



**Public Health Officer
Certification Report 2007**

**Oregon Patient Safety Commission
Adverse Event Reporting Programs**

**Oregon Department of Human Services
Public Health Division**

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Executive Summary

The Oregon Patient Safety Commission was created in July 2003 by the Legislature to improve patient safety by reducing the risk of serious adverse events and by encouraging a culture of patient safety in Oregon (Oregon Laws 2003 c.686). It was directed to establish a confidential, voluntary serious adverse event reporting system for six types of health care facilities: hospitals, retail pharmacies, nursing homes, ambulatory surgery centers (ASCs), outpatient renal dialysis facilities and freestanding birthing centers. Hospitals began reporting in May 2006. Nursing homes and ambulatory surgery centers began reporting in September 2007. Both programs were accepting reports during this recruiting/orientation phase. Implementation of the retail pharmacy reporting program has been delayed until 2008.

The legislation also established the annual Public Health Officer Certification as a distinctive public accountability feature of a statewide patient safety reporting system. No other state has anything like it. It certifies the overall integrity of the reporting program as well as the completeness, thoroughness, credibility and acceptability of each participant's reporting.

This is a report of the Public Health Officer Certification for the Oregon Patient Safety Commission's reporting programs for hospitals, nursing homes, ambulatory surgery centers and retail pharmacies. The certification assesses the quantity and quality of the reports submitted by facilities in 2007 as well as the overall integrity of the reporting programs. It is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon healthcare facilities. The Patient Safety Commission provides analysis and information about facility reports received (www.oregonpatientsafety.org).

The Patient Safety Commission received:

- 94 adverse event reports from 30 of 54 of participating hospitals – full year
- 1 adverse event report from one of 87 participating nursing homes – recruiting/orientation phase
- 12 adverse event reports from 5 of 39 participating ambulatory surgery centers – recruiting/orientation phase

Certification Results:

The **report quality** assessment uses the certification criteria to evaluate all of the submitted adverse event reports (Appendix A). Each report receives a total report quality score, which is a sum of all the points from the quality section of the certification tool. The score is expressed as percent of total quality points possible and then assigned a broader category of *low*, *medium* or *high* quality (see Appendix A and Methods section for more detail). Together, these criteria address overall aspects of completeness, thoroughness and credibility of the reports.

The **report quantity** is assessed broadly by comparing to similar programs in other states and by considering various adverse event rates from the patient safety literature.

The assessment of the **overall integrity of the reporting programs** is also done with questions and data elements as described in the Public Health Officer Certification Tools (Appendix A).

Quality:

Hospitals: The Public Health Officer Certification found that the total report quality was very good in 2007. The proportion of “high quality” adverse event reports increased from 67.3% in 2006 to 89.4% in 2007. Areas for improvement include: quality of the adverse event descriptions and action plans.

Nursing homes, ambulatory surgery centers and retail pharmacies: No report quality assessment for 2007.

Quantity:

Hospitals: The number of adverse event reports submitted by hospitals increased from 55 in 2006 to 94 in 2007. The Public Health Officer Certification finds the adverse event rates are within the range of those found in other comparable statewide programs. This is a remarkable achievement for a voluntary reporting program. Oregon still has the only purely voluntary adverse event reporting system in the nation. All others have some mandatory component.

Although reporting levels in Oregon are within the range of that seen in similar state programs, this should not be regarded as the “universal” standard. The Public Health Officer Certification finds that the total number of submitted reports from all hospitals is lower and the proportion of hospitals that have not submitted any reports is higher than the literature would suggest^{1,2,3}.

Increasing levels of reporting also have a transparency value for the public and may serve as a motivation for overall system change. The PHO Certification anticipates that the number of reports received will better reflect estimates from the literature in the future (see above), and the number of hospitals involved in reporting and sharing lessons learned will also increase. Each hospital participant stands to make a contribution to statewide learning.

Nursing homes, ambulatory surgery centers and retail pharmacies: No report quantity assessment for 2007.

Overall Integrity:

The overall integrity criteria include facility participation rates, reporting tool design and implementation, report review process, action plan follow-up, learning and best practice dissemination and rates of written notification (Appendix A). The PHO found that the adverse event reporting programs are demonstrating acceptable to good overall integrity as Oregon Patient Safety Commission works to establish and grow a strong statewide adverse event reporting system.

Hospitals (full year):

- Excellent hospital enrollment rates

¹ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

² Institute for Healthcare Improvement. *Frequently Asked Questions about the 5 Million Lives Campaign*. IHI Website. 2007. Available at <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=6>. Accessed on March 31, 2007.

³ Commonwealth of Pennsylvania, Patient Safety Authority. *2007 Annual Report*. Available at http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2007.pdf. accessed on May 2, 2008.

- The adverse event reporting tool provides clear definitions and includes standard patient safety information about contributing factors and action plans strategies
- Good progress in implementation of the reporting program
- The internal review process for submitted reports was implemented for the 2007 reports. Expert analysis is done by the hospital technical advisory committee
- Action plan follow-up with hospitals was very low
- Very good, reliable sharing of relevant patient safety information and resources
- The rate of completed written notification to the patients and families decreased from 67% in 2006 to 44% in 2007

Nursing Homes (recruiting/orientation phase):

- Too few reports and program development to assess all certification elements
- Good initial nursing home enrollment rates
- Acceptable reporting tool design and excellent companion guide
- Reporting program implementation and report review process are in development
- Good initial activities to promote the development of value-added nursing home best practices
- Written notification not completed for the one report submitted in 2007

Ambulatory Surgery Centers (recruiting/orientation phase):

- Too few reports and program development to assess all certification elements
- Acceptable initial ASC enrollment rates
- Acceptable reporting tool design
- Reporting program implementation and report review process are in development
- Acceptable initial activities to promote the development of value-added ASC best practices
- Written notification not applicable since only less-serious reports were submitted in 2007

Retail Pharmacies (program recruiting):

- Program development stage too early for assessment
- Slow progress toward reporting program development
- The program enrollment rates are currently too low to build reporting program

The Public Health Officer Certification is implemented using a phased approach to accompany the developmental stages of the reporting programs. In the first year, we assess the status, offer recommendations and anticipate progress for the coming year. In the second year we note the progress and adopt some standards for the third year. After the third year, the Public Health Officer officially certifies the reporting program using established standards.

Conclusions:

While still in the growth phase the Oregon Patient Safety Commission is transforming the concept of reporting serious adverse events into a trusted statewide quality improvement program. Whereas the hospital program is in the second year of reporting in 2007, the new programs were recruiting and building internal and external capacity for adverse event reporting. The new participants were in various stages of developing and strengthening their formal patient safety programs and their ability to report adverse events to a state wide organization.

Success of the Patient Safety Reporting Program will be built on the strong partnership between the Commission and participants. Many healthcare facilities have signed up to participate, which shows a commitment to improving patient safety for Oregonians. However, the reduction of adverse events will require more than enrollment. It will involve the solid integration of patient safety systems to prevent

unanticipated harm into daily practice. The Public Health Officer challenges all healthcare facilities to learn about strategies for safer systems for the benefit of all patients in Oregon.

Hospitals:

The hospital reporting program has made good progress in the second year. The program is stronger and more established in the hospital landscape. They are demonstrating recognizable value and showing that sharing the lessons learned in hospitals has benefits for the broader health care community.

The Public Health Officer finds that the total hospital report quality was very good in 2007 and the reporting levels are improving. The overall reporting program integrity continues to be good as illustrated by the very strong enrollment levels and key aspects of program implementation. The annual action plan follow-up and the written notification requirement represent opportunities for improvement.

The 2008 adverse event reports will be reviewed in 2009 and the hospital program will receive its first full certification with established standards. In recognition of changing nature of the hospital reporting program since the development of the certification tool criteria (Appendix A), the PHO proposes some draft standards. The PHO will engage in a process to review the hospital certification elements and methods to establish final standards. The process will include input from interested parties beyond the Patient Safety Commission. The final standards will be completed by the end of 2008.

Proposed minimum standards[#] for future certification of the hospital reporting program:

- Report Completeness: ≥90% complete
- Adverse Event Description quality: ≥90% in the met or partially met category
- Adverse Event Analysis quality: ≥90% in the high quality category
- Adverse Event Preventive Action Plans quality: ≥75% in the high quality category
- Total Report quality: ≥90% in the high quality category
- Report quantity: Reduce the proportion of cumulatively non-reporting hospitals to ≤20% after 3 full years of report submissions (2007-2009)
- Program Enrollment: maintain participants that represent ≥90% of statewide annual discharges
- Action Plan follow-up: ≥90% completed for serious adverse events
- Written Notification: 100% for all serious adverse events (with stated exceptions)

Overall Certification levels:

- Pass with no reservations – 7-9 standards achieved
- Pass with reservations – 4-6 standards achieved
- No pass – 3 or less standards achieved

Nursing Homes:

The nursing home reporting program achieved a promising start in their first year. Most of the Commission work in 2007 was focused on recruiting and orientation. By the end of the year, 61% of all eligible nursing homes signed participation agreements. The report quality and quantity assessment was waived for 2007 in anticipation of more robust reporting in 2008.

The Public Health Officer finds that the overall reporting program integrity is good as illustrated by the solid initial enrollment levels, the very strong reporting program guide and quick start on developing relevant best practices to prevent pressure ulcers. The PHO recommends supporting facilities in their

[#] subject to change

ability to report events and also continuing to pursue a workable solution to fulfill written notification for nursing homes. Other elements of the program will emerge as the program rolls out its first full year of nursing home reporting.

Ambulatory Surgery Centers:

The Commission has demonstrated movement toward a unique ambulatory surgery center reporting program in the first year. Unlike many other state reporting programs, Oregon has a list of ASC reportable events more closely aligned with the type of work done in surgery centers. The list includes many of the serious events that occur in hospitals but also other events such as unplanned admission to hospital or visit to the emergency department within 48 hours of discharge (see Appendix B). Thus, Oregon's ASCs can report events that are useful for internal and also statewide quality improvement. As with the nursing home program, much of the Commission work in 2007 was focused on recruiting and orientation. The report quality and quantity assessment was waived for 2007 until facilities receive training and guidelines in 2008.

The Public Health Officer finds that the overall reporting program integrity is acceptable at this early stage as seen in the initial participation rates and reporting tool design. The PHO recommends that the Commission work with ASCs to support their readiness to report and to anticipate that ASCs will need options that make written notification a success for all.

Retail Pharmacies:

The retail pharmacy reporting program was still in development at the end of 2007. Progress has been much slower than with the other programs. Although some retail pharmacies are to be commended for willingness to engage in statewide patient safety improvement, most national chains and many independents have shown resistance to participation in the program. The Commission made numerous efforts to recruit retail pharmacy participants and build the program in the first year using existing resources. Oregon has a one-of-a-kind opportunity to pursue state-wide patient safety in the retail pharmacy area.

The PHO Certification will waive the report quality and quantity and reporting program integrity assessment for 2007 in anticipation of program implementation solutions in 2008. The program implementation for retail pharmacies was postponed until there is a critical mass (at least 3 large chains) of participants. With only one large chain participating, any publicly reported adverse event data may become attributable to that one large pharmacy chain. The Commission would only be able to provide confidentiality guarantees with more participants.

The Public Health Officer finds that the program needs greater participation in order to be successful. The PHO strongly urges the Commission to continue to seek strategies that will produce a critical mass of pharmacy participants and challenges the retail pharmacy industry to join the new reporting program to find some value-added for patient safety improvement.

Introduction

This is a report of the Public Health Officer (PHO) Certification for the Oregon Patient Safety Commission's Reporting Program for hospitals and also the newly added programs for freestanding ambulatory surgery centers, nursing homes and retail pharmacies. The 2007 report does not include a detailed assessment of the reports from the new programs due to the low numbers submitted. The PHO Certification is an **assessment of the quantity and quality of the reports submitted by hospitals in 2007 and the overall integrity of all reporting programs**. It is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon health care facilities. The Patient Safety Commission provides analysis and information about facility reports received (www.oregonpatientsafety.org).

Background

What is Patient Safety?

Patient Safety in the broadest sense is freedom from accidental injury. One way to measure patient safety is to look at the rate of accidental injury or death as a result of medical care. They are sometimes described as adverse events. More narrowly defined, an adverse event is an injury caused by medical management rather than the underlying condition of the patient. A preventable adverse event is an adverse event attributable to an error or system failure⁴. Further, an error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)⁵. It should be appropriately noted that not all adverse outcomes are the result of an error nor do all errors result in harm to a patient.

The patient harm due to preventable adverse events can vary in severity from minimal temporary harm to serious permanent harm and death. The Oregon Patient Safety Reporting Programs for hospitals and nursing homes (OAR 325, Division 10 and OAR 325, Division 20) and focus mainly on **serious adverse events**, which are defined as objective and definable negative consequences of patient care, or the risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury (Oregon Laws 2003 c.686 §1). Programs for ambulatory surgery centers and retail pharmacies (OAR 325, Division 25 and OAR 325, Division 15) have a slightly different adverse event profile developed by advisory groups from each area. The reportable adverse events differ for each of the programs according to the variation in the respective practice settings (Appendix B for lists of reportable adverse events in reporting templates)

The Oregon Patient Safety Commission: A Year of Growth

The mission of the Oregon Patient Safety Commission is to improve patient safety by reducing the risk of serious adverse events and by encouraging a culture of patient safety in Oregon. The statute directed the Commission specifically to do three things to accomplish their mission: 1) establish a confidential, voluntary serious adverse event reporting system to identify adverse events, 2) establish quality improvement techniques to reduce systems' errors contributing to serious adverse events and 3) disseminate evidence-based prevention practices to improve patient outcomes (Oregon Laws 2003, c. 686). The PHO Certification addresses specifically the first activity. The health care entities eligible for

⁴ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

⁵ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

the reporting programs include hospitals, retail pharmacies, nursing homes, ambulatory surgery centers, outpatient renal dialysis facilities and freestanding birthing centers.

In 2007, nursing homes, freestanding ambulatory surgery centers and retail pharmacies were added to the list of reporting programs (Fig. 1). The programs were developed using advisory groups from each of the facility types. The groups included practitioners and stakeholders that defined the reportable adverse events and other program parameters.

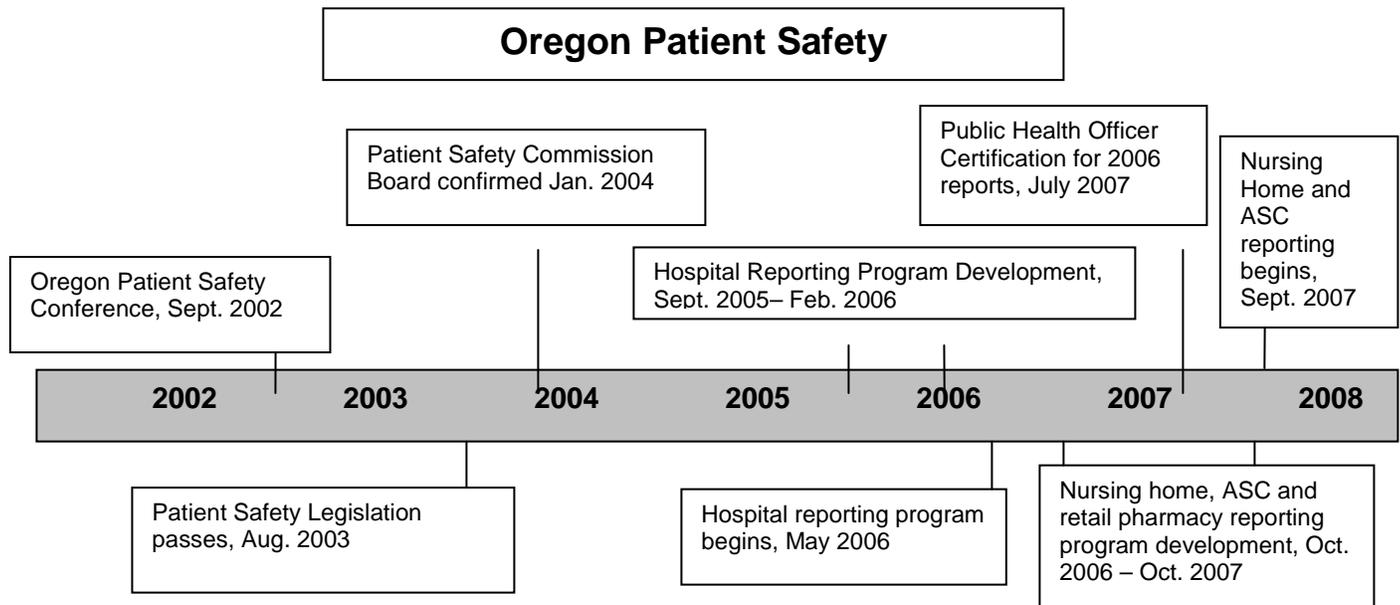


Figure 1 Oregon Patient Safety Progress

While the hospital program entered a second year of reporting in 2007, the new programs were recruiting and building internal and external capacity for adverse event reporting. The new participants were in various stages of developing and strengthening their formal patient safety programs to be able to track and report adverse events to a state wide organization.

Public Health Officer Certification Process

The PHO Certification is an assessment of the adverse event reporting programs, which represent a central component of the Commission's work. Measuring and understanding adverse events from a statewide perspective is an important step toward helping health care facilities make real change. These reporting programs are not solely a method of tracking serious adverse events in Oregon, but moreover, the collected patient safety data can be analyzed and interpreted by experts to provide a dynamic learning tool for participating facilities. A reporting program can also help facilities focus on their internal patient safety programs and harm reduction strategies. The Commission uses a quality improvement approach to improving patient safety, which includes sharing lessons learned among and across health care facilities about adverse events and their prevention.

The Oregon model of patient safety reporting integrates several **public accountability** aspects into the confidential voluntary program:

- Public Health Officer Certification of reports and reporting program
- Broad representation in Commission governance

- Commission publishes a list of those facilities that have voluntarily agreed to participate, non-participants and terminated participants
- Required notification in writing to patients and families following a reported serious adverse event
- Public meetings and transparency of the Commission's work
- Progress reports to the Legislature
- Possible transition to a mandatory system if the voluntary approach is not deemed effective
- Annual Commission summary report for all Oregonians

The Statute (Oregon Laws 2003, c. 686) created the annual Public Health Officer Certification as a distinctive public accountability feature of a statewide patient safety reporting system. No other state has anything like it. It certifies the overall integrity of the reporting program as well as the completeness, thoroughness, credibility and acceptability of each participant's reporting. The Public Health Officer independently assesses the reporting programs using basic criteria and existing data (Appendix A). The certification tool for each facility type was designed to match the information available in the Commission adverse event report forms (Appendix B). The tool for hospitals was developed, tested and finalized in late 2006. In 2007, the tool was adapted for the new programs. The certification of participant reporting includes all reports submitted in 2007.* Commission staff provide additional data to the Public Health Officer to answer the overall integrity questions in the certification tool.

At the request of the Commission, the certification also attempts to answer the overarching question: Are the reporting programs working to achieve the goal of improved patient safety? The PHO initially uses the quality of reporting and actions of the Commission to reach conclusions about the reporting program. However, as the programs progress, sufficient data become available and clear patient safety indicators are defined, the standards may also include some measurement of patient safety outcomes. The certification elements are meant to evolve with the developmental stages of the reporting program. The hospital program certification is planned for review to determine the final standards and the best criteria to answer the questions. The included elements may need to vary for other facility types.

Table 1: Public Health Officer Certification – proposed timetable[#]

	Reports submitted in 2006	Reports submitted in 2007	Reports submitted in 2008	Reports submitted in 2009	Reports submitted in 2010
Hospitals	Assessment	Setting standards	Certification	Certification	Certification
ASCs	Progress development	Progress development	Assessment	Setting standards	Certification
Nursing homes	Progress development	Progress development	Assessment	Setting standards	Certification
Retail pharmacies	Progress development	Progress development	Assessment	Setting standards	Certification
Birthing Centers	Program deferment	Program deferment	Program development	Program development	Assessment

* Note that the Commission annual assessment of hospital reporting defines "2007 reports" as those events that *occurred* in 2007. This may lead to discrepancies in overall reporting volumes.

[#] Note that the actual review and assessment occurs in the year following report submission (i.e. the reports submitted in 2008 will be certified in 2009).

Renal dialysis centers	Program deferment	Program deferment	Program development	Program development	Assessment
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The Public Health Officer will apply a phased-approach with the initial emphasis on assessment of program status and develop more concrete certification standards as the reporting programs progress. Each facility type will be on a certification schedule according to their program maturity (Table 1).

The hospital program is due for PHO Certification in 2009 (reports from 2008 calendar year) according to standards created in 2008. With recruiting activities consuming most of 2007 for the nursing home and ambulatory surgery center program will have their first data assessment for reports submitted in 2008. They will move forward in manner similar to hospitals after that. Retail pharmacies data will not be assessed until the program has officially launched.

Certification – How are they doing?

The first phase of PHO Certification for hospitals, nursing homes and ambulatory surgery centers was completed in April 2008 by reviewing all de-identified adverse event reports using the certification criteria (Appendix A). Commission staff provided additional data where necessary. The results are reported in sections for the individual facility types: hospitals, nursing homes, ambulatory surgery centers and retail pharmacies. The assessment aligns with the developmental stages of each program. Each facility type includes Certification in the following categories:

Reporting Assessment

- Report Quality
 - Completeness
 - Adverse Event Description
 - Adverse Event Analysis
 - Adverse Event Action Plans
- Report Quantity

Overall Integrity of the Reporting Program Assessment

- Program Participation Rates
- Reporting Tool Design
- Implementation of Reporting Program
- Adverse Event Report Review Process and Action Plan Follow-up
- Dissemination of learning and best practices
- Rates of written notification

Methods

The report quality is determined by the completeness, thoroughness and credibility of the individual reports. These overarching criteria are specified in the statute (Oregon Laws 2003 c.686 §9) and originate from similar review guidelines of Sentinel Event Reports submitted to the Joint Commission⁶.

All participants report adverse events using a facility-type-specific reporting form provided by the Commission (Appendix B). The lists of required reportable events (Appendix C) were adapted from a definitions created by the Joint Commission and the National Quality Forum (NQF)⁷. Oregon's lists for hospitals and nursing homes focus on events that result in death or serious physical injury. The reportable events for freestanding ambulatory surgery centers and retail pharmacies were adapted by the expert advisory groups to better reflect their clinical realities. As a result they include some specific types of low harm adverse events.

The adverse event reporting forms are divided into two parts: Part I required for all adverse events and Part II only for serious adverse events. The form collects information about general demographics, adverse event description, investigation of contributing factors and causes (also root cause analysis) and action plans to prevent similar adverse events in the future.

⁶ Joint Commission Sentinel Event Policy and Procedures http://www.jointcommission.org/NR/rdonlyres/690008C7-EAB2-4275-BC7B-68B37481D658/0/SE_Chap_Sept06.pdf. Accessed on November 14, 2006.

⁷ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

The PHO report quality assessment is measured using the PHO Certification Tools (Appendix A). There are four main areas of quality that mirror elements in the report form:

- Report completeness
- Event description
- Event analysis and
- Action plan development.

Please refer to question #3 in the certification tool (Appendix A) for more detailed information about these areas. Each area is determined separately using one or more data elements as described in the detailed sections below. The areas are also combined to assess **total report quality**.

There was one change made to the certification tool from 2007 to 2008: one of the questions relating to action plan acceptability for serious adverse events was removed. The certification question, “Are action plans specific and concrete?”, was difficult to answer using the information submitted in the reports and offered no extra value.

The quality areas are evaluated using a scoring system for each of the criteria elements. Most questions scored as criteria *met*, *partially met* or *not met*, which results in two, one or zero points respectively. Some certification questions are scored as only met or not met, but result in the same point levels, two or zero in this case. Finally, there is one question under the action plan criteria that is scored as met (two points) if 75% of the submitted action plans are focused on systems solutions instead of individual provider focused.

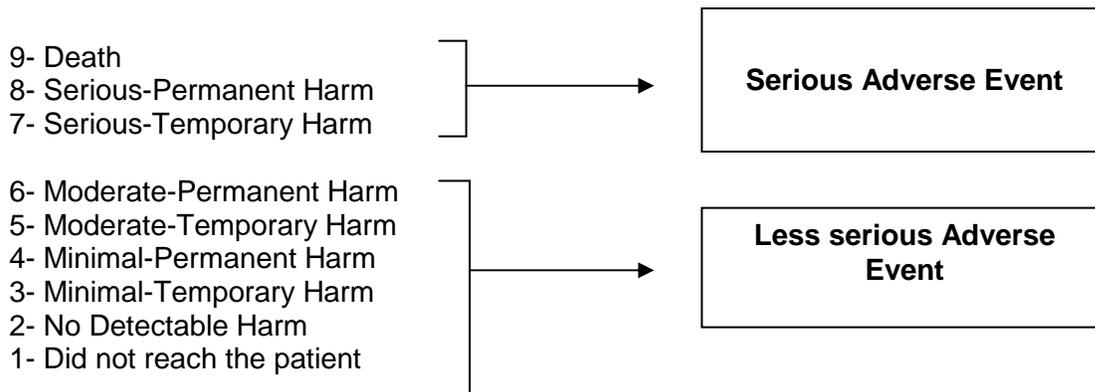


Figure 2 Level of Patient Harm Scale.

As previously described, the reporting form submitted by participants requires a higher level of investigation and action plans for the most serious events. Accordingly, the certification analysis is also broken down by serious and less serious events. The severity of an adverse event is determined by the reporting facility using a modified harm-level scale from one to nine and confirmed by Commission staff (Fig. 2). Harm-level seven to nine are defined as serious adverse events and levels six and below are less-serious events. Serious can also be defined as an event that severely impacts a patient’s status or functional ability or for example requires transfer to a higher level of care, surgical intervention, any increase in length of stay, or readmission. Permanent is defined by the Commission as: present at discharge and the resolution is uncertain or expected to continue for six months or more. It is important to note that some of the required reportable adverse events are less-serious events such as some retained foreign objects and wrong surgical procedures. This is consistent with NQF standards.

Each of the four report quality areas is scored separately. Completeness is either *met* or *not met*, contributing two or zero points to the total quality score. Event description is scored as *met*, *partially*

met or *not met* and resulting in two, one or zero points. The adverse event analysis is a combined score from two data elements for less serious events or four for serious events (Table 2). The maximum points were 4 or 8 for less serious or serious events respectively. Action plan assessment is also a combined score from 2 data elements for less serious and serious events resulting in 4 maximum points. The maximum points for a serious adverse event were therefore 18 and 12 for a less serious event. Together, these criteria address overall aspects of completeness, thoroughness and credibility.

Table 2: Quality Scoring

	Less serious (max. points possible)	Serious (max. points possible)
Completeness (1 data element)	2	2
Event description (1 data element)	2	2
Event analysis (2 or 4 data elements)	4	8
Action plan (2 data elements)	4	4
Total	12	18

The quality is reported for serious and less serious separately and combined as proportion of total number of reports in each category. Completeness and event description are categorized as *met/not met* and *met/partially met/not met* respectively. Adverse event analysis, action plan development and total quality are reported in categories of *low*, *medium* or *high*. The scores in each area are calculated as a percent of total possible.

They are then grouped into quality categories:

- *low* (0-33%),
- *medium* (34-66%)
- *high* (67-100%)

For example, a less serious event report that received 4 points for the analysis area would be 100% of possible points and thus be categorized as high quality.

The Public Health Officer reports the quality as composite scores for serious and less serious adverse events combined and separately.

Hospitals

Hospital participants began reporting in May 2006 and were asked to submit any events that occurred between January and May if feasible. Some hospitals were able to provide retroactive reports while many could not. Thus, although 2007 is the second year of reporting it is the first full calendar year.

Reports Received

Hospitals submitted adverse event reports for the full calendar year in 2007.

In 2007, the Patient Safety Commission received a total of 94 adverse event reports from 30 of 54 participating hospitals. Of the 94 reports, 34 were less serious and 60 were serious adverse events. There were 55 total reports in 2006, of which 22 were less serious and 33 were serious adverse events.

Report Quality

Report Completeness:

Of reports submitted, 94% were determined to be complete (Fig. 3). A report is considered complete if reporting form contained no more than one unanswered question. The reasons for incompleteness ranged from missing questions to a whole section not filled out. The completeness rate is down from the 2006 level of 100%.

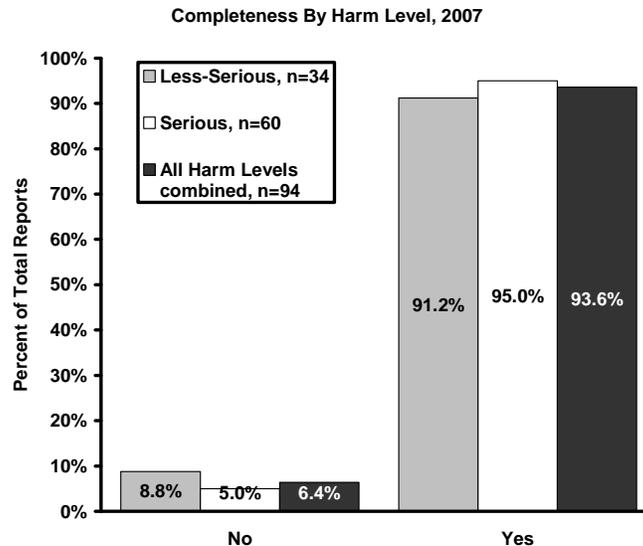


Figure 3 Report Completeness

- *Assessment: Very good level of report completeness*
- *Recommendations: Continue to expect all reports to be complete*
- *Proposed standard for 2008*: ≥90% reports are complete*

Adverse Event Description:

The event description is an integral part of the adverse event report. The narrative component builds the foundation for understanding the event and also the investigation and prevention strategies that follow. Without a comprehensive description, it is more difficult to utilize the data to generate best practices. Hospitals are required by the Commission reporting form to submit a clear and concise summary of the event. An adverse event should be described more from a systems perspective and less from a purely clinical view.

The PHO Certification criteria are met if the event narrative fully explains the event by including who, what, when, where and how in the event description. If there are one to three ambiguities it is considered partially met and if there are more than three questions about the description, it is unmet.

* PHO Certification for 2008 will occur in 2009, subject to change

Most event descriptions were found to meet (27.7%) or at least partially meet (43.6%) the certification criteria (Fig. 4). The remaining reports (28.7%) did not meet the event description criterion, which means there were more than three unclear elements in the description. Compared to the 2006 reports, the combined rate in the *met* category increased slightly (from 25.5% to 27.7%). At the same time the percentage of reports not meeting the event description criteria increased from 16.4% in 2006 to 28.7% in 2007. This may be partially due to one particular facility that submitted very brief event descriptions of one to three sentences. The event description quality would improve by concisely providing basic information of who, what, where, when and how of the event.

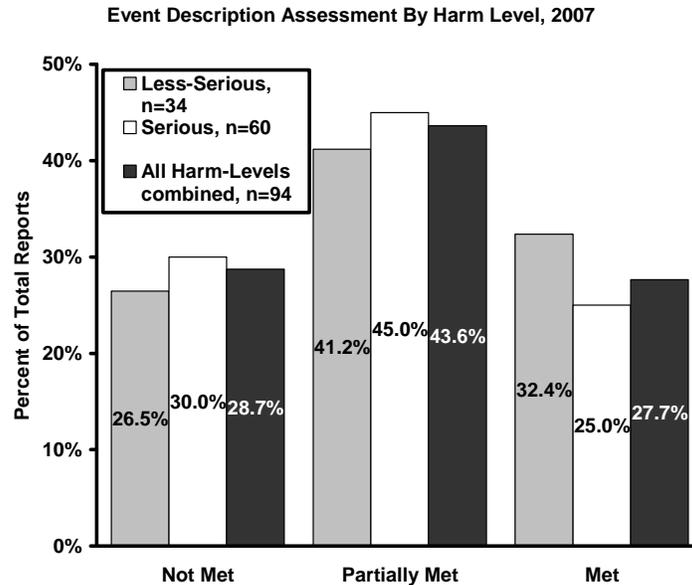


Figure 4 Event Description Quality.

As Hospitals submit more reports they are becoming more familiar with the Patient Safety Commission expectations. They are also building and refining their adverse event investigation skills. With the implementation of the new web-based reporting system and improved reporting skills, the PHO would anticipate more reports to fully meet the event description criteria.

- *Assessment: Acceptable quality of event description: 27.7% of the reports met Certification criteria, while 43.6% were found to partially meet and 28.7% did not meet the criteria for an acceptable event description.*
- *Recommendations: Set clear expectations for an acceptable event description with a focus on systems issues*
- *Anticipated Progress: ≥90% of all reports in the “met” or “partially met” category*

Adverse Event Analysis:

Each reported adverse event requires an investigation into the causes and contributing factors. Hospitals usually perform a root cause analysis to identify the contributing and causal factor(s). As with the event description, the investigation data collected will allow the Commission to generate best

practices to prevent events and share with all Oregon hospitals. The depth of analysis reporting that is required depends on the severity of the event. Investigations of serious adverse events that cause temporary or permanent serious physical injury or death are reported to the Commission in more detail than less serious events. The specific certification questions include: does the analysis focus primarily on systems as opposed to individual performance and identify causes most directly associated with the event. There are additional questions about investigation participants and internal consistency of the investigation for serious adverse events (Appendix A).

As previously described, analysis quality is a combined score from all analysis elements (Appendix A). The questions address both thoroughness and credibility of the adverse event report. They are expressed as a percent of total possible points and categorized into low (0-33%), medium (34-66%) and high (67-100%) quality categories. Figure 5 shows the proportion of reports in each category.

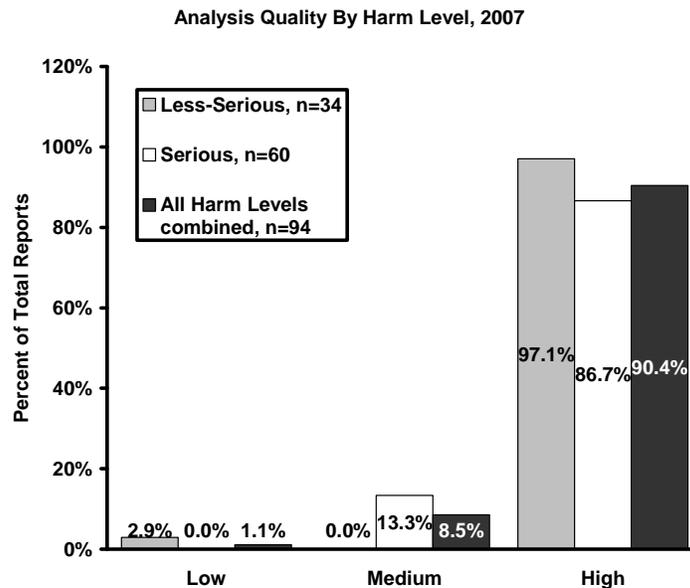


Figure 5 Analysis Quality.

Overall, the analysis quality was excellent with over 90% in the high quality category (Fig. 5). This is up from 76.4% in 2006. There was a slight difference seen in analysis quality between serious and less serious events, which may have been due to missing answers for some of the analysis questions.

Hospitals were successful at focusing on systems issues that contributed to the adverse event in about 90.8% of the reports and somewhat less so in identifying the contributing factors most directly associated with the event (87.2% reports met). The serious adverse event reports were found to have good participation of senior management and personnel with relevant expertise in the investigation with over 95% for both. Internal consistency of the analysis was scored as met, partially met or not met. Submitted reports showed over one third (37%) completely met and about half (56%) were partially met, while about 7% had more than 3 inconsistencies and therefore did not meet the criteria.

The analysis quality is strong for the second year. Improving patient safety and reduction of preventable harm to patients involves a chain of activities that build upon one another. Hospitals will need excellent root cause analysis results to effectively develop useful action plans for future harm prevention. The

PHO review only examines the data submitted to the Commission and is therefore a partial look at the adverse event analysis in hospitals.

- *Assessment: Acceptable analysis quality: 90.4% of the reports were found to be high quality, while 8.5% were in the medium quality category and 1.00% were determined to have a low quality for adverse event analysis*
- *Recommendations: Maintain expectations with feedback about quality from the Commission report review tool assessment and continue to provide support to hospital participants*
- *Proposed standard for 2008*: $\geq 90\%$ reports are in the high quality adverse event analysis*

Adverse Event Action Plans:

The submitted reports must also include strategies to address prevention of recurrence of the adverse events. These are commonly called action plans, which are a measure of thoroughness and credibility of a well-done investigation. Here again, the prevention strategy data is collected for best practice generation to be shared with all Oregon hospitals. Commission report forms require hospitals to list the contributory factor, describe the action item. The certification tool (Appendix A) assesses all reports with questions about addressing the identified root cause and the action plans' probability of reducing the likelihood of similar events in the future.

Assessment of action plan quality is also expressed similarly to the adverse event analysis quality as a combined score that is grouped into low (0-33%), medium (34-66%) and high (67-100%) quality categories.

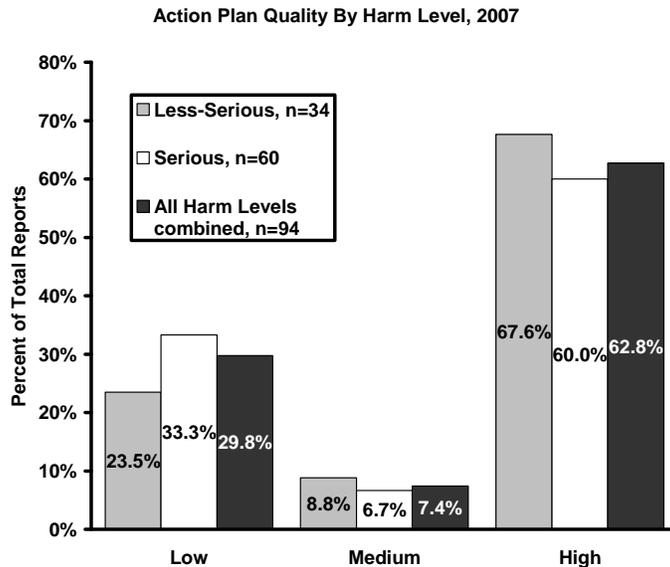


Figure 6 Action Plan Quality.

The action plan quality was good with 62.8% in the high quality category, 7.4% of medium quality and 29.8% low quality (Fig. 6). Compared to 2006, there were increases on both ends of the spectrum: 52.7% high, 30.9% medium and 16.4% low quality. Designing system level action plans is a

* PHO Certification for 2008 will occur in 2009, subject to change

challenging step in patient safety improvement. Again, there was little difference seen in action plan quality between serious and less serious events (Fig. 6).

Hospitals appear to have made progress toward developing and reporting preventive action plans in 2007 as shown by the higher proportion in the “high quality” category. However, there is also a greater number in the “low quality” category. The PHO would expect a shift in the quality levels in this area to the higher categories for certification in 2008.

- *Assessment: Acceptable action plan quality: 62.8% of the reports were found to be high quality, while 7.4% were in the medium quality category and 29.8% were determined to be low quality for action plan development*
- *Recommendations: Provide more feedback when action plans seem to be less than high quality and set expectations. Continue to provide support to hospital participants*
- *Anticipated Progress: $\geq 75\%$ of action plans in high quality category*

Total Report Quality

The total report quality combines the completeness, event description, analysis and action plan scores and is reported here for serious and less serious adverse events separately and combined (Fig. 7). As previously described the total report quality score is calculated by adding all scores and reporting as a percent of total possible. The total scores are then grouped into the same low, medium and high quality categories.

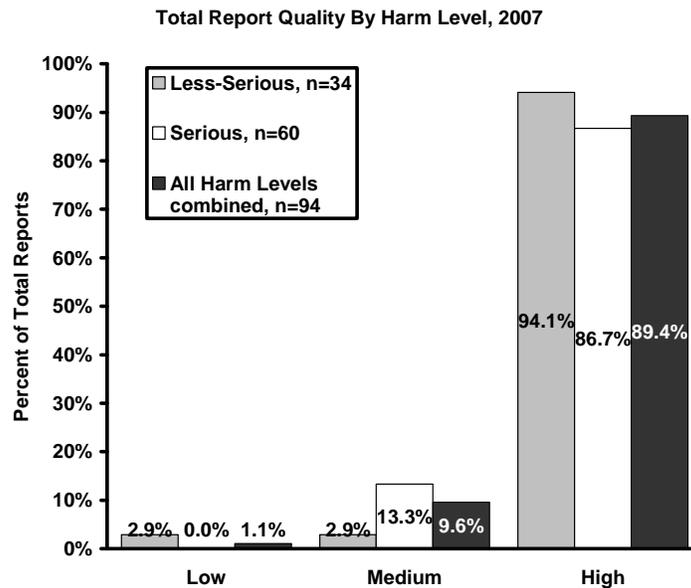


Figure 7 Total Adverse Event Report Quality.

The submitted reports for 2007 were noticeably stronger than 2006 with over 20% increase in the proportion of high total quality (from 67.3 % to 89.4%). Reports assessed as medium and low total quality were 13.3% and 1.1% (Fig. 7). When separated by harm level, there is minor difference in total report quality. In contrast to 2006, the less serious event reports showed higher total quality.

Overall, hospitals have improved the total report quality and met the anticipated progress from 2006. Although adverse event reporting and report quality are only one aspect of improving patient safety, we

regard it as an essential step in the process. In the coming years, the PHO would anticipate that all hospitals would submit reports in the high quality category.

- *Assessment: Good total report quality: 89.4% of the reports were found to be high quality, while 13.3% were in the medium quality category and 1.1% were determined to have a low total report quality*
- *Recommendations: Continue to set expectations for hospitals and provide feedback when a report does not meet the Commission standards.*
- *Anticipated Progress: $\geq 90\%$ in the high quality category*

Report Quantity: How much is Enough?

The assessment of the absolute quantity of reports submitted by hospitals is a challenging task. The PHO Certification attempts to make sense of the number of reports and set broad expectations for future standards. The Reporting Program represents a tool to understand the types of adverse events occurring in Oregon along with their characteristics and causes. Information collected can be analyzed and shared with all health care providers across the state. Robust reporting from hospitals will enable the Commission to facilitate the work of generating and sharing best practices and convening statewide patient safety improvement projects for the benefit of all Oregonians. Increasing levels of reporting also have a transparency value for the public and may serve as a motivation for overall system change.

Table 3: Events Reported by Hospital Size

Size	# Hospitals in Program	Total # Reports filed
Small (0-3000 Discharges)	27	12 (13%)
Medium (3001-10,000 Discharges)	16	21 (22%)
Large (Over 10,000 Discharges)	11	61 (65%)
TOTAL	54	94 (100%)

In 2007 (January 1 – December 31) the Patient Safety Commission received a total of 94 adverse event reports from 30 of 54 (56%) participating hospitals (Table 3). Of these 94 reports, 60 were serious adverse events and 34 were less than serious events as defined in the harm-level scale (Fig. 2). In 2006 there were 55 total events, 33 serious adverse events and 22 less serious events. About 56% of the participating hospitals submitted at least one report (Table 3) and they represent about 78% of the annual statewide discharges. This is an increase from 2006, when 27 hospitals submitted at least one report.

What is robust reporting? Currently, there is no well-established measure of serious adverse event rates available. This is due, in part, to the many definitions of what constitutes an adverse event and also to the controversy over what is unanticipated and usually preventable. It is certainly also due to the current lack of reliable systems to prospectively identify preventable harm. Some research refers to medical errors, while others study serious adverse events and still others would prefer to examine harm to patients no matter if it is caused by an error or not. In this report, we attempt to make sense of the number of adverse event reports received by the Commission by considering some estimates from the literature and reporting volumes from similar state programs.

There are many estimates of harm to patients. We illustrate a few examples here. The most commonly cited number is 44,000 to 98,000 hospital deaths due to medical errors annually from the *To Err is Human* report⁸. This translates roughly to a range of 932 to 1837 potentially preventable deaths of Oregonians cared for in inpatient settings (using hospital discharge numbers from 2004 [365,031]). The studies that contributed to these approximations used retrospective medical record review in hospitals to make their estimates, which is not the common method that hospitals use to prospectively identify adverse events. The IOM estimates have been controversial due to the question of whether the reported deaths were directly attributable to the adverse events, or whether some patients would have died from their disease anyway. This estimate presumes simple mortality rates for patients experiencing adverse events, but is not intended to infer clear causality^{9,10}. Multiple authors included on the IOM Quality of Health Care in America Committee answered the criticism by stating that the estimates may actually be too low for two main reasons: medical records do not always contain information about errors and injuries and estimates exclude harm that is caused in the outpatient setting¹¹. Whatever the number, the IOM estimates make the case that we need improve patient safety by building stronger systems to identify adverse events and prevent patient harm.

Other estimates of patient harm in the broadest sense come from the Institute for Healthcare Improvement's Global Trigger Tool¹². This tool is designed to assess harm instead of trying to separate events that can be seen as errors. The definition of harm in the Global Trigger tool is: Adverse event is an injury or harm related to the delivery of care. The harm identified by the tool ranges from temporary harm to the patient and required intervention or initial or prolonged hospitalization, permanent patient harm to death. The tool is used for chart review in a hospital setting and reveals approximately 40-50 patient injuries per 100 hospital admissions¹³.

The Pennsylvania Patient Safety Authority represents one of the more established state-level reporting programs. It is important to note that the definition of reportable events differ from those in the Oregon program. The reporting system collects two types of occurrences: incidents (events without harm to patients) and serious events (adverse events resulting in patient harm)¹⁴. They received reports of 7,277 serious events (and 204,706 incidents) from 511 hospitals, ambulatory surgery centers and birthing centers in 2007. Using this rate of 0.0043 events per hospital discharge, (2004 PA hospital discharge numbers) Oregon would have close to 1500 serious events as defined in Pennsylvania. Although Pennsylvania has been recognized for its strong reporting levels, their rates may not necessarily be considered the universal standard.

⁸ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

⁹ McDonald, J. et al. Deaths Due to Medical Errors Exaggerated in Institute of Medicine Report. *JAMA*. 2000;284:93-5.

¹⁰ Hayward, R. and Hofer, T. Estimating Hospital Deaths Due to Medical Errors Preventability Is in the Eye of the Reviewer. *JAMA*. 2001;286:415-420.

¹¹ Quality of Health Care in America Committee. The Institute of Medicine Report on Medical Errors: Misunderstanding Can Do Harm. *Medscape General Medicine* [serial online] September 19, 2000.

¹² Griffin FA, Resar RK. *IHI Global Trigger Tool for Measuring Adverse Events*. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2007. (Available on www.IHI.org). Accessed on April 25, 2007.

¹³ Institute for Healthcare Improvement. Frequently Asked Questions about the 5 Million Lives Campaign. IHI Website. 2007. Available at <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=6>. Accessed on March 31, 2007.

¹⁴ Pennsylvania Patient Safety Authority 2007 Annual Report. http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2007.pdf. accessed on May 2, 2008.

Oregon's Patient Safety statute defines serious adverse event as an objective and definable negative consequence of patient care, or risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury (Oregon Laws 2003, c. 686, §1).

For the purpose of comparison, there is no other state or system with exactly the same list of reportable events and a confidential voluntary program. However, we believe it is important to understand the Oregon data in a broad context in order to set some expectations for realistic numbers in our state. Oregon's list of reportable adverse events (Appendix C) for hospitals uses the National Quality Forum's *Never Events* as a starting point¹⁵ combined with the Joint Commission's sentinel event guidelines¹⁶. As previously mentioned, many other states have embraced using this list or a modified version to define what is reportable in their mandatory reporting programs. Specifically, Minnesota¹⁷, Connecticut¹⁸, New Jersey¹⁹ and Washington²⁰ have released annual reports describing their results (Table 4). It is crucial to understand that there are limitations to the applicability of such a comparison for the following reasons:

Caveats in the cross state comparison:

- Maturity of adverse event reporting program
- Definition of reportable events
- Structure of program [i.e. mandatory, public reporting, electronic reporting, funding for communication and training, etc.]
- Support from stakeholder and regulatory organizations
- Legal risks, confidentiality of reports
- Statewide culture of patient safety

Like Oregon, Connecticut, Washington and New Jersey publicly report adverse events only in the aggregate for all hospitals, while Minnesota discloses events at the facility level in their annual reports. Washington has since made several amendments to their statute (Washington Laws 2008 c. 70.56 and 42.56), which now includes public disclosure of facility-specific adverse event notifications. While Washington has accumulated about 18 months of reporting, Oregon is in the second year of reporting. Minnesota, Connecticut and New Jersey are more mature programs. Connecticut has a somewhat broader definition of the injury that could potentially lead to more such reports. Minnesota and Connecticut all have electronic reporting systems, which may contribute somewhat to ease of reporting. New Jersey, Washington and Oregon are in the process of developing their electronic reporting systems. Oregon, Washington, New Jersey and Minnesota require hospitals to submit an event description, root cause analysis and action plans. Connecticut requires an event description and an action plan. Any of these program variations may influence reporting levels functioning as incentives to provide more reports or disincentives against reporting.

¹⁵ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

¹⁶ *Joint Commission Sentinel Event Policy and Procedures* http://www.jointcommission.org/NR/rdonlyres/690008C7-EAB2-4275-BC7B-68B37481D658/0/SE_Chap_Sept06.pdf. Accessed on November 14, 2006.

¹⁷ Minnesota Department of Health. *Adverse Events in Minnesota: Fourth Annual Public Report* January 2008. Available at <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>. Accessed on February 14, 2008.

¹⁸ Connecticut Department of Public Health. *Legislative Report to the General Assembly: Adverse Event Reporting*, October 2007. <http://www.ct.gov/dph/lib/dph/hisr/hcqsar/healthcare/pdf/adverseeventreportoct2007.pdf>. Accessed on February 14, 2008.

¹⁹ 23 New Jersey Department of Health and Senior Services. *Patient Safety Initiative 2006 Summary Report*. Available at http://www.state.nj.us/health/ps/documents/ps_report_2006.pdf. Accessed on January 23, 2008.

²⁰ Washington State Department of Health. *2006-2008 Serious Reportable Events*. Available by public disclosure from Linda.Furkay@doh.wa.gov. Received on June 17, 2008.

Table 4: Selected Other States - Adverse Event Numbers from hospitals

State, Original Implementation Date	Number of Events, timeframe, year	Confidentiality	Definition of Reportable Events	Events/10,000 patients discharged per year	Non-reporting hospitals
Minnesota, 2003	125 / 12 months, 2006/2007	Public reporting at facility level	NQF definitions verbatim	2.6*	72%
Connecticut, 2004	206, 12 months, 2006/2007	Public reporting in aggregate only	NQF with additions	4.9	Not available
New Jersey, 2005	450 / 12 months, 2006	Public reporting in aggregate only	NQF with additions and exclusions	3.8	~12%
Washington, 2006	196 / 12 months, 2007	Public reporting in aggregate only**	NQF definitions verbatim	3.1	46%
Oregon, 2006	94 / 12 months, 2007	Public reporting in aggregate only	NQF with additions and exclusions	2.7	44%

*2006 utilization data, **After June 2008, public disclosure of adverse event notification by facility

The estimated rate of reported adverse events in Oregon is well within the range of what is being seen in other similar state reporting programs. In spite of the many minor differences, Table 4 does provide us with broad comparisons. The proportion of non-reporting hospitals (hospitals that have not submitted any adverse event reports to the program in 2007) in Oregon (44%) is lower than at least two other states. **All other comparator states have mandatory reporting systems.** In Oregon, after hospitals have signed the voluntary participation contract, they do agree to submit all reportable adverse events to the Commission.

It is common for reporting programs to experience lower levels of reporting in the early years of implementation. For example, Minnesota hospitals reported 99 events in their first 14 months, 106 events in the second year and finally 154 events in 2005/2006²¹. In their most recent report from January 2008, they report a slight reduction, 125 adverse events, in spite of increased utilization rates. Other states such as Pennsylvania and New York have seen similar trends²². The increase in reports submitted is generally not viewed as an actual increase in events, but rather as a result of other factors. These include proactive patient safety programs in facilities, more committed leadership, trust in a transition to a more systems-based approach to errors and patient harm rather than a culture of blame and shame, stronger adverse event surveillance capacity and much more. More high quality adverse event reports lead to more opportunity for learning and patient safety improvement.

²¹ Minnesota Department of Health. *Adverse Events in Minnesota: Fourth Annual Public Report* January 2008. Available at <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>. Accessed on February 14, 2008.

²² Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

The success of the quality-improvement approach as designed in Oregon depends on the willingness and ability of all program enrollees to become fully engaged participants. The Patient Safety Commission needs to have a robust level of reporting of adverse events in order to fulfill its mission.

The PHO finds that the total number of submitted reports in Oregon to be solidly within the range observed in similar mandatory state adverse event reporting systems. This could be an indication that Oregon's voluntary program may achieve broadly comparable reporting levels of mandatory programs in other similarly structured states.

Although reporting levels in Oregon are within the range of that seen in similar state programs, this should not be regarded as the standard. Realizing that there is currently no clear expected rate of serious adverse events as defined in Oregon, we do find estimated ranges from the literature^{23,24,25} to consider. The Public Health Officer Certification finds that the total number of submitted reports from all hospitals combined is lower and the proportion of hospitals that have not submitted any reports is higher than the literature would suggest. The broad analysis of other estimates leads us to believe that there are more reportable serious adverse events to be identified and reported by Oregon hospitals.

In the coming years, the PHO anticipates a continued gradual increase in reporting and a decrease in the number of non-reporting hospitals in Oregon. The Commission must do its part to encourage and enable hospitals to report adverse events. Hospitals also have a key role to play. Although participation in the reporting program is voluntary, each participant has agreed to fully communicate all reportable serious adverse events to the Commission. This is essential for maximized statewide learning

- *Assessment: Total number of submitted reports from all hospitals combined is increasing as expected, but still lower than literature estimates. The proportion of non-reporting hospitals is still too high*
- *Recommendations: Set clear expectations and develop systems of accountability. Continue to identify and work to help hospitals reduce barriers to reporting, build additional trust in the confidentiality aspect of the program, keep the administrative burden as low as possible without compromising the data needed for effective quality-improvement, launch the electronic web-based reporting effectively, and remind hospitals of participation agreement to report all events on the list of reportable events, support more diffusion to the frontline providers and continue to gain the support of executive and clinical leadership in hospitals*
- *Anticipated Progress: Reduce the proportion of non-reporting hospitals to $\leq 20\%$ after three full years of report submissions and continue to increase the number of reported events to better reflect the likely rates of occurrence.*

²³ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

²⁴ Institute for Healthcare Improvement. *Frequently Asked Questions about the 5 Million Lives Campaign*. IHI Website. 2007. Available at <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=6>. Accessed on March 31, 2007.

²⁵ Pennsylvania Patient Safety Authority 2007 Annual Report.

http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2007.pdf. accessed on May 2, 2008.

Overall Integrity of the Reporting Program

Participation Rates

Hospitals have shown a strong commitment to the Oregon Patient Safety Reporting Program with excellent levels of voluntary enrollment. Fifty four of Oregon's 57 acute care hospitals participated in the program in 2007, representing 99.3% of total annual discharges. The distribution of participation by hospital size is 100%, 100%, and 90% for large, medium and small facilities respectively (see Table 5). These numbers symbolize persistent work on the part of the Commission and continued willingness of hospitals to share adverse event data.

Table 5: Voluntary Hospital Enrollment

Size	Hospitals in Oregon	Percent of Total Statewide Discharges	Participation Agreement	Percent of Total Statewide Discharges Participating
Small 0-3000 Discharges	30	10.9%	27 (90%)	9.8%
Medium 3001-10,000 Discharges	16	24.8%	16 (100%)	27.2%
Large over 10,000 Discharges	11	64.2%	11 (100%)	62.3%
Totals	57	100%	54 (94.7%)	99.3%

- *Assessment: Excellent hospital enrollment rates*
- *Recommendations: Maintain enrollment in the future by continuing to show value added for hospitals and work to convert the non-reporting enrolled hospitals to true reporting participants*
- *Proposed standard for 2008*: Maintain number of participants that represent $\geq 90\%$ of statewide annual discharges*

Reporting Tool Design

The certification tool inquires about three main aspects of reporting form design: clear definitions of reportable adverse events and reporting guidelines, inclusion of broadly accepted patient safety principles and support for the assessment of completeness, thoroughness and credibility of the adverse events (Appendix B). The report form alone forms the foundation for adverse event reporting. Well planned implementation is the next layer of reporting.

In May 2007, the report form was revised after feedback from hospitals. Changes include clarification of reportable events, added definition of "serious physical disability", expansion of the event type section, added pharmacy-related adverse event section and other minor edits. Moreover, the Commission created an annotated version of the reporting template to assist hospitals in filling out the form.

* PHO Certification for 2008 will occur in 2009, subject to change

Overall, adverse event reporting template has improved over the original version. Many of the recommendations from the 2006 PHO Certification were integrated. The changes balance comprehensiveness with utility and feasibility.

The annotation of the report form is a step in the right direction. However, to ensure strong report submissions we recommend setting clear expectations and providing sample reports in a brief accompanying guide. In particular, the event description is often cursory and does not contain enough information to allow the PHO review of reports. It is difficult to establish reports as thorough and credible if crucial summary details are missing.

- *Assessment: The adverse event reporting tool provides clear definitions and includes standard patient safety information about contributing factors and action plan strategies. There are some questions that do not appear to result in consistent high quality answers, which may be due, in part to understanding clear expectations of the form*
- *Recommendations: Provide brief written guidelines with set expectations and sample reports for participants*
- *Anticipated Progress: Use an adverse event report form that allows and expects the hospital to submit high quality summaries of their patient safety work. The reporting template, including additional written guidance, should also enable hospitals to fully summarize their work in a reasonable time frame.*

Implementation of Reporting Program

Robust communication with participants is an important part of program integrity. Certification elements for reporting program implementation include timely support for program participants in completing the adverse event report form and adequate feedback to hospitals during the report submission process.

Commission staff contact hospitals within 10 business days of the receipt of an event report if they believe that a report is incomplete or unacceptable. There is an official contact log for tracking. The default is notice through the secure email confirmation that the report has been opened. Telephone contact is initiated only if deemed necessary to clarify any outstanding questions. In addition, the field coordinator is always available by email and phone to assist with submission logistics, completing the form and deciding whether an adverse event is reportable.

Feedback to hospitals following report submission is usually by secure email. The field coordinator notes the successful parts of the report and other possible considerations for investigating and preventing similar events in the future. She also shares relevant resource material as it becomes available.

The reporting program has institutionalized good contact and rapport with many hospitals supporting their efforts to submit reportable adverse events to the Commission. Still there is much work to do to reach all hospitals and keep them updated with timeline requirements. In 2008, the web-based reporting will begin and the Commission will enter a new phase of implementation. The new reporting system is expected to help reduce the administrative burden on the field coordinator. The PHO recommends having a clear system for tracking the reporting timelines, questions and feedback to hospitals.

- *Assessment: The Commission entered a stabilization phase for reporting program implementation in 2007 and developed good contact to many of the hospitals. Questions and feedback were handled in an efficient and timely manner.*
- *Recommendations: Set expectations for report submissions and reporting timelines. Continue to track interactions surrounding these areas to measure Commission performance and responsiveness.*
- *Anticipated Progress: Continue to assess the needs of hospital participants and find the best ways to assist facilities with report submission*

Review Process

Certification elements for the review process ask about systematic and consistent review tools used by the Commission and inclusion of expert analysis of reports for the generation of sharable useful information for the participants (Appendix B).

In 2007 Commission staff implemented a more formal report review tool to determine complete, thorough, credible and acceptable for each submitted report. We recommend regular sharing of the review scores with hospitals to improve the quality of the data submitted.

The Technical Advisory Committee (TAC) is the expert group formed in late 2006. The Committee examines and gives advice about individual reports, identifies best practices from the action plans and provides direction from improving the depth and breadth of reports. Members include clinicians, a safety engineer, a healthcare administrator, an ethicist and others. The TAC also looks at patterns of reports and identify issues for the Commission, such as need for educational efforts, initiatives, and policy considerations. The group develops suggestions around clinical, investigative, organizational, and other issues. This work provides value-added patient safety information and is an additional source of data for the Commission's contribution to patient safety in the state.

- *Assessment: The formal internal review process for submitted reports was implemented for the 2007 reports. Expert analysis and review occurs with the Technical Advisory Committee.*
- *Recommendations: Communicate the results of report review to hospitals*
- *Anticipated Progress: Continue to assess report quality and share that information with the hospital participants. Support the full potential of the TAC to provide value added to the hospital reporting program.*

Action Plan Follow-up

The Certification element asks about follow-up of implementation and evaluation of effectiveness of the action plans. This element originates from a statutory requirement to oversee action plans to assess whether participants are taking sufficient steps to prevent occurrence of serious adverse events (Oregon Laws 2003 c.686 §4).

The annual Commission follow-up with hospitals regarding their proposed action plans for prevention of recurrence was scheduled to take place in 2007 for reports submitted in 2006. It was done for 6 out of 94 reports (6.4%).

The follow-through on action plans is a challenging step for many patient safety improvement teams. After the hard work of investigation and planning to address root causes, the actual work of testing of proposed action plans requires a high level of commitment. This stage of patient safety improvement

also carries great potential for the statewide program to share lessons learned. Following up with hospitals on serious adverse events and their action plans is an important activity that the Commission should perform annually. It serves as one of the public accountability elements of the voluntary reporting program.

- *Assessment: The action plan follow-up with hospitals was very low*
- *Recommendations: Create a strategy for prioritizing and tracking for serious adverse events and any other relevant adverse events/action plans. Offer support to hospitals on how to best track the success of action plans.*
- *Anticipated Progress: Moving toward $\geq 90\%$ follow-up of action plan for serious adverse events on an annual basis.*

Dissemination of Learning and Best Practices

The true work of improving patient safety will take place in the individual health care facilities and at the bedside. However, many pillars support this work including organizational level policies, executive level endorsement, nurse and physician champions and all levels of public policy. One way that the Commission contributes to supporting patient safety work is using a quality improvement approach of sharing knowledge across hospitals and other health care facilities. PHO Certification elements inquire about number and quality and relevance of the issued safety alerts and also any other communication tools for best practice sharing.

There were three safety alerts sent out electronically in 2007. They were well received by hospitals for quality and relevance.

Additional communications include monthly patient topics, retained foreign object recommendations and case study from the TAC and the Spring 2007 Five Million Lives Network conference.

The Commission continues to provide participants and the broader health care community with local technical support in all things “patient safety”. The TAC will progress in scope and begin to produce more patient safety recommendations of value.

- *Assessment: Very good, reliable sharing of relevant patient safety information and resources*
- *Recommendations: Continue to stay connected to hospital participants and understand how the collected patient safety data can contribute to improvements in facilities. Look for ways to use the data and analysis to support the patient safety initiatives already being pursued in hospitals (e.g. CMS measures, IHI Five Million Lives Campaign planks, Joint Commission Patient Safety Goals and NQF Safe Practices)*
- *Anticipated Progress: Maintain the close connections to participants to best understand how to provide value-added information and activities*

Rates of Written Notification

The written notification requirement was created as an opportunity for health care providers to demonstrate that the patient is at the center of what they do. In its own way it is also a crucial public accountability component of the Patient Safety Commission. The commitment of hospitals to communicate openly with patients and families about preventable adverse events and systems errors is a testament to patient-centered care. The statutory expectation is that participating hospitals will

provide written notification to all patients that have experienced a serious adverse event in a timely and consistent manner (Oregon Laws 2003 c.686 § 4).

The rate of written disclosure to patients and families who have experienced serious adverse events declined in 2007. In 25 (44%) of the cases hospitals sent letters to patients and family as part of the disclosure process, while 32 cases received no written disclosure. There were 60 serious adverse events submitted in 2007, of which 57 required written notification. The remaining 3 events were cases where family members could not be identified or located. In a few cases hospitals provided explanations for not sending a letter such as it was too late or the time between the event and the completed investigation was too long. Many simply answered no on the report form.

The concept of disclosure regarding adverse events in writing remains a relatively new and unfamiliar one for health care providers and patients alike. There is some concern from risk managers and medical malpractice insurers about the implications of such written communication. However, growing evidence is showing that oral disclosure done well with executive level support has some positive effects^{26,27,28}. National health care quality organizations such as the Joint Commission and the National Quality Forum are strongly supporting the improved communication with patients about medical errors and adverse events²⁹.

Overall, hospital participants in Oregon have signed agreements to fulfill the written disclosure requirement even though it can be a complicated arrangement between physician, hospital and the various medical malpractice insurers. Many have successfully completed the process and are looking for ways to honor the concept of patient-centeredness. Others are not complying and it is important to understand where the challenges and barriers lie. The Commission fielded a survey of all hospital CEOs in April/May 2008 and is currently analyzing the results. The responses will help hospitals move forward on this important requirement.

The PHO Certification will continue to expect a move toward 100% written notification for each serious adverse event, while accepting that there may be rare exceptions. We recommend that the Commission move forward to offer further assistance to hospitals to do this well for the benefit of the patients and families.

- *Assessment: The rate of completed written notification to the patients and families has decreased from 67% in 2006 to 44% in 2007.*
- *Recommendations: Continue to help hospitals address the barriers and provide a clear vision of the patient-centered foundation of the written notification. Set expectations for 2008.*
- *Anticipated Progress: Moving toward 100% written notification for all serious adverse events with the exception of inability to locate an appropriate recipient.*

²⁶ Quinn, R. *COPIC's 3Rs Program - Recognize, Respond to and Resolve Patient Injury*.

<http://www.sorryworks.net/article33.phtml> Accessed on April 4, 2007.

²⁷ Wojcieszak, D., Banja, J., Houk, C. The Sorry Works! Coalition: Making the Case for Full Disclosure. *Joint Commission Journal on Quality and Patient Safety* 2006;32:344-350.

²⁸ Studdert, D.M., Mello, M.M., Gawande, A.A. Disclosure Of Medical Injury To Patients: An Improbable Risk Management Strategy. *Health Affairs* 2007;1:215-226.

²⁹ National Quality Forum. *Safe Practices for Better Healthcare: 2006 Update*. Washington, DC: National Quality Forum; 2007.

Setting Standards for Certification for 2008

As described in the methods section the Public Health Officer is using a phased approach for certification. The hospital program is collecting its third year of data in 2008, which means it is time to propose some standards for certification in 2009*. The identification of reasonable standards was done using the PHO assessment outcomes from 2006-2007 combined with statutory expectations.

In recognition of changing nature of the hospital reporting program since the development of the assessment tool criteria (Appendix A), the PHO proposes some draft standards. Nine certification elements were selected for quantitative standards. These elements focus mainly on reporting quality and quantity but also on enrollment and written notification. The remaining elements will be reviewed and recommendations issued.

Proposed minimum standards# for future certification of the hospital reporting program:

- Report Completeness: $\geq 90\%$ complete
- Adverse Event Description quality: $\geq 90\%$ in the met or partially met category
- Adverse Event Analysis quality: $\geq 90\%$ in the high quality category
- Adverse Event Preventive Action Plans quality: $\geq 75\%$ in the high quality category
- Total Report quality: $\geq 90\%$ in the high quality category
- Report quantity: Reduce the proportion of cumulatively non-reporting hospitals to $\leq 20\%$ after 3 full years of report submissions (2007-2009)
- Program Enrollment: maintain participants the represent $\geq 90\%$ of statewide annual discharges
- Action Plan follow-up: $\geq 90\%$ completed for serious adverse events
- Written Notification: 100% for all serious adverse events (with stated exceptions)

The proposed overall certification will be a composite of total standards with three possible levels:

- Pass with no reservations – 7-9 standards achieved
- Pass with reservations – 4-6 standards achieved
- No pass – 3 or less standards achieved

The Public Health Officer strives to find the best way to communicate to the public about the overall integrity of the hospital adverse event reporting program. The goal is to fulfill the statutory expectations of this one-of-kind accountability aspect of Oregon's patient safety legislation. Acknowledging the reporting program progress (increased reporting and additional qualitative data) the PHO will engage in a process to review the hospital certification elements and methods to establish final standards. The process will include input from interested parties beyond the Patient Safety Commission. The final standards will be completed by the end of 2008.

* The PHO Certification for reports submitted in 2008 will occur in 2009

subject to change

Nursing Homes

The administrative rules for nursing homes were adopted in March 2007 and recruitment began shortly thereafter. There are 142 eligible nursing homes in Oregon, many of which belong to multi-facility groups. With strong support from the Oregon Health Care Association and Oregon Alliance of Senior and Health Services the Commission finished the first round of enrollment at about 60%.

As previously described the nursing home list of reportable adverse events (see Appendix B) is different from the hospital list in order to account for the differences in practice scope and care. All required reporting for nursing homes are events that result in death or serious physical injury although participants are encouraged to submit less serious events that may provide valuable learning for others.

The Commission has since been engaged in orienting the nursing home participants to the requirements of the reporting program. Nursing homes have traditionally looked at incidents from a different perspective, often seeking individual culpability to explain problems. Efforts are underway to spread new knowledge and skills in more in depth event investigation and action plan development based on systems thinking.

The certification tool for nursing homes (see Appendix A) mirrors that for hospitals with a few exceptions. This first year of PHO Certification will be brief since the main program activities were recruiting and orientation.

For 2007 the emphasis is on the reporting program integrity portion of the certification. Nursing homes have a different quality improvement infrastructure than hospitals and are in the early development stages using root cause analysis tools. Applying the phased approach for the first year, the Public Health Officer makes assessments, offers mostly general recommendations about the reporting program and proposes anticipated progress where appropriate.

Reports Received

Nursing homes submitted one adverse event report in 2007. Most participants were just getting oriented and had less than three months in the program. The PHO Certification will not include an official report on quality and quantity with the low number of available reports.

Report Quality & Report Quantity

Assessment waived for 2007

Overall Integrity of the Reporting Program

Participation Rates

As of December 31, 2007 there were 87 nursing home participants enrolled. This represents 61% of all eligible nursing homes and 62% of total nursing facility beds in Oregon. The charter members represented 72% multi-facility organization beds and 28% independent (single-facility) organization beds.

Summary: The enrollment levels represent a solid foundation for a new and voluntary reporting program. The Patient Safety Commission should continue to pursue remaining nursing homes by

demonstrating value-added activities. The Public Health Officer would expect to see a substantial increase in 2008.

Reporting Tool Design

The reporting template used for nursing home adverse events was originally developed and piloted by ad-hoc advisory groups of experts from long-term care industry and then revised before the program rollout to more closely mirror the 2007 hospital report form. The template alone does not contain guidelines on how to report. This may cause confusion for some participants. It does, however, include clear definitions and comprehensive elements needed to improve patient safety. It also adequately supports the assessment of completeness, thoroughness and credibility of the reports.

The reporting template contains questions that are well adapted to the nursing home environment. It will need to be monitored in the future as more facilities report and discover potential improvements in the report form.

The Commission developed an extensive guide and training materials for participants. The reference notebook includes guidelines for filling out the report form, multiple examples, overviews of patient safety and quality improvement and a summary of the written notification requirement. These materials will undoubtedly support the first steps in adverse event reporting for nursing home leadership and staff.

Summary:

The reporting tool design is acceptable and is accompanied by an excellent companion guide.

Implementation of Reporting Program

As with the hospital program, the certification asks about timely support for program participants in completing the adverse event report form and adequate feedback to nursing homes during the report submission process (Appendix A).

The field coordinator reviewed the one report submitted and communicated with the nursing home about scheduling future orientation training. The assessment of one instance does not indicate much for the program as a whole. It will be important that all participants receive the orientation and training so that they are well prepared to truly participate.

Summary:

The reporting program implementation and report review process are in development.

Review Process, Action Plan Follow-up

As part of the integrity of the system, the PHO certification asks about systematic and consistent review tools used by the Commission and inclusion of expert analysis of reports for the generation of sharable useful information for the participants (Appendix A).

The report review tool used by the Commission to assess acceptability of submitted adverse event reports is identical to that for the hospital program. The single 2007 submission was reviewed as intended. At this early stage of the program, no expert analysis was performed. The Commission formed a Nursing Home Expert Panel to generate best practices using reports and the professional literature.

Summary:

The action plan follow-up will be required after the first year.

Dissemination of Learning and Best Practices

The PHO Certification asks about the details of active development and sharing of best practices for nursing homes.

Since the program was in an early developmental stage at the end of 2007, there is no extensive certification assessment possible. There were no safety alerts specifically for nursing homes in 2007.

The nursing home reporting program is currently involved in several activities to provide information about best practices for nursing homes:

- Nursing Home Expert Panel to review reports and work in specific improvement projects as chosen
- Development of an adapted Root Cause Analysis protocol
- Guide for the nursing home environment and the Pressure Ulcer & Transitional Care Project.

Summary:

The Public Health Officer found good initial activities to promote the development of value-added nursing home best practices.

Rates of Written Notification

As with the hospital program, nursing home participants are required to notify residents and their families in writing about reported serious adverse events in a timely and consistent manner. The care environment in nursing homes is quite different from the acute care setting of a hospital. The statute leaves much flexibility about how this requirement may be satisfied. As some hospitals are still developing their policies, nursing homes will also need to find the best way to meet this resident-centered accountability feature of the reporting program.

The only report submitted did not complete the written notification. They explained that the resident was already informed because they were involved in the adverse event.

The Commission fielded a survey to all nursing homes in Oregon in December 2007 to better understand how the written notification might be best implemented in nursing homes. They are actively looking for best practices to share and improve the completion rates.

The PHO Certification will expect 100% written notification for each reported serious adverse event, while accepting that there may be rare exceptions. We recommend that the Commission continue to help nursing homes to identify the best solution to fit their unique environment of care.

Summary:

Written notification not completed for the one report submitted in 2007. There were too few reports to assess for 2007.

- *Assessment: Good initial nursing home participation rates. Acceptable reporting tool design and excellent companion guide. Reporting program implementation and report review process are in development. Good initial activities to promote the development of value-added nursing home best practices. Written notification not completed for the one report submitted in 2007. Too few reports to assess other certification elements.*

- *Recommendations: Continue to pursue the remaining nursing homes by demonstrating value-added activities. Monitor usability of the form with nursing homes and adapt as necessary. Follow through with the report review and feedback plan. Share the results of the report quality assessment done by the Commission with each submission. Communicate with nursing homes about the review results. Engage the newly formed Nursing Home Expert Panel to find and share best practices. Continue to pursue useful best practices and share as widely as possible. Continue to assist nursing homes in identifying best solutions for written notification.*
- *Anticipated Progress: Participation rates will rise substantially by the end of 2008. As the program is implemented in 2008 it will address the PHO Certification criteria. 100% written notification for all serious adverse events with the exception on inability to locate an appropriate recipient.*

Ambulatory Surgery Centers

The administrative rules for freestanding ambulatory surgery centers (ASCs) were adopted in May 2007 and recruitment began about six weeks later. There were 76 eligible ambulatory surgery centers in Oregon in 2007. Since that time the number of licensed facilities continues to climb. There are additional hospital-associated ASCs that are reporting through their hospital programs. Most ASCs are individually owned with a few belonging to larger corporate entities. ASCs vary by specialty of services provided. Most are single specialty centers and the rest offer services in a number of different areas. After an extensive communications and recruiting campaign, just over 50% of the ASCs had joined the voluntary adverse event reporting program as of December 2007.

The list of reportable adverse events for ASCs (see Appendix B) was specifically developed for the unique care that is provided in these facilities. Required reporting in ASCs includes events that may, but do not necessarily result in death or serious physical injury. Starting from the National Quality Forum- based list used in hospitals the ad hoc advisory groups selected events according to expected relevance and frequency to make the reporting program useful for ASCs.

In 2007, ASCs received general orientation about the requirements of the reporting program. A more in-depth and systematic orientation is planned for 2008 after implementation of the web-based reporting system. Numerous ASCs participate in an accreditation program and are familiar with tracking unanticipated events and surgical complications such as infections and hospital admission. They investigate events but do not generally complete in-depth root cause analyses using a systems approach. The Commission is engaged in spreading new knowledge and skills with more detailed event investigation and action plan development based on systems thinking.

The certification tool for ASCs (see Appendix A) mirrors that for hospitals with a few exceptions. As with nursing homes, this first year of PHO Certification will be brief since the main program activity was recruiting. For 2007 there is emphasis on the reporting program integrity portion of the certification. Nursing homes have a different quality improvement infrastructure than hospitals and are in the development stages using root cause analysis tools.

Reports Received

ASC participants submitted adverse event reports for the partial year in 2007.

The Patient Safety Commission received a total of 12 adverse event reports from 5 of 39 participating ASCs. Of the 12 reports, all were less serious adverse events.

Due to the very short reporting period and lack of systematic training and orientation received by ASC participants the Public Health Officer will postpone the first year assessment of submitted reports until 2008. The 2007 review is mainly a status report with some assessment and recommendations.

Report Quality & Report Quantity

Assessment waived for 2007

Overall Integrity of the Reporting Program

Participation Rates

As of December 31, 2007 there were 39 ASC participants enrolled. This represents 51% of all eligible ASCs in Oregon.

Summary:

The enrollment levels represent a good initial commitment for a new and voluntary reporting program. The Public Health Officer would expect to see a substantial increase in 2008.

Reporting Tool Design

The reporting template for ASCs was developed by the Commission staff together with an advisory group in 2006-2007. The group used the hospital template as a starting place and was adapted to fit the needs of ASCs. In order to include elements of current ASC activities the group consulted the ASC accreditation programs: Joint Commission, American Association for Accreditation of Ambulatory Surgery Facilities and Accreditation Association for Ambulatory Health Care.

The reporting tool meets most PHO Certification requirements by incorporating clear definitions and comprehensive elements needed to improve patient safety. It also adequately supports the assessment of completeness, thoroughness and credibility of the reports. The missing piece is the reporting guidelines. The Commission will provide more detailed instructions along with an overview guide to support stronger reporting from ASCs.

There reporting elements are suitable for the broader ASC practice environment. As with all the programs the form will continue to evolve to meet the changing needs of the participants.

Summary:

The initial reporting tool design was acceptable. The Public Health Officer recommends a report form guide with training materials for 2008.

Implementation of Reporting Program

The PHO Certification assesses timely support for program participants in completing the adverse event report form and adequate feedback to ASCs during the report submission process (Appendix A).

The Patient Safety Commission field coordinator reviewed the reports and was available to answer questions about report submission on an as-needed basis.

Summary:

The reporting program implementation is in development. As the program is implemented in 2008, the Public Health Officer anticipates that it will address the certification criteria.

Review Process, Action Plan Follow-up

As part of the integrity of the system, the PHO certification asks about systematic and consistent review tools used by the Commission and inclusion of expert analysis of reports for the generation of sharable useful information for the participants (Appendix A).

The report review tool used by the Commission to assess acceptability of submitted adverse event reports from ASCs is identical to that for the hospital program. The twelve reports were reviewed with the review tool. ASCs were not informed of their review results.

At this early stage of the program, no expert analysis was performed. The Commission is currently building an ASC Expert Panel to generate best practices using reports and the professional literature.

Summary:

The report review process is in development. The action plan follow-up will be required after the first year.

Dissemination of Learning and Best Practices

The PHO Certification assesses active development and sharing of best practices for ASCs.

With the program was in early development at the end of 2007, there is no extensive certification assessment possible. There were no safety alerts specifically for ASCs in 2007.

The ASC reporting program is currently involved in several activities to provide information about best practices for ASCs: development of ASC Expert Panel to review reports and work in specific improvement projects as chosen, development of an adapted Root Cause Analysis protocol and guide for the ASC environment and bi-monthly meetings with the Oregon Ambulatory Surgery Center Association.

Summary:

The initial activities to promote the development of value-added ASC best practices are acceptable. There was too little activity in 2007 to assess more widely. The Public Health Officer anticipates that value-added activities for ASCs will have progressed by the end of 2008.

Rates of Written Notification

According to the Statute (Oregon Laws, c. 686), ASC participants are required to notify patients and families in writing about reported serious adverse events in a timely and consistent manner. The post-procedure care and communication varies for ASCs depending on their scope of practice and geographic location. Patients sometimes receive care at the ASC and then follow-up care is provided at a location closer to home. The variation raises some challenges in providing written notification to patients. The statute allows ample flexibility about how this requirement may be satisfied.

The Commission and ASCs may need to develop customized solutions to meet this patient-centered accountability feature of the reporting program. They must consider how the requirement might specifically affect the ASC environment.

Summary: The written notification requirement is not applicable since only less-serious reports were submitted in 2007. The PHO Certification will expect 100% written notification for each reported serious adverse event, while accepting that there may be rare exceptions. We recommend that the Commission work with ASCs to find options that make written notification a success for all.

- *Assessment: Acceptable initial ASC participation rates. Acceptable reporting tool design. Reporting program implementation and report review process are in development. Acceptable initial activities to promote the development of value-added ASC best practices. Written notification not applicable since only less-serious reports were submitted in 2007.*
- *Recommendation: Continue to recruit additional and new ASCs by demonstrating value-added activities. Develop a companion guide to support clarity and best quality adverse event reports. Seek out and integrate feedback from ASCs into the report form as necessary. Provide orientation and training materials to all ASC participants as planned and more feedback about the submitted reports. Communicate with ASCs about the review results. Engage the newly formed ASC Expert Panel to find and share best practices. Continue to pursue useful best practices and share as widely as possible. Begin to engage ASCs in identifying best solutions for written notification.*
- *Anticipated Progress: Participation rates will increase substantially by the end of 2008. Report form guide with training materials for 2008. As the program is implemented in 2008 it will address the PHO Certification criteria. 100% written notification for all serious adverse events with the exception on inability to locate an appropriate recipient.*

Retail Pharmacies

The retail pharmacy world divides itself broadly into two main categories: chain drug stores and independent pharmacies. There are also several subcategories: hospital-associated serving internal populations or outpatient populations, compounding pharmacies, mail order only, closed pharmacies serving limited populations by contract (such as nursing homes, home health or other), radiographic contrast media only and parenteral drugs only.

The retail pharmacy environment has traditionally been one of high accuracy performance requirements and individual pharmacist responsibility for any errors or failures. The systems view of patient safety is mostly an emerging approach. With continually changing external pressures (Medicare Part D, trend toward chain drug stores, expectations about clinical pharmacy services and much more) the retail pharmacy arena faces similar challenges as other health care providers.

Due to the developmental stage of the program, the detailed PHO Certification (Appendix A) for 2007 will be waived.

Status of Recruiting and Program Implementations

The administrative rules for the Retail Pharmacy Reporting Program were adopted in February 2007. Recruiting began shortly thereafter with strong support from the Oregon State Pharmacy Association. Retail pharmacies eligible for the Oregon Patient Safety Commission Adverse Event Reporting Program are defined in Statute (Oregon Laws 2003, c. 686) and pharmacy licensed under ORS chapter 689.

There are about 700 pharmacies total eligible although this number is constantly evolving with independent pharmacies becoming part of small and large chains. This total breaks down by three categories of participants: 444 large chains, 211 independents/small chains and 45 healthcare associated retail pharmacies. Although recruiting voluntary participants has been an uphill climb, 62

pharmacies agreed to participate in the Commission's reporting program by the end of 2007. Of these, 50 (81%) were large chain drug stores, 12 (19%) were independent retail pharmacies and small chains (<10 stores) and none were healthcare associated.

The reporting program was delayed for a few reasons. Most importantly, there was no critical mass of participants in 2007. The statutorily-required guarantees of confidentiality are only possible with at least 3 large pharmacy chains participating. Also, after consulting with large and small retail pharmacy representatives, the Commission decided that the most efficient way to report is web-based reporting. Electronic reporting would reduce confusion and excessive paperwork for both participants and the limited staff at the Commission.

There is a reporting template specifically designed for the retail pharmacy environment (Appendix B). Similar to the other reporting programs, the form was developed by an expert advisory group working with the Commission. It collects information that could potentially lead to improved patient safety and generally supports assessment of report acceptability. Supporting documentation will be helpful during the implementation phase.

The Commission has been engaged in additional activities to support patient safety in the retail pharmacy arena: regular patient safety contribution in the Oregon State Pharmacy Association (OSPA) newsletter, presentations at the annual conferences of the OSPA and frequent presentations and discussions with the Oregon State Board of Pharmacy about options for statewide improvement of pharmacy safety.

- *Assessment: Slow progress toward reporting program development. The program enrollment rates are currently too low to build reporting program.*
- *Anticipated Progress: Reporting program in place able to collect and review reports in 2008. Participation rates increased among independent and chain pharmacies.*

Conclusions

Hospitals

The hospital reporting program has made good progress in the second year. The program is stronger and more established in the hospital landscape. While still in the growth phase the Commission leadership is transforming the concept of reporting serious adverse events to a trusted statewide quality improvement organization. They are demonstrating recognizable value and showing that sharing the lessons learned in hospitals has benefits for the broader health care community.

The Public Health Officer finds that the total hospital report quality was very good in 2007 and the reporting levels are improving. The overall reporting program integrity continues to be good as illustrated by the very strong enrollment levels and key aspects of program implementation.

In 2007 the total report quality was very good. The proportion of “high quality” adverse event reports increased from 67.3% in 2006 to 89.4% in 2007. There are a few key areas of the reports that could use improvement: quality of the adverse event description and action plans. While the event descriptions fully met the certification criteria for 28% of the reports, they also failed to meet the criteria in 29% of the cases (the remainder partially met criteria). The increased proportion of non-met event descriptions may reflect unclear Commission expectations or some hospitals still having difficulty presenting a comprehensive picture of the event. The certification found a similar mixed result for the action plan quality: slight increase in high quality and substantial increase in low quality. The action plan quality is foundational for future harm prevention and is therefore considered a priority for certification.

As expected, more adverse event reports were submitted to the Commission in 2007, but still lower than literature estimates. The 94 reports do not necessarily reflect the actual number of adverse events in hospitals. More likely increased reporting is a representation of improving patient safety programs in hospitals that are more able to identify, investigate and report these events. It also demonstrates that hospitals trust the Commission to maintain confidentiality and use reported information for sharing learning.

The adverse event rate estimates are within the range of those found in other comparable statewide programs. This is a remarkable achievement for a voluntary reporting program. Oregon still has the only purely voluntary adverse event reporting system in the nation. All others have some mandatory component. Although hospitals join the program on a voluntary basis, each facility signs an agreement to report all serious adverse events. Robust reporting is a critical element of any patient safety program. In order to reduce unanticipated harm, it must first be identified and understood and then proactively prevented.

Since there is no absolute benchmark for the annual number of reports, the certification focuses on moving the number of reports received closer to the estimates from the literature (see above), maximizing the number of hospitals involved in reporting and sharing lessons learned. Each hospital stands to make a contribution to statewide learning.

Within the certification of reporting program integrity there are a few areas for improvement: systematic feedback to hospitals about the quality of submitted reports, setting clear expectations for report quality, strategy for action plan follow-up done by the Commission and setting clear expectations and accountability regarding written notification to patient and families after serious adverse events.

There are some activities that hospitals can pursue to contribute to their part of the partnership to build a strong reporting program. Here are a few examples:

- Revisit internal patient safety programs
- Review patient safety systems for identifying reportable adverse events and look for opportunities to improve identification
- Consider some more frequent lower-harm level events that could be reported and perhaps shared with other facilities
- Sustained demonstration of leadership at the CEO and Board levels
- Promote diffusion of Patient Safety Reporting Program to the frontline providers
- Design streamlined processes for root cause analysis and action plan development to expedite completion of Commission report form
- Communicate with Commission staff about reporting problems and suggestions for improvement to the reporting process
- Identify material for safety alerts and bulletins

The Public Health Officer Certification is implemented using a phased approach to accompany the developmental stages of the reporting program. In the first year, we assessed the status, offered recommendations and anticipated progress for the coming year. In the second year we now note the progress and propose some standards for the third year. After the third year, the Public Health Officer will officially certify the reporting program using established standards.

Proposed minimum standards* for future certification of the hospital reporting program:

- Report Completeness: $\geq 90\%$ complete
- Adverse Event Description quality: $\geq 90\%$ in the met or partially met category
- Adverse Event Analysis quality: $\geq 90\%$ in the high quality category
- Adverse Event Preventive Action Plans quality: $\geq 75\%$ in the high quality category
- Total Report quality: $\geq 90\%$ in the high quality category
- Report quantity: Reduce the proportion of cumulatively non-reporting hospitals to $\leq 20\%$ after 3 full years of report submissions (2007-2009)
- Program Enrollment: maintain participants that represent $\geq 90\%$ of statewide annual discharges
- Action Plan follow-up: $\geq 90\%$ completed for serious adverse events
- Written Notification: 100% for all serious adverse events (with stated exceptions)

Overall Certification levels:

- Pass with no reservations – 7-9 standards achieved
- Pass with reservations – 4-6 standards achieved
- No pass – less than 4 standards achieved

*subject to change

In recognition of changing nature of the hospital reporting program since the development of the assessment tool criteria (Appendix A), the PHO proposes some draft standards. The PHO will engage in a process to review the hospital certification elements and methods to establish final standards. The process will include input from interested parties beyond the Patient Safety Commission. The final standards will be completed by the end of 2008.

Nursing Homes

The nursing home reporting program has achieved a promising start in their first year. Most of the Commission work in 2007 was focused on recruiting and orientation. The patient/resident safety and quality environment in nursing homes is very different from hospitals and requires a customized approach. The reporting program received one report in 2007.

The PHO Certification waived the report quality and quantity assessment for 2007 in anticipation of more robust reporting in 2008. We did, however, do an initial assessment of the program integrity in areas where possible.

The Public Health Officer finds that the overall reporting program integrity is good as illustrated by the solid initial enrollment levels, the very strong reporting program guide and quick start on developing relevant best practices to prevent pressure ulcers. The PHO recommends supporting facilities in their ability to report events and also continuing to pursue a workable solution to fulfill written notification for nursing homes. Other elements of the program will emerge as the program rolls out its first full year of nursing home reporting.

Reducing unanticipated harm to residents will depend on the successful collaboration of nursing homes with the Commission. There is an opportunity for Oregon nursing home participants to actively contribute by:

- Reviewing internal incident reporting programs
- Ensuring knowledge and skills in comprehensive event investigation
- Providing leadership support for patient/resident safety activities
- Strengthening quality improvement activities such as implementation of preventive action plans

Similar to the hospital program the Public Health Officer Certification is implemented using a phased approach to accompany the developmental stages of the reporting program.

Ambulatory Surgery Centers

The Commission has demonstrated movement toward a unique ambulatory surgery center reporting program in the first year. Unlike many other state reporting programs, Oregon has a list of ASC reportable events more closely aligned with the type of work done in surgery centers. The list includes many of the serious events that occur in hospitals but also other events such as unplanned admission to hospital or visit to the emergency department within 48 hours of discharge (see Appendix B). Thus, Oregon's ASCs can report events that are useful for internal and also statewide quality improvement. As with the nursing home program, much of the Commission work in 2007 was focused on recruiting and orientation.

Although some surgery centers participate in accreditation programs, there is wide variation in the patient safety activities. The services provided by ASCs depend on the focus of the facilities. Some offer procedures in one specialty area such as eye surgery or endoscopies while others provide multi-specialty services. The Commission received 12 reports of less serious adverse events in 2007.

The PHO Certification will waive the report quality and quantity for 2007 in anticipation of more robust reporting in 2008. The Commission will have an opportunity to offer systematic orientation and training to all participants during 2008. In depth implementation was postponed until the web-based reporting system becomes available in 2008.

The Public Health Officer finds that the overall reporting program integrity is acceptable at this early stage as seen in the initial participation rates and reporting tool design. The PHO recommends that the Commission work with ASCs to support their readiness to report and to find options that make written notification a success for all.

Similar to the hospital program the Public Health Officer Certification is implemented using a phased approach to accompany the developmental stages of the reporting program.

Retail Pharmacies

The retail pharmacy reporting program was still in development at the end of 2007. Progress has been much slower than with the other programs. Although some retail pharmacies are to be commended for willingness to engage in statewide patient safety improvement, most national chains and many independents have shown resistance to participation in the program. The Commission made numerous efforts to recruit retail pharmacy participants and build the program in the first year. Oregon has a one-of-a-kind opportunity to pursue state-wide patient safety in the retail pharmacy area.

The PHO Certification will waive the report quality and quantity and reporting program integrity assessment for 2007 in anticipation of program implementation solutions in 2008. The program implementation for retail pharmacies was postponed until there is a critical mass (at least 3 large chains) of participants. With only one large chain participating, any publicly reported adverse event data may become attributable to that one large pharmacy chain. The Commission would only be able to provide confidentiality guarantees with more participants.

The Public Health Officer finds that the program needs greater participation in order to be successful. The PHO strongly urges the Commission to continue to seek strategies that will produce a critical mass of pharmacy participants and challenges the retail pharmacy industry to join the new reporting program to find some value-added for patient safety improvement.

Similar to the hospital program the Public Health Officer Certification is implemented using a phased approach to accompany the developmental stages of the reporting program.

Public Health Officer Certification Results – Summary

HOSPITALS

Report completeness

- **Assessment:** Very good level of report completeness
- **Recommendations:** Continue to expect all reports to be complete
- **Proposed standard for 2008*:** ≥90% reports are complete

Adverse event description

- **Assessment:** Acceptable quality of event description: 27.7% of the reports met Certification criteria, while 43.6% were found to partially meet and 28.7% did not meet the criteria for an acceptable event description.
- **Recommendations:** Set clear expectations for an acceptable event description with a focus on systems issues
- **Anticipated Progress:** ≥90% of all reports in the “met” or “partially met” category

Analysis quality

- **Assessment:** Acceptable analysis quality: 90.4% of the reports were found to be high quality, while 8.5% were in the medium quality category and 1.00% were determined to have a low quality for adverse event analysis
- **Recommendations:** Maintain expectations with feedback about quality from the Commission report review tool assessment and continue to provide support to hospital participants
- **Proposed standard for 2008*:** ≥90% reports are in the high quality adverse event analysis

Action plan quality

- **Assessment:** Acceptable action plan quality: 62.8% of the reports were found to be high quality, while 7.4% were in the medium quality category and 29.8% were determined to be low quality for action plan development
- **Recommendations:** Provide more feedback when action plans seem to be less than high quality and set expectations. Continue to provide support to hospital participants
- **Anticipated Progress:** ≥75% of action plans in high quality category

Total quality

- **Assessment:** Good total report quality: 89.4% of the reports were found to be high quality, while 13.3% were in the medium quality category and 1.1% were determined to have a low total report quality
- **Recommendations:** Continue to set expectations for hospitals and provide feedback when a report does not meet the Commission standards.
- **Anticipated Progress:** ≥90% in the high quality category

Quantity

* PHO Certification for 2008 will occur in 2009

- **Assessment:** Total number of submitted reports from all hospitals combined is increasing as expected, but still lower than literature estimates. The proportion of non-reporting hospitals is still too high
- **Recommendations:** Set clear expectations and develop systems of accountability. Continue to identify and work to help hospitals reduce barriers to reporting, build additional trust in the confidentiality aspect of the program, keep the administrative burden as low as possible without compromising the data needed for effective quality-improvement, launch the electronic web-based reporting effectively, and remind hospitals of participation agreement to report all events on the list of reportable events, support more diffusion to the frontline providers and continue to gain the support of executive and clinical leadership in hospitals
- **Anticipated Progress:** Reduce the proportion of non-reporting hospitals to $\leq 20\%$ after three full years of report submissions and continue to increase the number of reported events to better reflect the likely rates of occurrence.

Participation rates

- **Assessment:** Excellent hospital enrollment rates
- **Recommendations:** Maintain enrollment in the future by continuing to show value added for hospitals and work to convert the non-reporting enrolled hospitals to true reporting participants
- **Proposed standard for 2008*:** Maintain number of participants that represent $\geq 90\%$ of statewide annual discharges

Reporting tool design

- **Assessment:** The adverse event reporting tool provides clear definitions and includes standard patient safety information about contributing factors and action plan strategies. There are some questions that do not appear to result in consistent high quality answers, which may be due, in part to understanding clear expectations of the form
- **Recommendations:** Provide brief written guidelines with set expectations and sample reports for participants
- **Anticipated Progress:** Use an adverse event report form that allows and expects the hospital to submit high quality summaries of their patient safety work. The reporting template, including additional written guidance, should also enable hospitals to fully summarize their work in a reasonable time frame.

Program implementation

- **Assessment:** The Commission entered a stabilization phase for reporting program implementation in 2007 and developed good contact to many of the hospitals. Questions and feedback were handled in an efficient and timely manner.
- **Recommendations:** Set expectations for report submissions and reporting timelines. Continue to track interactions surrounding these areas to measure Commission performance and responsiveness.
- **Anticipated Progress:** The Commission will continue to assess the needs of hospital participants and find the best ways to assist facilities with report submission

Review process

- **Assessment:** The internal review process for submitted reports was implemented for the 2007 reports. Expert analysis and review occurs with the Technical Advisory Committee.

* PHO Certification for 2008 will occur in 2009

- **Recommendations:** Communicate the results of report review to hospitals
- **Anticipated Progress:** Continue to assess report quality and share that information with the hospital participants. Support the full potential of the TAC to provide value added to the hospital reporting program.

Action plan follow-up

- **Assessment:** The action plan follow-up with hospitals was very low
- **Recommendations:** Create a strategy for prioritizing and tracking for serious adverse events and any other relevant adverse events/action plans. Offer support to hospitals on how to best track the success of action plans.
- **Anticipated Progress:** Moving toward $\geq 90\%$ follow-up of action plan for serious adverse events on an annual basis.

Dissemination of learning and best practices

- **Assessment:** Very good, reliable sharing of relevant patient safety information and resources
- **Recommendations:** Continue to stay connected to hospital participants and understand how the collected patient safety data can contribute to improvements in facilities. Look for ways to use the data and analysis to support the patient safety initiatives already being pursued in hospitals (e.g. CMS measures, IHI Five Million Lives Campaign planks, Joint Commission Patient Safety Goals and NQF Safe Practices)
- **Anticipated Progress:** : Maintain the close connections to participants to best understand how to provide value-added information and activities

Written notification

- **Assessment:** The rate of completed written notification to the patients and families has decreased from 67% in 2006 to 44% in 2007.
- **Recommendations:** Continue to help hospitals address the barriers and provide a clear vision of the patient-centered foundation of the written notification. Set expectations for 2008.
- **Anticipated Progress:** Moving toward 100% written notification for all serious adverse events with the exception of inability to locate an appropriate recipient.

NURSING HOMES

No report quality or quantity assessment until 2008

Overall reporting program integrity:

- **Assessment:** Good initial nursing home participation rates. Acceptable reporting tool design and excellent companion guide. Reporting program implementation and report review process are in development. Good initial activities to promote the development of value-added nursing home best practices. Written notification not completed for the one report submitted in 2007. Too few reports to assess other certification elements.
- **Recommendations:** Continue to pursue the remaining nursing homes by demonstrating value-added activities. Monitor usability of the form with nursing homes and adapt as necessary. Follow through with the report review and feedback plan. Share the results of the report quality assessment done by the Commission with each submission. Communicate with nursing homes about the review results. Engage the newly formed Nursing Home Expert Panel to find and share

best practices. Continue to pursue useful best practices and share as widely as possible. Continue to assist nursing homes in identifying best solutions for written notification.

- **Anticipated Progress:** *Participation rates will rise substantially by the end of 2008. As the program is implemented in 2008 it will address the PHO Certification criteria. 100% written notification for all serious adverse events with the exception on inability to locate an appropriate recipient.*

AMBULATORY SURGERY CENTERS

No report quality or quantity assessment until 2008

Overall reporting program integrity:

- **Assessment:** *Acceptable initial ASC participation rates. Acceptable reporting tool design. Reporting program implementation and report review process are in development. Acceptable initial activities to promote the development of value-added ASC best practices. Written notification not applicable since only less-serious reports were submitted in 2007.*
- **Recommendation:** *Continue to recruit additional and new ASCs by demonstrating value-added activities. Develop a companion guide to support clarity and best quality adverse event reports. Seek out and integrate feedback from ASCs into the report form as necessary. Provide orientation and training materials to all ASC participants as planned and more feedback about the submitted reports. Communicate with ASCs about the review results. Engage the newly formed ASC Expert Panel to find and share best practices. Continue to pursue useful best practices and share as widely as possible. Begin to engage ASCs in identifying best solutions for written notification.*
- **Anticipated Progress:** *Participation rates will increase substantially by the end of 2008. Report form guide with training materials for 2008. As the program is implemented in 2008 it will address the PHO Certification criteria. 100% written notification for all serious adverse events with the exception on inability to locate an appropriate recipient.*

RETAIL PHARMACIES

No report quality or quantity assessment until 2008

Overall reporting program integrity:

- **Assessment:** *Slow progress toward reporting program development. The program enrollment rates are currently too low to build reporting program.*
- **Anticipated Progress:** *Reporting program in place able to collect and review reports in 2008. Participation rates increased among independent and chain pharmacies.*

Glossary

Action Plan

The product of the root cause analysis is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions³⁰.

Adverse Event

An injury caused by medical management rather than the underlying condition of the patient. A preventable adverse event is an adverse event attributable to an error or system failure³¹.

Commission Event Report Form for Hospitals

The form designated by the Commission to be used by Hospital Participants for the reporting of Reportable Hospital Adverse Events (Appendix C).

Error

Error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)³².

Harm Level

A harm scale adapted by the Patient Safety Commission to describe the severity of injury to patients. The scale ranges from levels one (error did not reach the patient) to nine (death) (Fig. 2). A serious adverse event is defined by harm level 7-9 and a less serious adverse event by harm level 1-6.

Hospital Participant

A hospital that has volunteered to participate in the Oregon Patient Safety Reporting Program. A hospital pharmacy is considered to be part of the hospital.

Joint Commission (also Joint Commission on Accreditation of Healthcare Organizations)

Private, non-profit organization with the mission to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.

Less serious Adverse Event

An adverse event with a harm level of one to six, see also Harm Level, Serious Adverse Event and Reportable Adverse Event.

³⁰ Joint Commission on Accreditation of Healthcare Organizations. *Sentinel Event Glossary of Terms, Online*. Available at http://www.jointcommission.org/SentinelEvents/se_glossary.htm . Accessed on May 2, 2007.

³¹ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

³² National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

Oregon Patient Safety Commission (also “Commission” and “Patient Safety Commission”)

A semi-independent state agency established to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's health care system and by encouraging a culture of patient safety in Oregon. (Oregon Laws 2003, c. 686]

Oregon Patient Safety Reporting Program

The Patient Safety Reporting Program, as defined in Oregon Laws 2003, Chapter 686, Section 4, and operated by the Commission. The Program collects adverse event data from six types of health care facilities: hospitals, retail pharmacies, ambulatory surgery centers, nursing homes, freestanding renal dialysis facilities and freestanding birthing centers. Program activities include broadly: receiving adverse event reports and other patient safety data, analyzing the patient safety data, providing technical assistance, auditing participant reporting, overseeing action plans, creating incentives to improve participation and distributing written reports and communication.

Patient Safety

Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur³³.

Public Health Officer Certification, (PHO Certification)

Annual certification of the completeness, thoroughness and credibility of participant reporting and the overall integrity of the Patient Safety Reporting Program. The Public Health Officer uses an established certification tool to perform the review. [Appendix A]

Report Form, see Commission Event Report Form (Appendix B)

Reportable Adverse Event - Hospitals

Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury, including the events described in Appendix A of the OAR 325-010-0001 to 325-010-0060. (Appendix C)

Root Cause Analysis

Root Cause Analysis is a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. RCAs have the following characteristics:

- The review is interdisciplinary in nature with involvement of those closest to the process.
- The analysis focuses primarily on systems and processes rather than individual performance.
- The analysis digs deeper by asking *what* and *why* until all aspects of the process are reviewed and all contributing factors are identified (progressing from looking at special causes to common causes).
- The analysis identifies changes that could be made in systems and processes through either redesign or development of new processes or systems that would improve performance and reduce the risk of event or close call recurrence³⁴.

³³ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

³⁴ US Dept. of Veterans Affairs, National Center for Patient Safety. *Glossary of patient safety terms*. Available at <http://www.patientsafety.gov/glossary.html>. Accessed on May 2, 2007.

Serious Adverse Event

An objective and definable negative consequence of patient care, or the risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury. (Oregon Laws 2003 c.686 §1)

Appendix A

Oregon Patient Safety Reporting Program for Hospitals Public Health Officer Certification Tool 2007

1. What are the participation rates of reporting entities in the following activities?
 - Reporting Program Enrollment
 - Number and percentage of hospitals enrolled in the Reporting Program
 - Distribution by hospital size
 - Percentage of statewide discharges represented by enrolled hospitals
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by hospital size
 - Percentage of statewide discharges represented by reporting hospitals
 - Average number of reports submitted per reporting hospital
 - Range of number of reports submitted by all enrolled hospitals
2. What are the rates of serious adverse event reporting compared to expected levels? Standards will initially express the reporting expectations as broad ranges and account for the development stage of the Program.
 - Expected range of number of serious adverse reports submitted annually
 - Total number of submitted adverse event reports in 2006
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Number of reports per 1000 discharges
3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
- Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Did senior management and individuals most closely involved in the processes and systems under review participate in the analysis?
 - Percentage of senior management participation/notification

- Percentage of closely involved personnel participation
- Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Percentage of met/partially met/not met (met: no inconsistencies, partially met: 1-3 inconsistencies, not met: more than 3 inconsistencies)
- Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root causes, partially met: some action plans address identified root cause, not met: none of the action plans address identified root causes, not all root causes have action plans, or no reasonable root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors

For Less Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
- Is the Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
- Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors
- 4. Does the design of the adverse event reporting tools -
 - Use clear definitions of reportable events and reporting guidelines?
 - Assessment and recommendations
 - Include comprehensive elements that use broadly accepted principles to improve patient safety?

- Assessment and recommendations
 - Support answering questions of completeness, thoroughness, credibility and acceptability?
 - Assessment and recommendations
5. Does implementation of the adverse event reporting tools include:
 - Support for reporting entities to complete reporting process in a timely manner?
 - Assessment and recommendations
 - Feedback to reporting entities?
 - Assessment and recommendations
 6. Is the report review process of the Commission performed using:
 - Systematic and consistent review tools?
 - Assessment and recommendations
 - Expert analysis and does it result in the generation of best practices?
 - Assessment and recommendations
 7. Is there follow-up of implementation and evaluation of the effectiveness of Action Plans? (Standards to be set in later stages of Reporting Program)
 - Percentage of met/not met
 - Assessment and recommendations
 8. Does the Reporting Program include broad dissemination of learning and sharing of best practices?
 - How many Safety Alerts? Quality and relevance?
 - Other communication tools for sharing of best practices?
 9. Does the Reporting Program demonstrate patient-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - Reasons for non-compliance: Unable to locate recipient, Pending, Sent outside the required time frame, Letter inadequate, other – percentage of total serious adverse event reports
 - Distribution of completed disclosure by facility

Oregon Patient Safety Reporting Program for Nursing Homes Public Health Officer Certification Tool 2007

1. What are the participation rates of reporting entities in the following activities?
 - Reporting Program Enrollment
 - Number and percentage of nursing homes enrolled in the Reporting Program
 - Distribution by nursing home size
 - Percentage of statewide annual beds represented by enrolled nursing homes
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by nursing home size
 - Percentage of statewide annual beds represented by reporting nursing homes
 - Average number of reports submitted per reporting nursing home
 - Range of number of reports submitted by all enrolled nursing homes
2. What are the rates of serious adverse event reporting compared to expected levels? Standards will initially express the reporting expectations as broad ranges and account for the development stage of the Program.
 - Expected range of number of serious adverse reports submitted annually
 - Total number of submitted adverse event reports in 2006
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Number of reports per 1000 annual beds
3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
- Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Did senior management and individuals most closely involved in the processes and systems under review participate in the analysis?
 - Percentage of senior management participation
 - Percentage of closely involved personnel participation

- Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Percentage of met/partially met/not met (met: no inconsistencies, partially met: 1-3 inconsistencies, not met: more than 3 inconsistencies)
- Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors

For Less Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
 - Is the Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors
4. Does the design of the adverse event reporting tools -
- Use clear definitions of reportable events and reporting guidelines?
 - Assessment and recommendations
 - Include comprehensive elements that use broadly accepted principles to improve patient safety?
 - Assessment and recommendations
 - Support answering questions of completeness, thoroughness, credibility and acceptability?
 - Assessment and recommendations

5. Does implementation of the adverse event reporting tools include:
 - Support for reporting entities to complete reporting process in a timely manner?
 - Assessment and recommendations
 - Feedback to reporting entities?
 - Assessment and recommendations
6. Is the report review process of the Commission performed using:
 - a. Systematic and consistent review tools?
 - Assessment and recommendations
 - b. Expert analysis and does it result in the generation of best practices?
 - Assessment and recommendations
7. Is there follow-up of implementation and evaluation of the effectiveness of Action Plans? (Standards to be set in later stages of Reporting Program)
 - Percentage of met/not met
 - Assessment and recommendations
8. Does the Reporting Program include broad dissemination of learning and sharing of best practices?
 - How many Safety Alerts? Quality and relevance?
 - Other communication tools for sharing of best practices?
9. Does the Reporting Program demonstrate patient-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - Reasons for non-compliance: Unable to locate recipient, Pending, Sent outside the required time frame, Letter inadequate, other – percentage of total serious adverse event reports
 - Distribution of completed disclosure by facility

Oregon Patient Safety Reporting Program for ASCs Public Health Officer Certification Tool 2007

1. What are the participation rates of reporting entities in the following activities?
 - Reporting Program Enrollment
 - Number and percentage of ASCs enrolled in the Reporting Program
 - Distribution by ASC size
 - Percentage of statewide annual procedures represented by enrolled ASCs
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by ASC size
 - Percentage of statewide discharges represented by reporting ASCs
 - Average number of reports submitted per reporting ASC
 - Range of number of reports submitted by all enrolled ASCs
2. What are the rates of serious adverse event reporting compared to expected levels? Standards will initially express the reporting expectations as broad ranges and account for the development stage of the Program.
 - Expected range of number of serious adverse reports submitted annually
 - Total number of submitted adverse event reports in 2006
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Number of reports per 1000 annual procedures
3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
- Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Did senior management and individuals most closely involved in the processes and systems under review participate in the analysis?
 - Percentage of senior management participation
 - Percentage of closely involved personnel participation

- Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Percentage of met/partially met/not met (met: no inconsistencies, partially met: 1-3 inconsistencies, not met: more than 3 inconsistencies)
- Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors

For Less Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
 - Is the Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors
4. Does the design of the adverse event reporting tools -
- Use clear definitions of reportable events and reporting guidelines?
 - Assessment and recommendations
 - Include comprehensive elements that use broadly accepted principles to improve patient safety?
 - Assessment and recommendations

- Support answering questions of completeness, thoroughness, credibility and acceptability?
 - Assessment and recommendations
- 5. Does implementation of the adverse event reporting tools include:
 - Support for reporting entities to complete reporting process in a timely manner?
 - Assessment and recommendations
 - Feedback to reporting entities?
 - Assessment and recommendations
- 6. Is the report review process of the Commission performed using:
 - a. Systematic and consistent review tools?
 - Assessment and recommendations
 - b. Expert analysis and does it result in the generation of best practices?
 - Assessment and recommendations
- 7. Is there follow-up of implementation and evaluation of the effectiveness of Action Plans? (Standards to be set in later stages of Reporting Program)
 - Percentage of met/not met
 - Assessment and recommendations
- 8. Does the Reporting Program include broad dissemination of learning and sharing of best practices?
 - How many Safety Alerts? Quality and relevance?
 - Other communication tools for sharing of best practices?
- 9. Does the Reporting Program demonstrate patient-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - Reasons for non-compliance: Unable to locate recipient, Pending, Sent outside the required time frame, Letter inadequate, other – percentage of total serious adverse event reports
 - Distribution of completed disclosure by facility

Oregon Patient Safety Reporting Program for Retail Pharmacies Public Health Officer Certification Tool 2007

1. What are the participation rates of reporting entities in the following activities?
 - Reporting Program Enrollment
 - Number and percentage of retail pharmacies enrolled in the Reporting Program
 - Distribution by retail pharmacy size
 - Percentage of statewide discharges represented by enrolled retail pharmacies
 - Reporting Program – Reports Submitted
 - Number and percentage of participating entities submitting at least one report
 - Distribution by retail pharmacy size
 - Percentage of statewide prescriptions filled represented by reporting retail pharmacies
 - Average number of reports submitted per reporting retail pharmacy
 - Range of number of reports submitted by all enrolled retail pharmacies
2. What are the rates of serious adverse event reporting compared to expected levels? Standards will initially express the reporting expectations as broad ranges and account for the development stage of the Program.
 - Expected range of number of adverse reports submitted annually
 - Total number of submitted adverse event reports in 2006
 - Distribution of reports by harm-level determination
 - Distribution of reports by event type
 - Number of reports per 1000 prescriptions filled
3. Are the submitted reports complete, thorough, credible, and acceptable?

For Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
- Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
- Is the Serious Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Did senior management and individuals most closely involved in the processes and systems under review participate in the analysis?
 - Percentage of senior management participation
 - Percentage of closely involved personnel participation

- Is the analysis internally consistent? (i.e. does not contradict itself or leave obvious questions unanswered)
 - Percentage of met/partially met/not met (met: no inconsistencies, partially met: 1-3 inconsistencies, not met: more than 3 inconsistencies)
- Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors

For Less Serious Adverse Events:

- Are the reports complete? (i.e. all data included/reported for each and every “reported event”)
 - Percentage of complete reports in total sample
 - Percentage of complete reports by facility
 - Is the Event Description acceptable?
 - Does the event narrative fully explain the event by including the “who, what, when, where and how” in the description?
 - Percentage of met/partially met/not met (met: no questions unanswered, partially met: 1-3 questions unanswered, not met: more than 3 questions unanswered)
 - Is the Adverse Event Analysis acceptable?
 - Does the analysis focus primarily on systems and processes although individual performance may be considered?
 - Percentage of met/not met
 - Does the analysis identify the causes and other contributing factors most directly associated with the event?
 - Percentage of met/not met
 - Are the Action Plans acceptable?
 - Do the action plans address the identified root cause(s)?
 - Percentage of met/partially met/not met/no root cause identified (met: all action plans address identified root cause, partially met: some action plans address identified root cause, not met: none of the action plans address identified root cause, no root cause identified)
 - Do the action plans identify improvement in processes or systems that would decrease the likelihood of such events in the future?
 - Percentage of system-level action plans that address contributing factors
4. Does the design of the adverse event reporting tools -
- Use clear definitions of reportable events and reporting guidelines?
 - Assessment and recommendations
 - Include comprehensive elements that use broadly accepted principles to improve patient safety?
 - Assessment and recommendations

- Support answering questions of completeness, thoroughness, credibility and acceptability?
 - Assessment and recommendations
5. Does implementation of the adverse event reporting tools include:
 - Support for reporting entities to complete reporting process in a timely manner?
 - Assessment and recommendations
 - Feedback to reporting entities?
 - Assessment and recommendations
 6. Is the report review process of the Commission performed using:
 - a. Systematic and consistent review tools?
 - Assessment and recommendations
 - b. Expert analysis and does it result in the generation of best practices?
 - Assessment and recommendations
 7. Is there follow-up of implementation and evaluation of the effectiveness of Action Plans? (Standards to be set in later stages of Reporting Program)
 - Percentage of met/not met
 - Assessment and recommendations
 8. Does the Reporting Program include broad dissemination of learning and sharing of best practices?
 - How many Safety Alerts? Quality and relevance?
 - Other communication tools for sharing of best practices?
 9. Does the Reporting Program demonstrate patient-centeredness with
 - Acceptable rates of written disclosure for serious adverse events?
 - Percentage of met/not met
 - Reasons for non-compliance: Unable to locate recipient, Pending, Sent outside the required time frame, Letter inadequate, other – percentage of total serious adverse event reports
 - Distribution of completed disclosure by facility

Appendix B

Hospital Adverse Event Reporting Form 2007



Serious Adverse Event Report Form

Please report all **Serious Adverse Events** and the results of your investigation to the Oregon Patient Safety Commission within 45 days of discovery. If you believe the situation requires an immediate alert to Oregon hospitals, please contact us within 3 business days of discovery. The full report must be submitted within 45 days.

A serious adverse event that requires a report to the Commission is an event that is

1. An unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury * (harm level of 7 or greater), including but not limited to the following types of events:

Burn	Maternal - Labor or Delivery
Contaminated drugs, devices, or biologics	Medication Error
Electric Shock	Neonatal hyperbilirubinemia
Equipment	Patient elopement (disappearance) for more than four hours
Fall	Patient suicide or attempted suicide
Healthcare acquired infection	Perinatal
Hemolytic reaction	Pressure ulcer - Stage 3 or 4, acquired after admission
Hypoglycemia	Restraints/Bedrails
Intraoperative or immediate post-operative death in ASA Class I patient	Spinal Manipulative Therapy
Intravascular air embolism	

2. Any of the following events, regardless of level of harm to the patient:

- Infant discharged to the wrong person
- Retention (unintended) of a foreign object in a patient after surgery or other procedure
- Surgery or invasive procedure performed on the wrong body part
- Surgery or invasive procedure performed on the wrong patient
- Wrong surgical or invasive procedure performed on a patient
- Wrong/contaminated gas given to a patient

***serious physical injury** (harm level 7 or greater) is that which severely impacts a patient's status or functional ability or that requires transfer to a higher level of care, additional procedures/testing, surgical intervention, prescription medication, any increase in length of stay, or readmission.

Other Adverse Events

We invite participating organizations to report other adverse events including those mentioned above that have a harm level of 6 or lower and close calls/near misses. Please do so because other organizations can benefit from your experience. For these less serious events, you only need to complete Part 1 and Part 1A if applicable, of the reporting form. Please report the events within 45 days of discovery.

For questions regarding reporting or use of the form, please call Leslie Ray at the Oregon Patient Safety Commission. Telephone: 503/224-9227

Revised May 2007

Comment [LNR1]: Commission staff will complete this box.

Serious Adverse Event Reporting Form

PART 1

What type of event occurred? (Check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> *Infant discharged to the wrong person | <input type="checkbox"/> Hypoglycemia |
| <input type="checkbox"/> *Retention (unintended) of a foreign object | <input type="checkbox"/> Intraoperative/immediate post-operative death in ASA Class I patient |
| <input type="checkbox"/> *Surgery or invasive procedure performed on the wrong patient | <input type="checkbox"/> Intravascular air embolism |
| <input type="checkbox"/> *Surgery/ <u>invasive procedure</u> on the wrong body part | <input type="checkbox"/> Maternal - Labor or Delivery |
| <input type="checkbox"/> *Wrong surgical or invasive procedure performed on a patient | <input type="checkbox"/> <u>Medication Error</u> TYPE: |
| <input type="checkbox"/> *Wrong/contaminated gas given to a patient | <input type="checkbox"/> Neonatal hyperbilirubinemia |
| <input type="checkbox"/> Burn | <input type="checkbox"/> Patient elopement (disappearance) for more than four hours |
| <input type="checkbox"/> Contaminated drugs, devices, or biologics | <input type="checkbox"/> Patient suicide or attempted suicide |
| <input type="checkbox"/> Electric Shock | <input type="checkbox"/> Perinatal |
| <input type="checkbox"/> <u>Equipment</u> | <input type="checkbox"/> Pressure ulcer - Stage 3 or 4, acquired after admission |
| <input type="checkbox"/> Fall | <input type="checkbox"/> Spinal Manipulative Therapy |
| <input type="checkbox"/> Healthcare acquired infection | <input type="checkbox"/> Restraints/Bedrails |
| <input type="checkbox"/> Hemolytic reaction | |
| <input type="checkbox"/> Other (please describe briefly): | |

Comment [LNR2]: In describing the event, consider anesthesia, diagnostic tests as invasive procedures

Comment [LNR3]: This includes contrast, other diagnostic medium, local, and topical agents, regional or general anesthetic, etc. in addition to what is commonly considered a medication.

Comment [LNR4]: Check this only if equipment/device is used or functions other than as intended or is difficult to use as intended. If the wrong equipment was used, check Other and describe briefly.

*Report required regardless of Harm Level - see OAR 325-325-010, Appendix A for full descriptions

Level of Patient Harm Check one box only

- | | |
|---|---|
| <input type="checkbox"/> 9. Death | <input type="checkbox"/> 6. Moderate-Permanent Harm |
| <input type="checkbox"/> 8. <u>Serious/Permanent</u> Harm | <input type="checkbox"/> 5. Moderate-Temporary Harm |
| <input type="checkbox"/> 7. Serious-Temporary Harm | <input type="checkbox"/> 4. Minimal-Permanent Harm |
| | <input type="checkbox"/> 3. Minimal-Temporary Harm |
| | <input type="checkbox"/> 2. No Detectable Harm |
| | <input type="checkbox"/> 1. Did not reach the patient |

Comment [LNR5]: Indicate eventual harm. If patient was transferred, but ultimately died, select Level 9. Comparison with NCC MERP harm categories is attached

Comment [LNR6]: Serious: severely impacts a patient's status or functional ability or requires transfer to a higher level of care, additional procedures/tests, surgical intervention, prescription medication, any increase in length of stay, or readmission

* If the harm was 6 or lower, was the patient at risk for serious harm? Yes No

Comment [LNR7]: Permanent: present at discharge and the resolution is uncertain or expected to continue for 6 months or more.

Where did the event occur? (Check all that apply)

- | | | | |
|--|--|---|---|
| <input type="checkbox"/> Critical Care - Adult | <input type="checkbox"/> Emergency Dept | <input type="checkbox"/> Labor & Delivery | <input type="checkbox"/> PACU |
| <input type="checkbox"/> Critical Care - Pediatric | <input type="checkbox"/> Inpatient - Adult | <input type="checkbox"/> Mother-Baby | <input type="checkbox"/> <u>Radiology</u> |
| <input type="checkbox"/> <u>Diagnostic or Procedure Area</u> | <input type="checkbox"/> Inpatient - Pediatric | <input type="checkbox"/> Operating Room | <input type="checkbox"/> <u>Pharmacy</u> |
| <input type="checkbox"/> Other (please describe) | | | |

Comment [L8]: Include interventional radiology under diagnostic/procedure area

Comment [LNR9]: This also includes all ambulatory or outpatient surgery unless licensed separately as an Ambulatory Surgery Center. Please specify area under 'Other' (e.g. interventional radiology, cath lab)

Patient Descriptors

- | | |
|--|---|
| Age _____ | Sex _____ |
| Race/Ethnicity (Check all that apply) | |
| <input type="checkbox"/> American Indian or Alaska Native | <input type="checkbox"/> Asian <input type="checkbox"/> Other |
| <input type="checkbox"/> Native Hawaiian or Other Pacific Islander | <input type="checkbox"/> White <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Black or African American | <input type="checkbox"/> Hispanic |

Comment [LNR10]: If a source of event was in Pharmacy, please also complete Part 1A for events at all harm levels.

Date Admitted YYYY ____ MM ____ DD ____
 Date of Event YYYY ____ MM ____ DD ____ Time of Event [24hr clock]

Comment [LNR11]: Date of the incident being reported, not date of the outcome

Date reported to Quality Management: YYYY ____ MM ____ DD ____

Please provide a complete account of the event:

Comment [LNR12]: It should be specific enough that a "cold" reader would have a clear understanding of the event, the sequence of actions, and surrounding circumstances. Also please include pertinent negatives.

What were the most important contributing causes to this adverse event?

Comment [LNR13]: If this was a pharmacy-related event, please also complete Part 1A which focuses on the pharmacy aspects for events at all harm levels.

Comment [L14]: This includes all health care staff: nurses, physicians, respiratory therapists, pharmacists, etc.

Comment [L15]: Note reasons for noncompliance, including organizational or system influences

- | | | |
|--|--|---|
| Communication
<input type="checkbox"/> Hand-offs or shift reports
<input type="checkbox"/> Available information
<input type="checkbox"/> Between healthcare personnel & patient/family
<input type="checkbox"/> Among healthcare personnel
Please describe
Other: | Patient Management
<input type="checkbox"/> Delegation of clinical care
<input type="checkbox"/> Response to changing condition
<input type="checkbox"/> Patient consent process
<input type="checkbox"/> Care plan
<input type="checkbox"/> Initial diagnosis
<input type="checkbox"/> Tracking or follow-up
Other: | Training or Supervision
<input type="checkbox"/> Job Orientation
<input type="checkbox"/> In-service education/competency training
<input type="checkbox"/> Supervision
<input type="checkbox"/> Routine job training
<input type="checkbox"/> Availability of training programs
Other: |
| Organizational Factors
<input type="checkbox"/> Overall culture of safety
<input type="checkbox"/> Staffing levels
<input type="checkbox"/> Staff assignment/work allocation
<input type="checkbox"/> Leadership/Management
<input type="checkbox"/> Systems to identify risks
<input type="checkbox"/> Adequacy of budget
<input type="checkbox"/> Internal reporting
Other: | Policies, Procedures
<input type="checkbox"/> Absent
<input type="checkbox"/> Too complicated
<input type="checkbox"/> Outdated
<input type="checkbox"/> Not followed/compliance
Other: | Technology
<input type="checkbox"/> Software (please list)
<input type="checkbox"/> Equipment meeting code, specifications, regulation
<input type="checkbox"/> Equipment design (function, displays, controls)
<input type="checkbox"/> Defective/non-working equipment
<input type="checkbox"/> Other |
| Other Factors | Patient Factors
<input type="checkbox"/> Family Dynamics/Relationships
<input type="checkbox"/> Language/Culture
<input type="checkbox"/> Behavioral Problems
<input type="checkbox"/> Mental Status
Other: | Work Area/Environment
<input type="checkbox"/> Work area design and specifications
<input type="checkbox"/> Distractions
<input type="checkbox"/> Relief/float healthcare staff
<input type="checkbox"/> Interruptions (please describe)
Other: |

J. Were there any factors that helped reduce the seriousness or consequences of the event? Yes No
 (If yes) Please describe

Approximately how many person-hours did the event investigation and review take?

*****If reporting an adverse event with harm level of 7 or above, skip to Part 2*****

Comment [LNR16]: For example, 2 people working 30 minutes each would be 1 person hour; 2 people working 2 hours each would be 4 person hours.

Comment [LNR17]: Specifically, indicate what system changes you put in place to prevent recurrence of similar events, indicate time frame if has not been started or is in process.

What were the findings of your investigation?

What corrective actions did your organization take?

Additional Comments:

Whom should we contact for clarification/feedback?

Comment [LNR18]: Often the person completing the form is not the person familiar with the reported event. To save multiple phone calls, please include the name and phone number of the appropriate contact person here.

Name Phone

*****If reporting an adverse event with harm level of 6 or less, STOP here and submit report*****

This document contains confidential and privileged patient safety data pursuant to ORS 442.820 to 442.835 and Sections 1, 4 to 6, 8 to 10 and 12, chapter 686, Oregon Laws 2003.

Revised May 2007

PART 1A – Complete this section ONLY if reporting a Pharmacy-related event.

Indicate what types of adverse event you are reporting: (Check all that apply)

- Wrong Patient Wrong Strength/Dose Wrong Route Adverse Reaction Medication Contraindicated Incorrect Directions
 Wrong Medication Wrong Dosage Form Medication Interaction Allergic Reaction Generic Substitution Expired Medication
 Other (Please Describe) Incomplete Labeling

Comment [L19]: Complete this section if the medication error involved any aspect of the pharmacy process.

Indicate where in the workflow process the adverse event occurred: Check all that apply...

- Prescribing process Receipt of Rx Review Entry Process
 Compounding Filling Process Delivery Other (Please Describe)

Comment [L20]: You may also use this to provide any explanation related to the type/s identified above.

Did this event involve: (Check all that apply) Automated dispensing (e.g. Pyxis) Electronic prescribing (CPOE) Medication administration checking (e.g. MAK)

Number of prescriptions filled concurrently for this patient:

Was this event related to a new prescription? or a refill?

Please help us understand what contributed to the event you are reporting.

Communication

- Among pharmacy staff
 Between pharmacy staff and prescribing provider
 Between pharmacy staff and patient
 Look-alike/sound-alike drug
 Hard to read handwriting/fax
 Inaccurate/Incomplete patient profile
 Patient profile missing/absent
 Other

Equipment, software or material defects

- Software
 Equipment meeting code, specifications, regulation
 Equipment design (function, displays, controls)
 Defective/non-working equipment
 Other (please list)

Organizational Factors

- Overall culture of safety
 Staffing levels
 Staff assignment/work allocation
 Leadership/Management
 Systems to identify risks
 Adequacy of budget
 Internal reporting
 Other

Policies, Procedures

- Absent
 Too complicated
 Outdated
 Not followed/compliance
 Other

Work Area/Environment

- Work area design and specifications
 Distractions
 Relief/float pharmacist
 Noise
 Clutter
 Lighting
 Interruptions (please describe)

Training or supervision

- Job Orientation
 Continuing education
 Supervision
 Routine job training
 Availability of training
 Other

Comment [L21]: Check all that apply to the *pharmacy* aspect of the event only. Use previous contributing causes factors list for aspects of the event occurring outside of pharmacy.

Comment [L22]: Include any language barriers

Comment [L23]: Note reasons for noncompliance, including organizational or system influences

PART 2 – Complete if reporting an event with a harm level of 7 or greater

What was the patient's admitting diagnosis (ICD9)?

Comment [LNR24]: Note diagnosis for the admission during which the event occurred

Please list relevant co-morbidities:

Please list relevant procedures:

Comment [LNR25]: Include only major diagnoses or those that had a direct influence on patient's status

What was the patient's discharge status?

Date review and analysis completed:

YYYY MM DD

Who was on the Review and Analysis Team? (Check all that apply)

- Physician(s)
- Nursing staff
- Nursing Management
- Quality Management
- Risk Management
- Senior Administration
- Pharmacist(s)
- Engineering staff
- Other (please list):
- Other (please list):
- Other (please list):
- Other (please list):

Notification of the event made to: (Check all that apply)

- YES
- NO
- Senior Management Comment
- Board of Directors Comment
- Patient or personal representative in writing Comment

Comment [LNR26]: This is required for all events with a harm level of 7 or above. If letter has not yet been sent/given, please let us know what the status of letter is.

List findings regarding the cause/causes of this event:	Describe the Action Plans developed:

Comment [LNR27]: Findings should clearly show a cause & effect relationship, avoid negative descriptions, and identify a preceding cause or chain of causes

Comment [LNR28]: Action plans should be specific and clear with timeline and measures of success. Strong plans focus on system changes rather than upon individual memory and vigilance

Did the Review Team have a post-analysis briefing with senior management? Yes No
Comment

Additional comments:

Comment [LNR29]: Use this for any additional information or comments regarding the event.

Whom should we contact for clarification/feedback?

Name Phone

Comment [LNR30]: Often the person completing the form is not the person familiar with the reported event. To save multiple phone calls, please include the name and phone number of the appropriate contact person here.

Thank you for completing this report. Please submit to the Patient Safety Commission via secure email process, e.g. Certified Email.

This document contains confidential and privileged patient safety data pursuant to ORS 442.820 to 442.835 and Sections 1, 4 to 6, 8 to 10 and 12, chapter 686, Oregon Laws 2003.

Revised May 2007

**COMPARISON OF OREGON PATIENT SAFETY COMMISSION HARM LEVELS
WITH NCC MERP HARM CATEGORIES
MAY 2007**

NCC MERP Category	Definition	Patient Safety Commission 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	No detectable harm
		3	Minimal Temporary Harm
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	5	Moderate Temporary Harm
		7	Serious Temporary Harm
F	An 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	Minimal Permanent Harm
		6	Moderate Permanent Harm
		8	Serious Permanent Harm
H	An error occurred that required intervention necessary to sustain life	7	Serious Temporary Harm
		8	Serious Permanent Harm
I	An error occurred that may have contributed to or resulted in the patient's death.	9	Death

Serious Harm (harm level 7 or greater) is that which significantly impacts a patient's status or functional ability or that requires transfer to a higher level of care, additional procedures/testing, surgical intervention, prescription medication, any increase in length of stay, or readmission



Nursing Facility Serious Adverse Event Report Form

Please submit a report for **Serious Adverse Events** and the results of your investigation to the Oregon Patient Safety Commission within 30 days of discovery. If you believe the situation requires an *immediate* alert to Oregon nursing facilities, please contact us within 3 business days of discovery. The full report must be submitted within 30 days.

What to report:

Please report any listed serious adverse event with a harm level of 7, 8 or 9 (see *Type of Event* and *Level of Harm* on page 2).

Definitions:

A **serious adverse event** that requires a report to the Commission is an unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury. “Unanticipated, usually preventable” refers to adverse events that are caused, at root, by an issue of medical or patient management, rather than the underlying disease.

Serious physical injury (harm level 7 or greater) includes, but is not limited to, injuries that require a patient to be transferred to a higher level of care.

For more information, please refer to Reporting Form Guidelines, Tab 5 in the Oregon Patient Safety Commission Nursing Facility Reference & Training Manual.

Other Adverse Events:

We invite participating organizations to report other adverse events including those mentioned above that have a harm level of 6 or lower and close calls/near misses. Please do so because other organizations can benefit from your experience. For these less serious events, you only need to complete Part 1 and Part 1A if applicable, of the reporting form. Please report the events within 30 days of discovery.

**For questions regarding reporting or use of the form, please call
Amy Gryzic at the Oregon Patient Safety Commission
Telephone: 503.227.2632**

Serious Adverse Event Reporting Form

PART 1

What type of event occurred? (Check all that apply)

- | | |
|---|--|
| <input type="checkbox"/> Elopement, requiring notification of emergency personnel | <input type="checkbox"/> Suicide or attempted suicide |
| <input type="checkbox"/> Medication Error TYPE: | <input type="checkbox"/> Strangulation (not restraint related) |
| <input type="checkbox"/> Device or equipment related event | <input type="checkbox"/> Poisoning |
| <input type="checkbox"/> Aspiration or choking | <input type="checkbox"/> Treatment related event (includes omission and incorrect treatment) |
| <input type="checkbox"/> Food allergy | <input type="checkbox"/> Event related to use of restraints |
| <input type="checkbox"/> Medication allergy | <input type="checkbox"/> Fall |
| <input type="checkbox"/> Burn – second or third degree | <input type="checkbox"/> Facility acquired infection |
| <input type="checkbox"/> Other (please describe briefly): | |

Level of Patient Harm (Check one box only)

- | | |
|--|---|
| <input type="checkbox"/> 9. Death | <input type="checkbox"/> 6. Moderate-Permanent Harm |
| <input type="checkbox"/> 8. Serious-Permanent Harm | <input type="checkbox"/> 5. Moderate-Temporary Harm |
| <input type="checkbox"/> 7. Serious-Temporary Harm | <input type="checkbox"/> 4. Minimal-Permanent Harm |
| | <input type="checkbox"/> 3. Minimal-Temporary Harm |
| | <input type="checkbox"/> 2. No Detectable Harm |
| | <input type="checkbox"/> 1. Did not reach the patient |

* If the harm was 6 or lower, was the patient at risk for serious harm? Yes No

Where did the event occur? (Check all that apply)

- | | | | |
|--|--|--|--|
| <input type="checkbox"/> Resident's Room | <input type="checkbox"/> Bathroom | <input type="checkbox"/> Nurses' Station | <input type="checkbox"/> Stairs |
| <input type="checkbox"/> Outdoors; facility property | <input type="checkbox"/> Outdoors: non-facility | <input type="checkbox"/> Dining Room | <input type="checkbox"/> Tub/Shower |
| <input type="checkbox"/> Beauty/Barber Shop | <input type="checkbox"/> Recreation/Activity Rm. | <input type="checkbox"/> Elevator | <input type="checkbox"/> Rehab/Therapy |
| <input type="checkbox"/> Elevator | | | |
| <input type="checkbox"/> Other (please describe) | | | |

Patient Descriptors

Age _____ Sex _____

Payor Source (Check all that apply)

- | | | |
|--|--|----------------------------------|
| <input type="checkbox"/> Medicaid per diem | <input type="checkbox"/> TriCare per diem | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Medicare per diem | <input type="checkbox"/> VA per diem | <input type="checkbox"/> Other |
| <input type="checkbox"/> Medicare ancillary part A | <input type="checkbox"/> Self/family/pvt pay | |
| <input type="checkbox"/> Medicaid resident liability or Medicare copay | <input type="checkbox"/> Private insurance | |

Race/Ethnicity (Check all that apply)

- | | | |
|--|-----------------------------------|----------------------------------|
| <input type="checkbox"/> American Indian or Alaska Native | <input type="checkbox"/> Asian | <input type="checkbox"/> Other |
| <input type="checkbox"/> Native Hawaiian or Other Pacific Islander | <input type="checkbox"/> White | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> Black or African American | <input type="checkbox"/> Hispanic | |

Level of Care (Check all that apply)

- | | | |
|---|----------------------------------|--------------------------------------|
| <input type="checkbox"/> Skilled | <input type="checkbox"/> Respite | <input type="checkbox"/> Psychiatric |
| <input type="checkbox"/> Nursing Facility (ICF) | <input type="checkbox"/> Hospice | <input type="checkbox"/> Pediatric |

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Other (please describe)

Dementia

Date Admitted YYYY ____ MM ____ DD ____

Date of Event YYYY ____ MM ____ DD ____ Time of Event [24hr clock]

Date Discovered YYYY ____ MM ____ DD ____ Time Discovered [24hr clock]

Admitted from (Complete only if event occurred within 30 days of admission)

Home

Hospital

Other N.F.

Assisted Living

Adult Foster Home

Other (please describe)

Residential Care

Date DNS notified: YYYY ____ MM ____ DD ____

Date Administrator notified: YYYY ____ MM ____ DD ____

Please provide a complete account of the event:

What were the most important contributing factors to this adverse event?

Communication

- Hand-offs or shift reports
 - Available information
 - With Physician or RN Practitioner
 - Between departments
 - Involving resident transfers
 - With other organizations or outside Providers
 - Between healthcare personnel & resident/family
 - Among healthcare personnel
- Please describe

Other:

Resident Care Management

- Developing a care plan
- Implementing a care plan
- Following a care plan
- Updating a care plan
- Availability of Resources
- Responding to change of condition
- Identifying a resident
- Resident consent process

Other:

Training or Supervision

- Job Orientation
- In-service education/competency training
- Supervision
- Skills demonstration
- Continuing education
- Availability of training programs

Other:

Organizational Factors

- Overall culture of safety
- Commitment to resident safety
- Accountability for resident safety
- Unit staffing levels
- Staffing turnover
- Temporary staffing
- Staff assignment/work allocation
- Shift leadership/Management
- Systems to identify risks
- Adequacy of budget
- Adequacy of Safety Committee
- Internal reporting

Other:

Resident Factors

- Family Dynamics/Relationships
- Language/Culture
- Behavioral Problems
- Mental Status
- Sensory Impairment
- Resident to resident issue
- Resident assumption of risk

Other:

Technology

- Software (please list)
- Equipment meeting code, specifications, regulation
- Equipment design (function, displays, controls)
- Defective/non-working equipment
- Other

Other Factors

Policies, Procedures

- Absent
 - Too complicated
 - Outdated
 - Not followed/compliance
- Other

Work Area/Environment

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

J. Were there any factors that helped reduce the seriousness or consequences of the event? Yes No

(If yes) Please describe

Approximately how many person-hours did the event investigation and review take?

This document contains confidential and privileged patient safety data pursuant to ORS 442.820 to 442.835 and Sections 1, 4 to 6, 8 to 10 and 12, chapter 686, Oregon Laws 2003.

*******STOP: If reporting an adverse event with harm level of 7 or above, skip to Part 2*******

List your findings regarding the causes of this event

Describe your action plans

List your findings regarding the causes of this event	Describe your action plans

Additional Comments:

Whom should we contact for clarification/feedback?

Name Phone

*******If reporting an adverse event with harm level of 6 or less, STOP here and submit report*******

PART 1A – Complete this section ONLY if reporting a Pharmacy-related event.

Indicate what types of adverse event you are reporting: (Check all that apply)

- Wrong Patient Wrong Strength/Dose Wrong Route Adverse Reaction Medication Contraindicated Incorrect Directions
- Wrong Medication Wrong Dosage Form Medication Interaction Allergic Reaction Generic Substitution Expired Medication
- Other (Please Describe) Incomplete Labeling

Indicate where in the workflow process the adverse event occurred: Check all that apply...

- Prescribing process Receipt of Rx Review Entry Process
- Compounding Filling Process Delivery Other (Please Describe)

Did this event involve: (Check all that apply) Automated dispensing (e.g. Pyxis) Electronic prescribing (CPOE) Medication administration checking (e.g. MAK)

Number of prescriptions filled concurrently for this patient:

Was this event related to a new prescription? **or a refill?**

Please help us understand what contributed to the event you are reporting.

Communication

- Among pharmacy staff
- Between pharmacy staff and prescribing provider
- Between pharmacy staff and patient
- Look-alike/sound-alike drug
- Hard to read handwriting/fax
- Inaccurate/Incomplete patient profile
- Patient profile missing/absent
- Other

Equipment, software or material defects

- Software
- Equipment meeting code, specifications, regulation
- Equipment design (function, displays, controls)
- Defective/non-working equipment
- Other (please list)

Organizational Factors

- Overall culture of safety
- Staffing levels
- Staff assignment/work allocation
- Leadership/Management
- Systems to identify risks
- Adequacy of budget
- Internal reporting
- Other

Policies, Procedures

- Absent
- Too complicated
- Outdated
- Not followed/compliance
- Other

Work Area/Environment

- Work area design and specifications
- Distractions
- Relief/float pharmacist
- Noise
- Clutter
- Lighting
- Interruptions (please describe)

Training or supervision

- Job Orientation
- Continuing education
- Supervision
- Routine job training
- Availability of training
- Other



Ambulatory Surgery Center Adverse Event Report Form

Please submit descriptions of all **reportable adverse events** and the results of your investigation to the Oregon Patient Safety Commission within 45 days of discovery. If you believe the situation requires an *immediate* alert to Oregon Ambulatory Surgery Centers, please contact us within 3 business days of discovery. The full report would follow within 45 days.

What to report:

1. Please report any adverse event with a harm level of 7, 8, or 9 (see *Level of Patient Harm* on page 2).
2. Please report any of the **listed** adverse events (see *Type of Event* on page 2). These events may have harm level between 3 and 9.

Definitions:

An **adverse event** is an unanticipated, usually preventable consequence of patient care that results in patient harm. A **serious adverse event** results in serious physical injury or death. Such events are typically unrelated to the natural course of the patient's illness or underlying condition.

Serious physical injury (harm level 7 or greater) is that which severely impacts a patient's status of functional ability or requires transfer to a higher level of care, surgical intervention or hospital admission and could also involve additional procedures/testing.

For more information, please refer to **ASC Report Form Guidelines**

Other Adverse Events

We invite participating organizations to report other adverse events including those mentioned above that have a harm level of 6 or lower, and close calls/near misses. Please do so because other organizations can benefit from your experience. For these less serious events, you only need to complete Part 1 and Part 1A, if applicable, of the reporting form. Please report the events within 45 days of discovery.

For questions regarding reporting or use of the form, please call
Amy Gryziec at the Oregon Patient Safety Commission
Telephone: 503.227.2632

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June 2007

Adverse Event Reporting Form

PART 1

What type of event occurred? (Check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Unplanned admission to hospital within 48-hours of discharge | <input type="checkbox"/> Contaminated drugs, devices or biologics |
| <input type="checkbox"/> Unplanned Emergency Dept. visit within 48-hours of discharge | <input type="checkbox"/> Equipment/medical device malfunction or misuse |
| <input type="checkbox"/> Postoperative nausea requiring hospital admission | <input type="checkbox"/> Intravascular air embolism |
| <input type="checkbox"/> Any blood products transfusion | <input type="checkbox"/> Medication Error TYPE: |
| <input type="checkbox"/> Immediate postoperative bleeding requiring surgical treatment | <input type="checkbox"/> Hypoglycemia |
| <input type="checkbox"/> DVT with or without pulmonary embolism | <input type="checkbox"/> Electric shock |
| <input type="checkbox"/> Unplanned retention of foreign object in patient | <input type="checkbox"/> Burn |
| <input type="checkbox"/> Postoperative death directly attributable to surgical procedure | <input type="checkbox"/> Restraints or bed rails |
| <input type="checkbox"/> Intraoperative or immediate postoperative death | <input type="checkbox"/> Patient injury associated with a fall |
| <input type="checkbox"/> Surgery performed on wrong body part | <input type="checkbox"/> Hemolytic reaction due to ABO-incompatible blood or blood products |
| <input type="checkbox"/> Surgery performed on wrong patient | <input type="checkbox"/> Line with wrong gas or toxic substances delivered to patient |
| <input type="checkbox"/> Wrong surgical procedure performed on patient | <input type="checkbox"/> <i>OPTIONAL</i> : Other adverse event with Harm Level </= 6 |
| <input type="checkbox"/> Surgical infection up to 30-days postoperatively | <input type="checkbox"/> <i>OPTIONAL</i> : Near Miss |
| <input type="checkbox"/> Other (please describe briefly): | |

Level of Patient Harm (Check one box only)

- | | |
|---|--|
| <input type="checkbox"/> 9. Death | <input type="checkbox"/> 6. Moderate-Permanent Harm |
| <input type="checkbox"/> 8. Serious-Permanent Harm | <input type="checkbox"/> 5. Moderate-Temporary Harm |
| <input type="checkbox"/> 7. Serious-Temporary Harm | <input type="checkbox"/> 4. Minimal-Permanent Harm |
| | <input type="checkbox"/> 3. Minimal-Temporary Harm |
| | <input type="checkbox"/> 2. No Detectable Harm |
| | <input type="checkbox"/> 1. Did not reach the patient |

* If the harm was 6 or lower, was the patient at risk for serious harm? Yes No

Where did the event occur? (Check all that apply)

- | | | |
|--|---|--|
| <input type="checkbox"/> Pre-Op Area | <input type="checkbox"/> Operating Room /Procedure Room | <input type="checkbox"/> Post-Anesthesia Care Unit |
| <input type="checkbox"/> Patient's Home (post-discharge) | | |
| <input type="checkbox"/> Other (please describe) | | |

Patient Descriptors

Age _____ Sex _____

ASA Class

<input type="checkbox"/> 1	<input type="checkbox"/> 3
<input type="checkbox"/> 2	<input type="checkbox"/> 4

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R

aRace/Ethnicity (Check all that apply)

- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Black or African American
- Asian
- White
- Hispanic
- Other
- Unknown

Procedure Date YYYY ____ MM ____ DD ____

Date of Event YYYY ____ MM ____ DD ____ Time of Event [24hr clock]

Date reported to Quality Management:

YYYY ____ MM ____ DD ____

Please provide a complete account of the event:

What were the most important contributing causes to this adverse event?

Communication

- Hand-offs or shift reports
- Available information
- Between healthcare personnel & patient/family
- Among healthcare personnel
- Please describe
- Other:

Patient Management

- Delegation of clinical care
- Response to changing condition
- Patient consent process
- Care plan
- Initial diagnosis
- Tracking or follow-up
- Other:

Training or Supervision

- Job Orientation
- In-service education/competency training
- Supervision
- Routine job training
- Availability of training programs
- Other:

Organizational Factors

- Overall culture of safety
- Staffing levels
- Staff assignment/work allocation
- Leadership/Management
- Systems to identify risks
- Adequacy of budget
- Internal reporting
- Other:

Policies, Procedures

- Absent
- Too complicated
- Outdated
- Not followed/compliance
- Other:

Technology

- Software (please list)
- Equipment meeting code, specifications, regulation
- Equipment design (function, displays, controls)
- Defective/non-working equipment
- Other:

Other Factors

Patient Factors

- Family Dynamics/Relationships
- Language/Culture
- Behavioral Problems
- Mental Status
- Other:

Work Area/Environment

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

J. Were there any factors that helped reduce the seriousness or consequences of the event? Yes No

(If yes) Please describe

Approximately how many person-hours did the event investigation and review take?

*******STOP: If reporting an adverse event with harm level of 7 or above, skip to Part 2*******

What were the findings of your investigation?

What corrective actions did your organization take?

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Additional Comments:

Whom should we contact for clarification/feedback?

Name Phone

*******If reporting an adverse event with harm level of 6 or less, STOP here and submit report*******

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PART 1A – Complete this section ONLY if reporting a Pharmacy-related event.

Indicate what types of adverse event you are reporting: (Check all that apply)

- Wrong Patient Wrong Strength/Dose Wrong Route Adverse Reaction Medication Contraindicated Incorrect Directions
- Wrong Medication Wrong Dosage Form Medication Interaction Allergic Reaction Generic Substitution Expired Medication
- Other (Please Describe) Incomplete Labeling

Indicate where in the workflow process the adverse event occurred: Check all that apply...

- Prescribing process Receipt of Rx Review Entry Process
- Compounding Filling Process Delivery Other (Please Describe)

Did this event involve: (Check all that apply) Automated dispensing (e.g. Pyxis) Electronic prescribing (CPOE) Medication administration checking (e.g. MAK)

Number of prescriptions filled concurrently for this patient:

Was this event related to a new prescription? **or a refill?**

Please help us understand what contributed to the event you are reporting.

Communication

- Among pharmacy staff
- Between pharmacy staff and prescribing provider
- Between pharmacy staff and patient
- Look-alike/sound-alike drug
- Hard to read handwriting/fax
- Inaccurate/Incomplete patient profile
- Patient profile missing/absent
- Other

Equipment, software or material defects

- Software
- Equipment meeting code, specifications, regulation
- Equipment design (function, displays, controls)
- Defective/non-working equipment
- Other (please list)

Organizational Factors

- Overall culture of safety
- Staffing levels
- Staff assignment/work allocation
- Leadership/Management
- Systems to identify risks
- Adequacy of budget
- Internal reporting
- Other

Policies, Procedures

- Absent
- Too complicated
- Outdated
- Not followed/compliance
- Other

Work Area/Environment

- Work area design and specifications
- Distractions
- Relief/float pharmacist
- Noise
- Clutter
- Lighting
- Interruptions (please describe)

Training or supervision

- Job Orientation
- Continuing education
- Supervision
- Routine job training
- Availability of training
- Other

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Draft Reportable Adverse Events

NOTE: *The final version of the pharmacy reporting form will be a web-based entry form. This version, however, contains all information that will be required in the final format. In the interim, pharmacies are invited to complete this draft version when reporting adverse events. Please feel free to give comments and suggestions on form design and content to Leslie Ray at leslie.ray@oregonpatientsafety.org.*

Participating pharmacies should complete this form for all **reportable adverse events**. Such events are defined in administrative rule, OAR 325-015-0001 (8).

Generally, a **Reportable Adverse Event** is any unanticipated, usually preventable consequence of patient care that result in patient harm or the risk of harm. This includes events that:

- (a) Are not related to the natural course of the patient's illness or underlying condition, and
- (b) Resulted in temporary and/or permanent physical harm, or
- (c) Posed a risk for harm.

This excludes events that did not reach the patient, that is, the patient did not receive or have control of the medication.

When to report Adverse Events:

Please report the event and the results of your investigation within 45 days of discovery, unless the situation requires an immediate alert to all Oregon pharmacies.

Based on this event, if you think the Commission should issue an immediate alert to other pharmacies in Oregon, please submit to the Patient Safety Commission within three business days. The results of your investigation would then follow within 45 days by submitting Section 1 (with any changes) and Section 2.

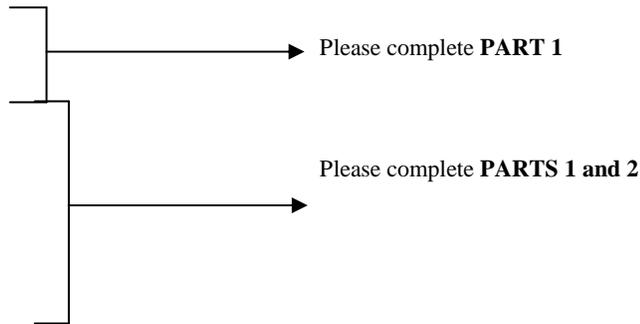
For questions regarding reporting, please call Leslie Ray at the Oregon Patient Safety Commission: 503.224.9227.

ADVERSE EVENT REPORT

Pharmacy Code

Level of Patient Harm (check one box only):

- 1. Patient did not use
- 2. No Detectable Harm
- 3. Minimal-Temporary Harm
- 4. Minimal-Permanent Harm
- 5. Moderate-Temporary Harm
- 6. Moderate-Permanent Harm
- 7. Serious-Temporary Harm
- 8. Serious-Permanent Harm
- 9. Death



PART 1. Event Overview

Indicate what types of adverse event you are reporting: Check all that apply...

<input type="checkbox"/> Wrong Patient	<input type="checkbox"/> Wrong Route	<input type="checkbox"/> Allergic Reaction	<input type="checkbox"/> Expired Medication
<input type="checkbox"/> Wrong Medication	<input type="checkbox"/> Wrong Dosage Form	<input type="checkbox"/> Medication Contraindicated	<input type="checkbox"/> Unsafe Packaging
<input type="checkbox"/> Wrong Directions	<input type="checkbox"/> Medication Interactions	<input type="checkbox"/> Medication Taken Incorrectly	<input type="checkbox"/> Incomplete Labeling
<input type="checkbox"/> Wrong Strength	<input type="checkbox"/> Adverse Reaction	<input type="checkbox"/> Patient Counseling Omitted	<input type="checkbox"/> Generic Substitution
<input type="checkbox"/> Other (Please Describe)			

Indicate where in the work flow process the adverse event occurred: Check all that apply...

<input type="checkbox"/> Prescribing process	<input type="checkbox"/> Receipt of Rx	<input type="checkbox"/> Entry Process	<input type="checkbox"/> Compounding	<input type="checkbox"/> Filling Process
<input type="checkbox"/> Review	<input type="checkbox"/> Delivery	<input type="checkbox"/> Counseling	<input type="checkbox"/> Other (Please Describe)	

Did this event involve: Check all that apply...

<input type="checkbox"/> Electronic prescribing	<input type="checkbox"/> TelePharmacy	<input type="checkbox"/> Automated refill lines
---	---------------------------------------	---

Who discovered the event:

- Patient Patient Representative Pharmacist Prescribing Provider Non-Pharmacist

Date of event

YYYY DD MM

Patient Gender Female Male **Patient Birth Year**

How many prescriptions were you filling for this patient when the event occurred?

Was this event related to a new prescription? or a refill?

Did you inform the patient's prescribing provider of this event? Yes No

What corrective actions did you/your organization take?

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PART 2. Event Description and Analysis

Please provide a COMPLETE description of the adverse event:

Date reported YYYY DD MM

Approximately how many person-hours were directly spent on reviewing this event?

Date Review and Analysis was completed? YYYY DD MM

If this was a serious adverse event, has your organization given written notification of the event to the patient or personal representative?

Yes No Unsure

Please help us understand what caused (or contributed to) the event you are reporting. For each category below check all boxes that apply:

<p>A. Communications (including language barriers):</p> <p><input type="checkbox"/> Communication between pharmacy staff and patient</p> <p><input type="checkbox"/> Communication between pharmacy staff and prescribing provider</p> <p><input type="checkbox"/> Communication among pharmacy staff</p> <p><input type="checkbox"/> Look-alike/sound-alike drug</p> <p><input type="checkbox"/> Hard to read handwriting/fax</p> <p><input type="checkbox"/> Other (please describe)</p>	<p>B. Training or supervision:</p> <p><input type="checkbox"/> Job Orientation</p> <p><input type="checkbox"/> In-service education/competency training</p> <p><input type="checkbox"/> Staff supervision</p> <p><input type="checkbox"/> Routine job training</p> <p><input type="checkbox"/> Special training</p> <p><input type="checkbox"/> Other (please describe)</p>
<p>C. Work Area/Environment:</p> <p><input type="checkbox"/> Work area design and specifications</p> <p><input type="checkbox"/> Noise</p> <p><input type="checkbox"/> Clutter</p> <p><input type="checkbox"/> Lighting</p> <p><input type="checkbox"/> Interruptions (please describe)</p> <p><input type="checkbox"/> Other distractions</p> <p><input type="checkbox"/> Other (please list)</p>	<p>D. Equipment, software or material defects:</p> <p><input type="checkbox"/> Software (please list)</p> <p><input type="checkbox"/> Inaccurate/Incomplete patient profile</p> <p><input type="checkbox"/> Patient profile missing/absent</p> <p><input type="checkbox"/> Equipment meeting code, specifications, regulation</p> <p><input type="checkbox"/> Equipment design (function, displays, controls)</p> <p><input type="checkbox"/> Defective/non-working equipment</p> <p><input type="checkbox"/> Other (please list)</p>
<p>E. Policies, Procedures:</p> <p><input type="checkbox"/> Absent</p> <p><input type="checkbox"/> Inaccurate</p> <p><input type="checkbox"/> Outdated</p> <p><input type="checkbox"/> Unrealistic</p> <p><input type="checkbox"/> Not followed</p> <p><input type="checkbox"/> Poorly presented</p> <p><input type="checkbox"/> Other (please list)</p>	<p>F. Organizational factors:</p> <p><input type="checkbox"/> Overall culture of safety</p> <p><input type="checkbox"/> Staffing levels</p> <p><input type="checkbox"/> Relief/float pharmacist</p> <p><input type="checkbox"/> Fatigue/stress</p> <p><input type="checkbox"/> Staff assignment/work allocation</p> <p><input type="checkbox"/> Leadership/management</p> <p><input type="checkbox"/> Systems to identify risks</p> <p><input type="checkbox"/> Adequacy of budget</p> <p><input type="checkbox"/> Internal reporting</p> <p><input type="checkbox"/> Other (please list)</p>
<p>G. Patient factors</p> <p><input type="checkbox"/> Language</p> <p><input type="checkbox"/> Hearing</p> <p><input type="checkbox"/> Culture</p> <p><input type="checkbox"/> Vision</p> <p><input type="checkbox"/> Physical Limitations</p> <p><input type="checkbox"/> Behavioral</p> <p><input type="checkbox"/> Other (please list)</p>	

Were there any *additional factors* that played a role in this event? Yes No

(If yes) Please briefly describe

General Comments

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SECTION 3.
System Level Action Plans

Please list each finding from your investigation of this adverse event and briefly describe the action/s taken to correct and the timeline:

Finding	Actions	What is implementation time frame?

Thank you for completing the report. Please send* via encrypted email to:
Oregon Patient Safety Commission
Pharmacy Reporting Program
1020 SW Taylor St. Ste 375
Portland, OR 97205-2554

*If you wish to fax your report, please call to assure someone is available to receive the report. Send by fax (503.224.9150) ONLY if you first speak with one of the Commission staff to arrange receipt: 503.224.9227.

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Appendix C

Reportable Hospital Serious Adverse Events From OAR 325-010-0001 to 325-010-0060

Type of Events	Additional Specifications
1. GENERAL CATEGORY	
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	Category includes: <ul style="list-style-type: none"> • Any unanticipated, usually preventable event that results in serious physical injury, even if the harm is temporary. • Only events that are not related to the natural course of the patient's illness or underlying condition. • Healthcare acquired infections that result in patient death or serious physical injury.
2. SURGICAL EVENTS	
A. Surgery performed on the wrong body part.	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
B. Surgery performed on the wrong patient.	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
C. Wrong surgical procedure performed on a patient.	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure.	Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an ASA Class I patient. (ASA is the American Society of Anesthesiologists. Class I means a healthy patient, no medical problems.)	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.

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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.	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
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.	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious physical injury associated with intravascular air embolism that occurs while being cared for in a healthcare facility.	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
4. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours.	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious physical injury, while being cared for in a healthcare facility.	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the 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).	Excludes reasonable differences in clinical judgment on drug selection and dose.
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 while being cared for in a healthcare facility.	Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.
D. 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.	

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