management* | QM to Review Completed | Review Completed to Submission |
|---|---|---|---|
| 2009-2010 (n=242) | 10.6 | 37.0 | 55.6 |
| 2009 (n=124) | 11.5 | 36.9 | 49.1 |
| 2010 (n=122) | 9.8 | 37.2 | 62.2 |

*may be lengthened in cases where events were discovered on chart review

Nine facilities were close to meeting, or did meet, the 45-day reporting goal in 2010. Two of the large hospitals, two medium hospitals, and five small were the most timely reporters. While there is no absolute rule regarding the time required to fully investigate and review an adverse event, a very short turnaround time may indicate a less than thorough investigation.

### Table 9. Hospitals with Most Timely Submissions

| Hospital* | L01 | L06 | M24 | M21 | S15 | S07 | S18 | S14 | S06 |
|---|---|---|---|---|---|---|---|---|---|
| Days | 48.9 | 59.0 | 42.6 | 46.5 | 9.4 | 14.5 | 19.0 | 33.5 | 54.5 |

*Hospitals are designated by size, for example L indicates a large hospital and the number reflects a confidential code used for program summaries.

## Quality of Adverse Event Reports

The Commission reviews submitted reports and determines whether they have met criteria for acceptability. The criteria are based upon the four Joint Commission Criteria. A report is *Complete* if it contains all of the information requested in the event report, 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

**QUALITY CRITERIA**

*Complete

*Thorough

*Credible

*Meaningful Action Plans

report is *Credible* if it shows evidence that the investigation included leadership participation and was internally consistent. *Meaningful action plans* clearly describe improvement strategies designed to minimize risk. If all criteria are met, the report is considered Acceptable.

As part of their mandate for review of the Commission, the Public Health Officer also reviews reports using the same criteria, and evaluates how well each report met the criteria, which identifies reports that exceed the minimum criteria and are of high quality. See Appendix III for a description of the criteria and how they are used to evaluate reports.

Hospitals submitted mostly acceptable, high quality reports in 2010. Overall, 91% were acceptable and 85% were high quality (see Table 10).

### Table 10. Comparison of Acceptability and Quality of Reports by Hospital Size

| | Number of Reports | Number Acceptable | Num. High Quality | % High Quality |
|---|---|---|---|---|
| **Large Hospitals** | 66 | 61 | 58 | 88% |
| **Medium Hospitals** | 35 | 32 | 30 | 86% |
| **Small Hospitals** | 24 | 21 | 19 | 78% |
| **All OR Hospitals** | **125** | **114** | **107** | **85%** |

## Written Notification

Written notification of an adverse event to the patient or family member is required for all serious events with a harm level of 7, 8, or 9. The requirement only states that the 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 is developing resources and tools to assist hospitals.

While this is a difficult requirement, nine hospitals always provided it, four have provided it most of the time and 17 facilities never provided written notification. In some circumstances the patient does not have anyone to notify, or attempts to notify have failed (such as return of the notification, unopened). In calculating completion of written notification, the Commission considers such circumstances.

### Table 11. Written Notification Rates by Hospital Size

| | Number of Facilities | Number of Notifications Completed | Number Required | % |
|---|---|---|---|---|
| **Large Hospitals** | 9 | 29 | 45 | 64% |
| **Medium Hospitals** | 10 | 3 | 23 | 13% |
| **Small Hospitals** | 11 | 4 | 12 | 33% |
| **All OR Hospitals** | **30** | **36** | **80** | **45%** |

When a reason for not providing written notification was stated on the report, the most common reason given was that verbal disclosure was done, followed closely by no policy in place and "other."

### Table 12. Most Common Reasons for No Written Notification

| | Verbal Disclosure | No Policy | Lack of Support | Patient Transferred | No Reason Given | Other* |
|---|---|---|---|---|---|---|
| **Large Hospitals** | 4 | 6 | | | 1 | 5 |
| **Medium Hospitals** | 10 | 3 | 1 | 1 | 1 | 4 |
| **Small Hospitals** | 3 | 2 | | | | 3 |
| **All OR Hospitals** | **17** | **11** | **1** | **1** | **2** | **12** |

*Other Reasons for not Providing Written Notification:
No contact information for patient
No family (for diseased patient)
Patient status (mental status, home life, imminent threat of danger, etc., usually at clinician's request)
Retrospective (too much time has passed)

## Conclusion

This report has summarized the adverse events reported by Oregon hospitals in 2010. The reports represented a variety of event types and harm levels that occur each year. There was a slight increase in the number of hospitals reporting adverse events, but no increase from the previous year in the numbers of events reported. This level of reporting activity will not provide for a strong database from which to identify specific factors to address and successful strategies for eliminating risk.

Based upon our review, we believe that there is much opportunity for enhanced understanding of adverse events, their contributing factors, and underlying or root causes through increased reporting. Two areas in particular -- healthcare associated infection and medication events -- would benefit from a greater number of reports being submitted. Increased reporting of these types of events will also begin to allow for identification of patterns across event types.

Adverse event reporting offers several ways to quantify gains in the sometimes imprecise concept of *culture of safety*:

- Growth in identification, investigation, and reporting of events;
- Responsiveness to adverse events in a timely manner;
- Recognition of more subtle adverse events;
- Improvements in written notification.

Hospital feedback and active engagement will, we believe, significantly accelerate the development of a robust statewide culture of patient safety. The Commission is pleased to partner with Oregon hospitals in this vital work.

# Appendix I List of Reportable Events[1]

**1. GENERAL CATEGORY**
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.
**2. SURGICAL EVENTS**
A. Surgery performed on the wrong body part.
B. Surgery performed on the wrong patient.
C. Wrong surgical procedure performed on a patient.
D. Retention of a foreign object in a patient after surgery or other procedure.
E. Intraoperative or immediately post-operative death in an ASA Class I patient.
**3. PRODUCT OR DEVICE EVENTS**
A. Patient death or serious physical injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility.
B. 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.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
**4. PATIENT PROTECTION EVENTS**
A. Infant discharged to the wrong person
B. Patient death/serious physical injury associated with patient elopement (disappearance) for over four hours.
C. Patient suicide/ attempted suicide resulting in serious physical injury while being cared for in a healthcare facility.
**5. CARE MANAGEMENT EVENTS**
A. 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).
B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
C. Maternal death or serious physical injury associated with labor or delivery in a low-risk pregnancy.
D. Patient death or serious physical injury associated with hypoglycemia.
E. Death or serious physical injury (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
G. Patient death or serious physical injury due to spinal manipulative therapy.
H. Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.
**6. ENVIRONMENTAL EVENTS**
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility.
B. 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.
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.
D. Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility.
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.

[1]From the National Quality Foundation's list of 'Never' events and a General category that includes other events resulting in serious harm. See Administrative Rules Chapter 35 Division 10, Appendix A -- Oregon Patient Safety Reporting Program for Hospitals.

# Appendix II Contributing Factors

### *Communications:*

| | |
|---|---|
| Hand-offs or shift reports | Available information |
| Between staff & patient/family | Hard to read handwriting/fax |
| Among staff | Look-alike/sound-alike drug |
| Other (please describe): | |

### *Training and Supervision:*

| | |
|---|---|
| Job orientation | In-service education/competency training |
| Staff supervision | Routine job training |
| Availability of training programs | Other (please describe): |

### *Patient Factors:*

| | |
|---|---|
| Language/culture | Family dynamics/relationships |
| Mental status | Behavioral status |
| Other (please describe): | |

### *Policies, Procedures:*

| | |
|---|---|
| Absent | Too complicated |
| Outdated | Not followed/compliant |
| Other (please describe): | |

### *Technology/Equipment:*

| | |
|---|---|
| Equipment meeting code, specifications, or regulations | Electronic Medical Records (EMR) |
| | Defective/non-working equipment |
| Automated dispensing (e.g., Pyxis) | Equipment design (function, displays, or controls) |
| Electronic prescribing (CPOE) | Medication admin checking (e.g., MAK) |
| Other (please describe): | Software (please list): |

### *Work Area/Environment:*

| | |
|---|---|
| Work area design and specifications | Distractions |
| Lighting | Noise |
| Relief/float healthcare staff | Interruptions (please describe): |
| Other (please describe) | |

### *Organizational Factors:*

| | |
|---|---|
| Overall culture of safety | Staffing levels |
| Leadership/management | Adequacy of budget |
| Systems to identify risks | Internal reporting |
| Staff assignment/work allocation | Other (please describe): |

### *Patient management:*

| | |
|---|---|
| Delegation of clinical care | Response to changing condition |
| Patient consent process | Care plan |
| Initial diagnosis | Tracking or follow-up |
| Two or more prescriptions filled at same time | Other (please describe) |

# Appendix III Criteria for Evaluation of Adverse Event Report Quality

Criteria for evaluation of adverse event report quality closely follow the Joint Commission's criteria* and are consistent with criteria used by the Public Health Officer in preparing annual certification reports. In evaluating a report we recognize that there are limitations in the reporting form's ability to capture fully information and the difficulty in summarizing hours of investigation and analysis into a few pages. How the criteria are applied to a specific event report is noted below. *Measure/s* refers to how the information is judged as meeting the criterion (that is, what is looked for); *Point Allocation* refers to the number of points given for each criterion in order to identify particularly high quality reports. In addition to allocating points for each criterion, the Commission evaluates the overall acceptability of the report, which requires that each criterion receive a minimum of one point.

| Criteria (points possible) | Definition OAR 325-010-0035 (1)a-d | Measure/s | Point Allocation |
|---|---|---|---|
| COMPLETE (2) | Contains all information requested in the Event report, or explains to the Commission's satisfaction why that information is not available or not necessary to provide | Event Description explains the event by including the sequence of actions and relevant environmental conditions in the description in addition to relevant clinical information | Event Description (0/1/2) |
| THOROUGH (3) | Includes analysis of all relevant systems issues and shows evidence of an inquiry into all appropriate areas | Primarily identify system-level contributing factors most directly associated with the event | Analysis (0/1) |
| | | At least one relevant root cause identified; presence of additional root or proximal causes | Analysis (0/1/2) |
| CREDIBLE (2) | Shows evidence that the investigation of the event included participation by leadership within the organization and was internally consistent | Notification (for serious events) of at least one of the following: administrator, senior management, leader on review team, or post-review briefing | Analysis (0/1) |
| | | Number of inconsistencies and/or contradictions among the sections: more than three inconsistencies = 0 points | Analysis (0/1) |
| ACTION PLANS (3) | Action plans clearly describe meaningful improvement strategies† designed to minimize risk | Emphasize strong and system-level solutions that would decrease the likelihood of such events in the future | Action Plans (0/1/2) |
| | | Action plans address the identified causes/findings | (0/1) |

* Joint Commission on Accreditation of Health Care Organization's Sentinel Event Policy and Procedures, June 2005

† based on the VA National Center for Patient Safety description of the strength of actions plans

November 2008; rev August 2009