



**Public Health Officer
Certification Report 2006**

**Oregon Patient Safety Reporting Program
For Hospitals**

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

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Dear Fellow Oregonians,

We submit to you the first annual Public Health Officer Certification of the Oregon Patient Safety Commission's Reporting Program. It represents an independent look at how the program is doing. During the "start-up" phase in 2006 hospitals were the initial participants and their information is presented in this report. In the coming years the reporting program will also include nursing homes, ambulatory surgery centers, retail pharmacies, renal dialysis facilities and birthing centers.

The Public Health Officer Certification is a novel approach to public accountability in a state reporting program that looks at adverse medical events. Public Health Division staff developed objective criteria to assess the quality and quantity of the adverse event reports as well as the overall integrity of the reporting system. I am pleased to present results from the program for the first year – results that document substantial accomplishments made by the Oregon Patient Safety Commission.

Almost four years ago, in July 2003, the Legislature created the Oregon Patient Safety Commission and embarked upon a path to address preventable harm to patients due to medical care. Its mission is to improve patient safety by reducing the risk of serious adverse events and by encouraging a culture of patient safety in Oregon.

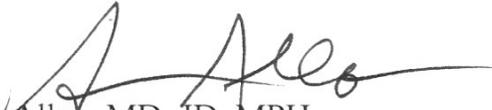
The work of the Commission includes establishing a confidential, non-punitive reporting program for serious adverse events for voluntarily enrolled hospitals and other health care facilities. The model is centered on the understanding that most medical errors are a result of system failures and not simply individual actions. It is built on the principle of learning and sharing best practices to prevent serious events across all health care organizations.

The Commission has made great strides since its inception. I am pleased with the overall implementation of the program and especially regarding the number of participating hospitals (52 of the 57 hospitals in the State). The quality of reporting is also good, although with room for improvement. The area of greatest concern is the volume of reporting. This suggests work to be done to more fully engage enrolled hospitals.

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The Commission is moving in the right direction and fulfilling its charge as set out in the founding legislation. I look forward to following the progress of the Commission as it implements similar reporting programs for nursing homes, ambulatory surgery centers and retail pharmacies.

This first certification provides an assessment of the program, makes recommendations for improvement and outlines anticipated future progress. Please read on to find out more about the certification of the Oregon Patient Safety Commission's Reporting Program.

A handwritten signature in black ink, appearing to read 'S. Allan', with a long horizontal flourish extending to the right.

Susan Allan, MD, JD, MPH
Public Health Director
Public Health Officer

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Executive Summary

The Patient Safety Commission has achieved an important milestone toward fulfilling their mission by establishing the Patient Safety Reporting Program for hospitals in 2006. The program plays a key role in reducing the harm from serious adverse events in Oregon. The program is demonstrating good overall integrity as seen in the strong design and implementation of the reporting program. The Public Health Officer finds that quality of hospital reporting at this early stage is good while the absolute quantity of reports is too low. Success of the Patient Safety Reporting Program will be the result of collaborative efforts of the Commission and hospitals as well as all future reporting health care facilities. The Public Health Officer looks forward to following the progress of the Commission's Reporting Programs in the coming years.

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. They were 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, outpatient renal dialysis facilities and freestanding birthing centers. Hospitals began reporting in May 2006.

The legislation also established the annual Public Health Officer Certification as a distinctive public accountability feature of a statewide patient safety reporting system. 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 has established independent and objective measurement criteria to assess the reporting program (Appendix A).

This is a report of the Public Health Officer Certification for the Oregon Patient Safety Commission's Reporting Program for hospitals. The Certification is an assessment of the quantity and quality of the reports submitted by hospitals in 2006 as well as the overall integrity of the reporting program. It is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon hospitals. That responsibility falls to the Patient Safety Commission which will continue provide analysis and information about hospital reports received (www.oregonpatientsafety.org).

The Patient Safety Commission received a total of 55 adverse event reports from 28 of 52 of participating hospitals. There were 11 retrospective reports, which means events occurred before May 1, 2006. Of the 55 reports, 47 were from the Commission's list of reportable adverse events (Appendix C) and the remaining 8 reports were optional reports.

Certification Results:

The Public Health Officer Certification results are reported in two categories:

- I. Hospital Reporting Assessment, which includes report quality and quantity
- II. Overall Integrity of the Patient Safety Reporting Program Assessment.

The hospital report quality assessment uses the certification criteria to evaluate all of the individual adverse event reports (Appendix A). Each report receives a total report quality score, which is a sum of all the results 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). The quantity or reporting level 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 program is also done with questions and data elements as described in the Public Health Officer Certification Tool.

Quality:

The Public Health Officer Certification found good overall quality in the submitted reports. About two-thirds (67.3%) of the reports were rated as high for the total quality, as medium in 21.2% of reports and low for 10.9% of the reports. The quality for adverse event investigation was generally higher than for event description and action plan development. With increased experience in the coming years, we would anticipate that all hospitals would submit reports in the high quality category.

Quantity:

The Public Health Officer Certification finds that the total number of submitted reports in Oregon to be within the wide range observed in similar although 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 states with comparable reportable adverse event definitions.

Although reporting levels in Oregon are within the range of that seen in similar state programs, this should not be regarded as the 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}. The broad consideration of other estimates from the Institute of Medicine report, Institute for Healthcare Improvement trigger tools and the Pennsylvania data leads us to believe that there are more reportable serious adverse events to be identified and reported by Oregon hospitals. As the program matures and participants gain experience, we anticipate a higher volume of reporting.

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. *2006 Annual Report*. Available at http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2006.pdf. accessed on March 31, 2007.

Overall Integrity:

We found that the Oregon Patient Safety Commission is demonstrating good overall integrity in the endeavor to create and put into practice a statewide adverse event reporting system. The Public Health Officer Certification looked beyond reporting quality and quantity to other activities that contribute to the integrity of the reporting program as a whole. The overall integrity criteria included hospital participation rates, reporting tool design and implementation, report review process, action plan follow-up, learning and best practice dissemination and rates of written notification.

- Excellent hospital enrollment rates for the first year of a voluntary program
- The adverse event reporting tool is generally clear and collects relevant information about contributing factors and action plan strategies
- Good progress in implementation of the reporting program
- The internal review process for submitted reports was improved and formalized the end of 2006 and has been implemented for the 2007 reports
- Good dissemination of learning with limited resources in a start-up year
- The rate of completed written notification to the patients and families was less than 100% for the first year, which may be expected considering the stage of development of the program and complexity of fulfilling this aspect of the program

Conclusions:

We recognize that the Commission is in an early phase of operation and will need time and resources to fully develop all aspects of the reporting program. In addition, the hospitals are also in a learning phase as they build up their internal patient safety programs and systems for identifying adverse events. The Public Health Officer understands that a strong reporting program able to use the collected patient safety data effectively to support real measurable change will require the continued collaboration of the Commission and hospitals.

The future success of the Patient Safety Reporting Program for hospitals will be built on the strong partnership between the Commission and hospitals. They have shown that they are willing to voluntarily enroll in the program, which indicates an impressive commitment to improving patient safety for Oregonians. However, the reduction of adverse events will require more than enrollment. It will likely involve the continual review of patient safety systems to identify adverse events and to efficiently and effectively share the data, both internally across departments and externally to the Commission reporting program. Hospitals can learn about strategies for safer systems for the benefit of all patients in Oregon.

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 have assessed the status, offered recommendations and anticipated progress for the coming year. In the second year we will note the progress and adopt some standards for the third year. After the third year, the Public Health Officer will officially certify the reporting program using objective standards.

Introduction

This is a report of the Public Health Officer (PHO) Certification for the Oregon Patient Safety Commission's Reporting Program for hospitals. The PHO Certification is an assessment of the quantity and quality of the reports submitted by hospitals in 2006 and the overall integrity of the reporting program. It is not a detailed analysis of the reported adverse events and implications for improving patient safety in Oregon hospitals. That responsibility falls to the Patient Safety Commission, which will continue provide analysis and information about hospital 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 events are the result of an error nor do all errors result in an adverse event.

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 Program for Hospitals focuses in part 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).

History- Moving from an Idea to Law

To get the best reporting, we will have to change the culture. We should focus on reducing harm, not on reducing error per se.

Dr. Grant Higginson, Administrator, Office of Community Health and Health Planning
Oregon Patient Safety Conference, February 2004

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.

In September 2002, the Office of the Public Health Officer convened a broad group of partners to explore the need for a patient safety reporting system in Oregon. The Patient Safety Workgroup included State health officials, health care providers, insurers, consumers and purchasers. The group expressed a growing concern about preventable harm to patients occurring as a result of medical care and a consensus about the value of public reporting of patient safety information. There was an acknowledgement that most medical errors are systems-related and not the result of individual negligence. Original goals of the workgroup were to reduce preventable adverse events and build public confidence in participating health care facilities and providers' abilities to detect, analyze and prevent serious adverse events.

The Institute of Medicine (IOM) illustrated the enormous scope of the problem of medical errors in the renowned publication, *To Err is Human: Building a Safer Health System*⁶. The report's core message is that errors are mostly the result of poorly defined systems and not careless providers and that the prevention of unintentional harm to patients could be prevented by redesigning systems rather than through punishing individuals. This point was embraced by many states and also national organizations. The IOM proposed strategies to address the patient safety challenge: establish leadership and knowledge about patient safety, identify and learn from errors, raise standards and expectations for improvements in safety and create safety systems within health care organizations. The work of the IOM strongly informed the work of the group.

The Patient Safety Workgroup met more than ten times during 2002/2003 to discuss the opportunities for meeting their goals. They considered reporting system structures, reportable event definitions, the central role of encouraging a culture of patient safety, and accountability features. National and state-level legislation also played a role in developing proposals for Oregon. Some states established mandatory reporting systems while others chose to pursue improvement in patient safety with more informal coalitions of interested parties. After extensive discussion and review, Oregon partners crafted an innovative consensus solution for our state. In 2003 the Oregon Patient Safety Commission was created (Oregon Laws 2003, c. 686). It was designed as a voluntary confidential reporting system with authentic public accountability components.

The Patient Safety Commission: Building the Patient Safety Reporting Program

It's always the three-step test: Will they sign up? Will they share and can we do something useful with the information?

Jim Dameron, Administrator of the Patient Safety Commission
Bend Bulletin, May 2007

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

⁶ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

serious adverse events and 3) disseminate evidence-based prevention practices to improve patient outcomes (Oregon Laws 2003, c. 686). The health care entities eligible for the reporting programs include hospitals, retail pharmacies, nursing homes, ambulatory surgery centers, outpatient renal dialysis facilities and freestanding birthing centers.

The confidential, voluntary reporting program in Oregon represents an alternative to mandatory approaches. Voluntary means that facilities can choose to enroll in the program. However, as participants, they agree to share all reportable adverse events with the Commission. Confidential means that the submitted reports and all patient safety data are protected similar to peer review data. It is a program that does not intend to shame and blame individuals involved in adverse events, but applies a systems-based approach to understanding the events and solutions for prevention of future occurrence. Hospitals participate in order to demonstrate their commitment to patient safety and to learn about and share best practices.

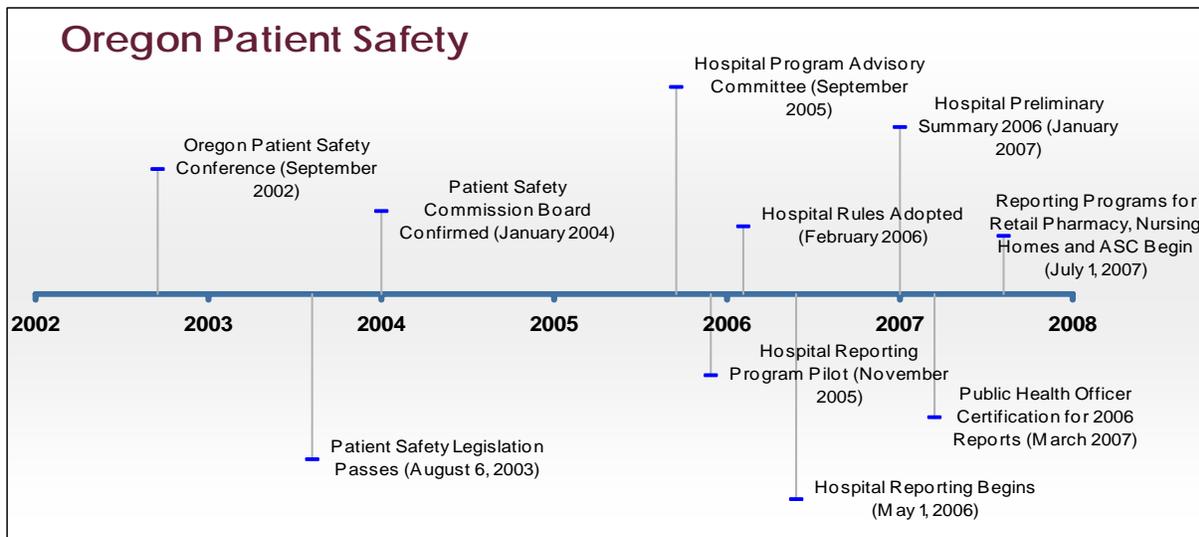


Figure 1 Oregon Patient Safety Progress

The progress toward establishing reporting programs for all facility types began with hospitals in 2006 and is expanding to retail pharmacies, nursing homes and ambulatory surgery centers in 2007 (Fig. 1). The process entails identifying an expert advisory committee, defining a list of reportable events, developing a reporting template, testing and revising that template and finally, adopting the administrative rules to guide the programs.

It is clear that both the Commission and hospitals require a learning period to effectively implement the reporting program. Hospitals find themselves at different stages of development of their internal patient safety programs. Participants started the reporting program with varying levels of expertise in identifying adverse events, completing the investigations and drafting meaningful action plans to prevent recurrences. All of these factors contribute to the quality of reports submitted to the Commission. The penetration of a culture of patient safety from the frontline providers to the highest levels of administration can also vary widely among facilities.

Culture will play a key role in a hospital's ability to report and build a strong patient safety infrastructure.

PHO Certification Process

I hear there are questions about the value of reporting, but reporting can help focus attention. Give the system time to succeed; you will need clear definitions and to remove impediments to reporting.

Frederick J. Heigel, Director, Bureau of Hospital and Primary Care Services, New York State Department of Health
Oregon Patient Safety Conference, February 2004

As previously stated, the PHO Certification applies explicitly to 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 hospitals 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. 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
- Publish an annual Commission summary report for all Oregonians

The Statute has created the annual Public Health Officer Certification as a distinctive public accountability feature of a statewide patient safety reporting system. 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 has established independent and objective measurement criteria to assess the reporting program (Appendix A). The certification tool for hospitals was designed to match the information available in the Commission adverse event report form (Appendix B). We developed and tested the tool and made final revisions in late 2006. The certification of hospital participant reporting includes all

reports submitted in 2006. Commission staff have provided 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: Is the reporting program working to achieve the goal of improved patient safety? The PHO will initially use the quality of reporting and actions of the Commission to reach conclusions about the reporting program. However, as the program progresses, 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 will evolve with the developmental stages of the reporting program. The included elements may need to vary for other facility types. 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.

Certification – How are they doing?

The PHO Certification was completed in March 2007 by reviewing all de-identified adverse event reports using the certification criteria (Appendix A). Commission staff provided additional data where necessary. We report the results in two parts in the outline below.

- I. Hospital Reporting Assessment
 - Methods
 - Report Quality
 - Completeness
 - Adverse Event Description
 - Adverse Event Analysis
 - Adverse Event Action Plans
 - Report Quantity

- II. 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

Reports Received

The reporting program officially began on May 1, 2006 for the initial participants. Hospitals were requested to submit any reportable adverse events retrospectively for all of 2006 in order to have a full year of data. Some hospitals were able to do this, while others could not comply due to administrative, technical or other difficulties.

The Patient Safety Commission received a total of 55 adverse event reports from 28 of 52 participating hospitals. There were 11 retrospective reports, which means events occurred before May 1, 2006. Of the 55 reports, 47 were compulsory reporting from the Commission's list of reportable adverse events (Appendix C) and the remaining 8 reports were optional reports.

I. Hospital Reporting Assessment

The first part of the PHO Certification is a review of the quality of the adverse event reports submitted by hospitals and an assessment of the quantity of those reports.

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 Commission⁷.

Hospitals use a reporting form provided by the Commission to report adverse events (Appendix B). The list of required reportable events (Appendix C) was adapted from a list developed by the National Quality Forum (NQF)⁸. Oregon's list for hospitals focuses on events that result in death or serious physical injury. Some adverse events that are reportable that do not necessarily result in serious harm to the patient, such as a retained sponge that is quickly discovered and removed. The Commission encourages facilities to report other adverse events that could provide useful learning for everyone. The NQF list or a modified version is currently used by about ten other states. The adverse event reporting form is 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.

The PHO report quality assessment is measured using the PHO Certification Tool (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 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.

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

⁷ *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.

⁸ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

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.

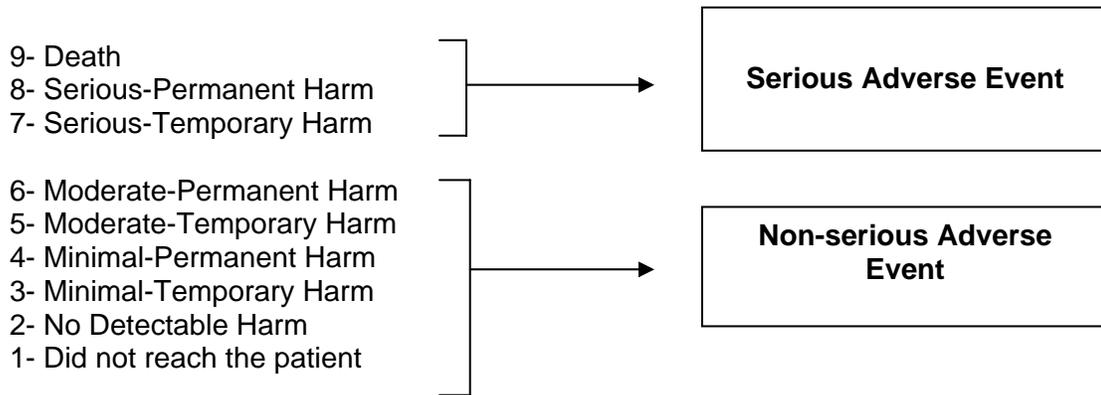


Figure 2 Level of Patient Harm Scale.

As previously described, the reporting form submitted by the hospitals requires a higher level of investigation and development of solutions for the most serious events. Accordingly, the certification analysis is also broken down by serious and non-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 described by 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.

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 not met, partially met or met and resulting in two, one or zero points. The adverse event analysis is a combined score from two data elements for non-serious events or five for serious events. The maximum points were 4 or 10 for non-serious or serious events respectively. Action plan assessment is also a combined score from 2 or 3 data elements for non-serious or serious events resulting in 4 or 6 maximum points. The maximum points for a serious adverse event were therefore 20 and 12 for a non-serious event.

The quality is reported for serious and non-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 low (0-33%), medium (34-66%) and high (67-100%) quality categories. For example, a non-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 non-serious adverse events combined and separately. Of the 55 adverse event reports submitted in 2006, 33 were classified as serious adverse events and 22 were non-serious adverse events.

Report Quality

Report Completeness:

All reports submitted were determined to be complete. A report is considered complete if all questions were answered. There was some variation across reports and facilities, however, in the depth of answers submitted. The thoroughness and credibility of the reports are measured by other certification questions.

- *Assessment: Excellent level of completeness as defined by all report form sections fully answered*
- *Recommendations: Continue to expect all reports to be complete*
- *Anticipated Progress: Maintain level of completeness*

Adverse Event Description:

The event description is an integral part of the adverse event report. It 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. 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.

Most event descriptions were found to meet (25.4%) or at least partially meet (58.2%) the certification criteria (Fig. 3). The remaining reports (16.4%) did not meet the event description criterion, which means there were more than three unclear issues in the description. The quality could improve by answering the basic questions of who, what, where, when and how of the event.

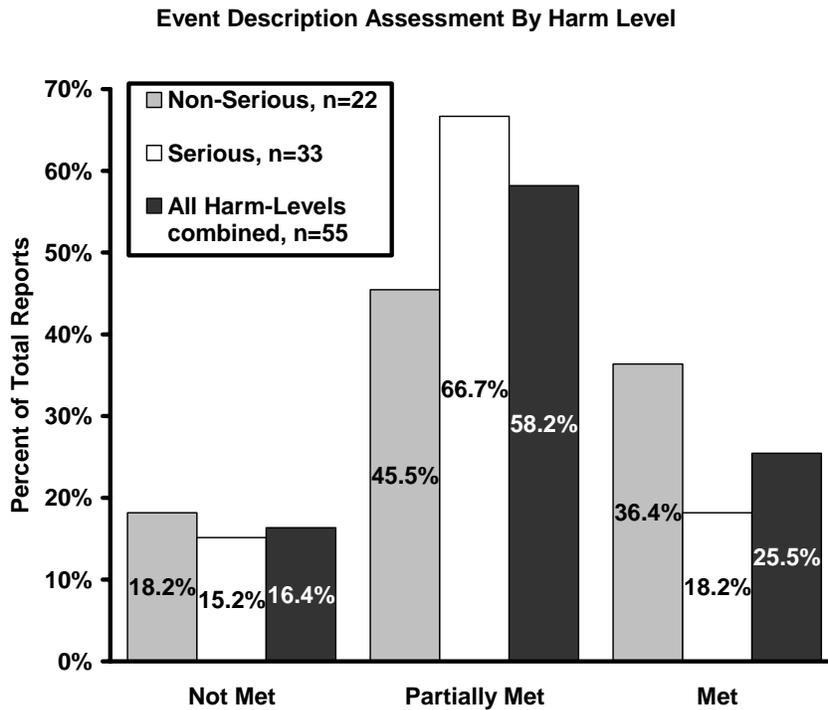


Figure 3 Event Description.

There were some differences in quality of event description between the serious and non-serious events (Fig. 3). With relatively low numbers, it is important to remember that none of these differences were tested for statistical significance. While the proportion of non-met was similar, serious events showed a lower amount of met compared to non-serious events, 18.2% vs. 36.4% respectively. This may be due to the difficulty of clearly and completely summarizing more complex serious adverse events.

The Patient Safety Commission and Hospitals are in the learning phase of adverse event reporting. As hospitals become familiar with the reporting process and the Commission revises the reporting form to get optimal results, we would anticipate more reports to fully meet the event description criteria.

- *Assessment: Acceptable quality of event description: 25.5% of the reports met Certification criteria, while 58.2% were found to partially meet and 16.4% did not meet the criteria for an acceptable event description*
- *Recommendations: Revise event description question in the Commission report form, provide training or guidelines for participants, set expectations with feedback about quality from the Commission report review tool assessment and continue to provide support to hospital participants*
- *Anticipated Progress: Increase the proportion of event descriptions in the “met” category for all harm levels to above 50%*

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 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 certification elements (Appendix A) in the event analysis section. 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 4 shows the proportion of reports in each category.

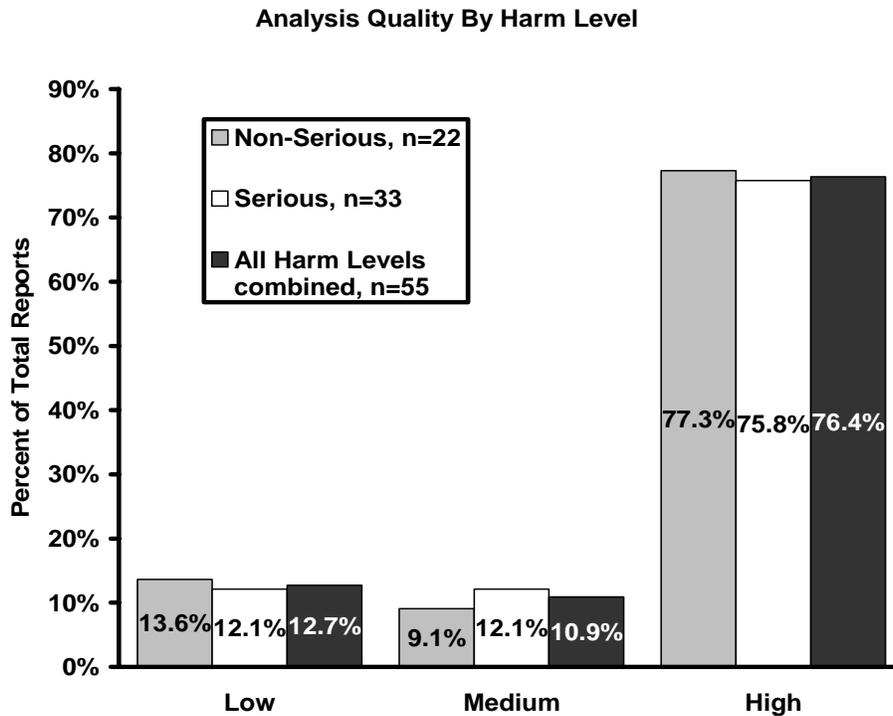


Figure 4 Analysis Harm Level.

Overall, the analysis quality was very good with over three quarters (76.4%) in the high quality category (Fig. 4). There was little difference seen in analysis quality between serious and non-serious events.

Hospitals were successful at focusing on systems issues that contributed to the adverse event in about 87% of the reports and somewhat less so in identifying the contributing factors most directly associated with the event (76% reports met fully). The serious adverse event reports were found to have good participation of senior management and personnel with relevant expertise in the investigation with about 88% for both. Internal consistency of the analysis was scored as met, partially met or not met. Submitted reports showed over a third completely met and about half were partially met, while 12% had more than 3 inconsistencies and therefore did not meet the criteria.

The analysis quality is strong for the first year and shows that hospitals are making a good faith effort to understand their adverse events. 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 prevention. We would expect the proportion of lower quality reports to move into the higher categories in the next year.

- *Assessment: Acceptable analysis quality: 76.4% of the reports were found to be high quality, while 12.1% were in the medium quality category and 12.7% were determined to have a low quality for adverse event analysis*
- *Recommendations: Provide training or guidelines for participants, set expectations with feedback about quality from the Commission report review tool assessment and continue to provide support to hospital participants*
- *Anticipated Progress: Increase the proportion of reports with high quality adverse event analysis to above 90%*

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 and include the estimated start and end dates for each. The Certification tool (Appendix A) assesses all reports with questions about addressing the identified root cause and about the specificity and clarity of the action plans. Serious adverse event reports must answer an additional question regarding 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.

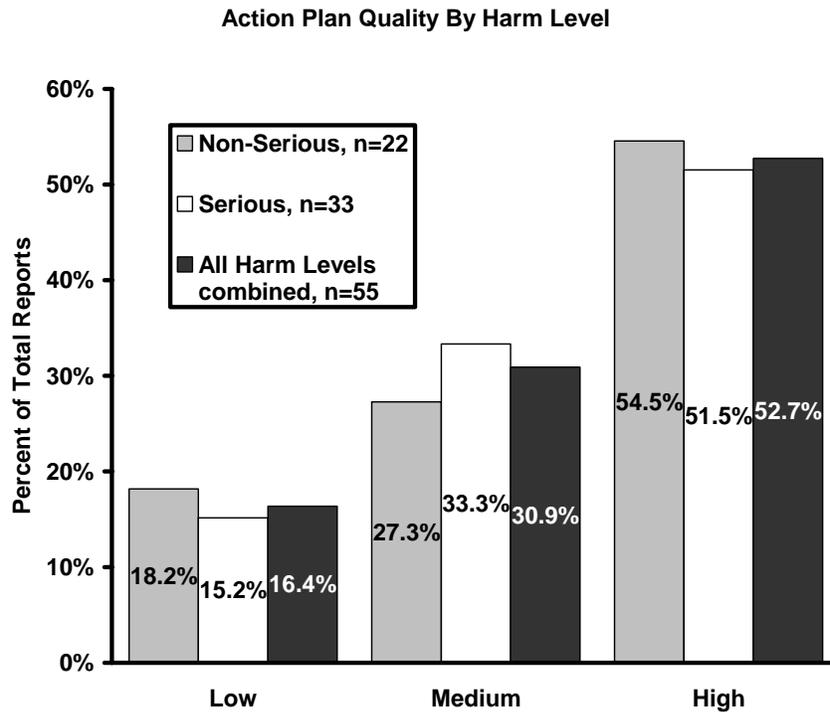


Figure 5 Action Plan Quality.

The action plan quality was good with over half (52.7%) in the high quality category, 30.9% of medium quality and 16.4% low quality (Fig. 5). Designing system level action plans may be a new activity for some hospitals, which might explain the relatively lower quality as compared to analysis quality. Furthermore, the Commission reporting form may be structured to allow clearer reporting of analysis vs. action plan summaries. Again, there was little difference seen in action plan quality between serious and non-serious events (Fig. 5).

Hospitals appear to have made a good start toward developing and reporting preventive action plans in 2006. The next crucial step will be to implement and adjust the action plans as necessary to reduce similar events in the future. We would expect a shift in the quality levels in this area to the higher categories for 2007.

- *Assessment: Acceptable action plan quality: 52.7% of the reports were found to be high quality, while 33.3% were in the medium quality category and 16.4% were determined to be low quality for action plan development*
- *Recommendations: Consider report form question revision, provide training or guidelines for participants, set expectations with feedback about quality from the Commission report review tool assessment and continue to provide support to hospital participants*
- *Anticipated Progress: Increase proportion of action plans in high quality category to 75%*

Total Report Quality

The total report quality combines the completeness, event description, analysis and action plan scores and is reported here for serious and non-serious adverse events separately and combined (Fig. 6). 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.

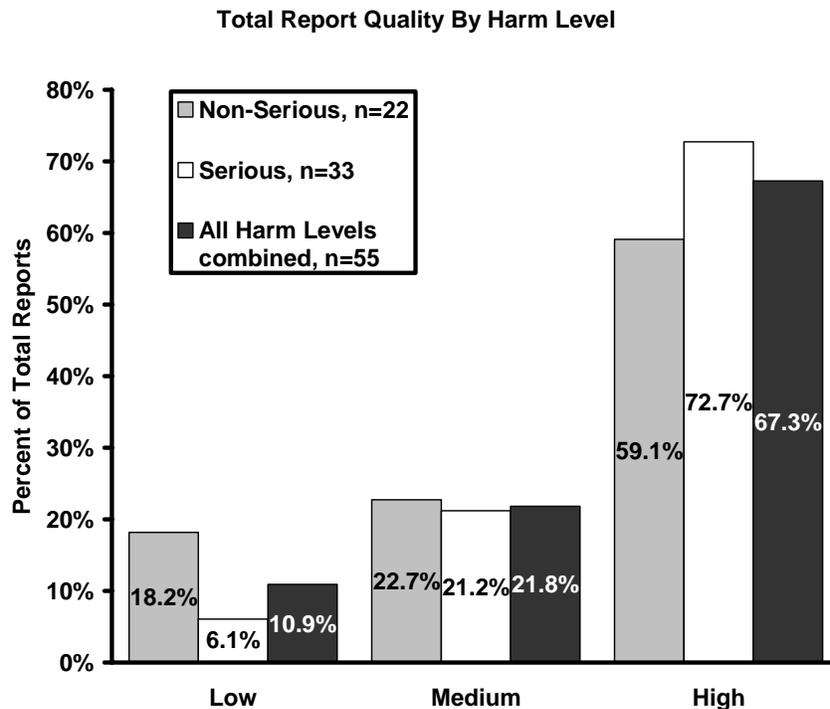


Figure 6 Total Adverse Event Report Quality.

Two thirds of the submitted reports showed a high total quality and another 22% were rated at medium quality (Fig. 6). Only about 11% resulted in low total report quality rating, which means that these reports did not meet many of the certification criteria. When separated by severity, it seems that hospitals may be better at reporting about serious adverse events with almost three quarters of the reports assessed as high quality (Fig. 6). This is perhaps due to increased effort put into investigating serious events. Alternatively, it may also be influenced by the differences in the Commission reporting form and the specific certification questions for serious vs. non-serious adverse events.

By and large, hospitals have done a reasonably good job in submitting high quality reports to the Commission. It is to be expected at this developmental stage that some facilities are still learning how to effectively investigate adverse events and subsequently precisely and effectively share that information with the Patient Safety Commission. 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, we would anticipate that all hospitals would submit reports in the high quality category.

- *Assessment: Good total report quality: 67.3% of the reports were found to be high quality, while 21.8% were in the medium quality category and 10.9% were determined to have a low total report quality*
- *Recommendations: Provide training or guidelines to complete Commission report form, share feedback to hospitals about their report quality as determined by Commission report review tool, consider clarification reporting form questions where applicable, set expectations for hospitals*
- *Anticipated Progress: Increase the percentage of total report quality to 80% 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.

Table 1: Events Reported by Hospital Size

Size	# Hospitals in Program	# Hospitals filing at least one report	Total # Reports filed
Small (0-3000 Discharges)	26	10	21 (38%)
Medium (3001-10,000 Discharges)	14	8	11 (20%)
Large (Over 10,000 Discharges)	12	11	23 (42%)
TOTAL	52	28	55 (100%)

In 2006 (May 1-Dec. 31) the Patient Safety Commission received a total of 55 adverse event reports from 28 of 52 participating hospitals (Table 1). Eleven of these reports were retrospective, which means they occurred before May 1, 2006. Of these 55 reports, 33 were serious adverse events and 22 were less than serious events as defined in the harm-level scale (Fig. 2). Of the 55 reports, 47 were from the Commission's list of reportable adverse events and the remaining 8 reports were optional reports. An optional report is not a serious adverse event nor is it on the list of reportable adverse events, but instead it is a preventable adverse event that can be shared with and benefit other hospitals in their prevention efforts. About 54% of the participating hospitals submitted at least one report (Table 1) and they represent about 74% of the annual statewide discharges.

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* report⁹. This translates roughly to a range of 932 to 1837 potentially preventable deaths of Oregonians care 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^{10,11}. 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 setting¹². 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 Tool¹³. 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

⁹ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

¹⁰ McDonald, J. et al. Deaths Due to Medical Errors Exaggerated in Institute of Medicine Report. *JAMA*. 2000;284:93-5.

¹¹ 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.

¹² 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.

¹³ 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.

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 admissions¹⁴.

The Pennsylvania Patient Safety Authority represents one of the more established state-level reporting programs. It is important to note that 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)¹⁵. They received reports of 6,937 serious events (and 188,895 incidents) from 464 hospitals, ambulatory surgery centers and birthing centers in 2006. Using this rate of 0.004 events per hospital discharge, (2004 PA hospital discharge numbers) Oregon would have approx. 1400 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.

Oregon's Patient Safety Reporting Program for hospitals 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 point¹⁶. 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 Indiana²⁰ have released annual reports describing their results (Table 2). It is crucial to understand that there are limitations to the applicability of such a comparison for the following reasons:

¹⁴ 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.

¹⁵ Pennsylvania Patient Safety Authority 2006 Annual Report. http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2006.pdf. accessed on March 31, 2007.

¹⁶ National Quality Forum. *Serious Reportable Events in Healthcare: A Consensus Report*. Washington, DC: National Quality Forum; 2002.

¹⁷ Minnesota Department of Health. *Adverse Events in Minnesota: Third Annual Public Report* January 2007. Available at <http://www.health.state.mn.us/patientsafety/ae/aereport0107.pdf>. Accessed on March 15, 2007.

¹⁸ Connecticut Department of Public Health. *Legislative Report to the General Assembly: Adverse Event Reporting*, October 2006. http://www.dph.state.ct.us/hcquality/Quality/General_Assembly_Annual_Report_June_2006.pdf. Accessed on January 20, 2007.

¹⁹ 23 New Jersey Department of Health and Senior Services. *Patient Safety Initiative 2005 Summary Report*. Available at http://www.state.nj.us/health/ps/documents/2005_summary_report.pdf. Accessed on January 20, 2007.

²⁰ Indiana State Department of Health. *Indiana Medical Error Reporting System: Preliminary Report for 2006*. Available at <http://www.in.gov/isdh/regsvcs/mers/pdf/FinalMedicalErrorPreliminaryReportFor2006-March-6-2007.pdf>. Accessed on March 8, 2007.

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 and New Jersey publicly report adverse events only in the aggregate for all hospitals, while Minnesota and Indiana disclose events at the facility level in their annual reports. Both Indiana and Oregon are in their first year of reporting, whereas 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, Indiana and Connecticut all have electronic reporting systems, which may contribute somewhat to ease of reporting. New Jersey and Oregon are in the process of developing their electronic reporting systems. Oregon, New Jersey and Minnesota require hospitals to submit an event description, root cause analysis and action plans. Indiana's hospitals submit only a notice of which event type occurred and where and 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.

Table 2: Selected Other States - Adverse Event Numbers from hospitals only

State, Original Implementation Date	Number of Events, timeframe, year	Confidentiality	Definition of Reportable Events	Events/10,000 patients discharged annualized *	Non-reporting hospitals
Minnesota, 2003	154 / 12 months, 2005/2006	Public reporting at facility level	NQF definitions verbatim	2.6**	70.8%
Indiana, 2006	72 / 12 months, 2006	Public reporting at facility level	NQF definitions verbatim	0.98 [#]	74.1%
Connecticut, 2004	211, 12 months, 2005/2006	Public reporting in aggregate only	NQF with additions	6.7 [#]	Not available
New Jersey, 2005	376 / 11 months, 2005	Public reporting in aggregate only	NQF with additions and exclusions	3.6	~15%
Oregon, 2006	44 / 8 months, 2006 [#]	Public reporting in aggregate only	NQF with additions and exclusions	1.8	46%

* Total number of reports was adjusted for 12 months, ** Discharge numbers do not include Mayo Clinic, which has several hospitals, [#] Discharges do not include normal newborns, ^{##} includes only prospective reports

Even with consideration of the program variations, total reports in Oregon are within the range of what is being seen in other similar state reporting programs. The calculated rates are fairly rough but they do help to gain a ballpark perspective on similar reporting structures being pursued in other states. The proportion of non-reporting hospitals (hospitals that have not submitted any adverse event reports to the program) in Oregon (46%) is lower than at least two other states. All other selected states have mandatory reporting systems. In Oregon, after hospitals have signed the voluntary participation contract, they 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 the most recent year²¹. 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 better awareness of patient safety in the 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. Only with solid information and improved dissemination of lessons learned can we hope to see the real frontline reduction of adverse events and patient harm.

We accept that focusing solely on the absolute number of events reported may be limiting in addressing the improvement of patient safety. However, it is critical to understand that robust reporting can build public confidence in hospitals' ability to detect, analyze and prevent serious adverse events. Furthermore, 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 at the lower end but within the wide 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 we do not currently have a clear expected rate of serious adverse events as defined in Oregon, we do have estimated ranges from the literature^{23,24,25} to consider. The Public Health Officer Certification finds that the total

²¹ Minnesota Department of Health. *Adverse Events in Minnesota: Third Annual Public Report January 2007*. Available at <http://www.health.state.mn.us/patientsafety/ae/aereport0107.pdf>. Accessed on March 15, 2007.

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

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.

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, we would anticipate a gradual increase in reporting and a decrease in the number of non-reporting hospitals in Oregon. Although participation in the reporting program is voluntary, each participant has agreed to fully communicate all reportable serious adverse events to the Commission.

- *Assessment: Total number of submitted reports from all hospitals combined is currently too low. The proportion of non-reporting hospitals is too high*
- *Recommendations: 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, keep the administrative burden low, pursue electronic web-based reporting option, set clear expectations 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 20%, All hospitals submitting some reports, even in lower harm level optional category if appropriate*

II. 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-two of Oregon's 57 acute care hospitals joined the program in 2006, representing 98.2% of total annual discharges. The distribution of participation by hospital size is 100%, 93%, and 87% for large, medium and small facilities respectively (see Table 3). These numbers symbolize impressive work on the part of the Commission and an initial willingness of hospitals to share adverse event data at a safe table and learn from the aggregate summaries.

²⁵ Commonwealth of Pennsylvania, Patient Safety Authority. *2006 Annual Report*. Available at http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2006.pdf. accessed on March 31, 2007.

Table 3: 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%	26 (87%)	10.2%
Medium 3001-10,000 Discharges	15	24.8%	14 (93%)	23.8%
Large over 10,000 Discharges	12	64.2%	12 (100%)	64.2%
Totals	57	100%	52 (91%)	98.2%

- *Assessment: Excellent hospital enrollment rates for the first year of a voluntary program*
- *Recommendations: Maintain enrollment for the second year by continuing to show value added for hospitals and work to convert the non-reporting enrolled hospitals to true reporting participants*
- *Anticipated Progress: Enrollment maintenance – hold the gains*

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).

Overall, the Commission adverse event reporting template appears to generally support clarity and ease of use. However, after reviewing the template, we recommend clarifying the definitions of reportable and serious adverse events and serious physical injury. The reporting program may also benefit from brief written guidelines or an annotated report form that explains the expectations when filling out the form. As a supplement, the Commission could also provide some sample reports for participants.

The quality results of the event description question may indicate that some facilities are unclear how much detail to include. The report form is intended to be a summary of a comprehensive root cause analysis and should prompt hospitals to give a clear and concise review. We recommend a reminder in the question or the guidelines to include basics such as what event happened, who was involved, when did events occur, how did they come about and how were they handled. Further, the guidelines should set clear expectations for the root cause analysis or investigation of the event. This could also be done through some sample reports. We also recommend that the Commission consider including a question about the strategy to share the

learning throughout the hospital and across department boundaries where appropriate. It may also be helpful for reporters to identify key learning for other facilities.

In the course of the certification, we looked to reporting templates from other states and identified some elements that may be useful in working to reduce adverse events:

- Include an option to submit the original root cause analysis or diagram
- Ask for outpatient/inpatient status in the patient demographics section
- Clarify the question about corrective action for the less serious events; ensure that reporters are providing corrective action plans that are the result of a formal investigation in addition to immediate action as a result of an event.
- Offer an option for an amendment report (may become more relevant as transition issues between other facility types arise)
- Add a question about other entities that have received notice of the event
- Add “ambulatory surgery/day surgery unit” to the possible locations where the event occurred

The reporting form collects information such as contributing factors and action plans, which is widely viewed as useful for improvement of patient safety on an individual case basis and also in aggregate analyses. The template also allows a reviewer to determine acceptability of the patient safety work done by the hospital. The PHO Certification review would benefit, however, from more clarity and detail in the event description and also action plans. It is difficult to establish reports as thorough and credible if crucial summary details are missing.

- *Assessment: The adverse event reporting tool is generally clear and collects relevant 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: Clarify the definition of reportable and serious adverse events and serious physical injury, provide written guidelines or an annotated report form with set expectations of detail required in answering questions, provide sample reports for participants and consider including additional questions if deemed appropriate*
- *Anticipated Progress: A reporting template that enables hospitals to understand the Commission’s expectations and fulfill them with reasonably low administrative burden*

Implementation of Reporting Program

Reporting program implementation means many things in the course of assessment. The certification asks about timely support for program participants in completing the adverse event report form and adequate feedback to hospitals during the report submission process (Appendix B). Robust communication with participants is considered to be an important part of program integrity. During the rollout period, the field coordinator contacted each hospital to explain how the reporting form works and answered any questions.

Commission staff are required to contact hospitals within 10 business days of the receipt of the event report if they believe that a report is incomplete or unacceptable. According to information submitted by staff, this requirement has been consistently followed. 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. The field coordinator is always available by email and phone for questions from the participants.

The Commission has made a good start toward implementation of the adverse event reporting through open communication with hospital participants. In response to feedback from hospitals, the reporting tool has been revised for 2007 to better suit the needs of hospitals as well as the Commission. As both parties were in the initial developmental stages in 2006, we might assume that experience will contribute to increased and more comfortable use of the reporting tool. In the future, however, the implementation may benefit from a formal orientation, more frequent communication with the hospitals and brief feedback about the assessed report quality for each submission.

- *Assessment: Commission has made good progress in implementation of the reporting program. The staff has communicated with hospitals and requested and acted upon their feedback regarding the report form. They have assisted personnel from hospitals in filling out the forms and done so in a timely manner*
- *Recommendations: Consider designing a more formal orientation for first time reporters, which could be written guidelines or in-person brief seminar style training. Some facilities may benefit from reviewing root cause analysis training. Staff should understand the need for training and find ways to offer an effective orientation*
- *Anticipated Progress: The Commission will continue to assess the needs of hospital participants and find ways to assist facilities*

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 B).

In the first year Commission staff collected reports and determined basic acceptability criteria. Reports were revised and improved by hospitals until they were deemed “acceptable”. Toward the end of 2006 the Commission designed a more formal report review tool to determine complete, thorough, credible and acceptable for each report. The new tool was implemented beginning in 2007. We recommend regular sharing of the review scores with hospitals to improve the quality of the data submitted.

Similarly, an expert review and analysis strategy was developed in late 2006 and has taken the form of a Technical Advisory Committee (TAC). As the absolute numbers and depth of reporting increase, it is more plausible to address the all-important work of improving patient safety through focused quality improvement projects. The results and learning can be shared with all Oregon hospitals. The Committee examines individual reports as well as aggregated information to achieve its goals. The activities of this group are poised to make a significant contribution to supporting hospitals in their patient safety efforts.

The annual Commission follow-up with hospitals regarding their proposed action plans for prevention of recurrence will be essential. At this time, the follow-up data are not yet available. The PHO will look at this activity in the next annual certification.

- *Assessment: The internal review process for submitted reports was improved and formalized the end of 2006 and has been implemented for the 2007 reports. This will allow Commission to provide feedback to hospitals about the quality of their reports relative to a clear standard*
- *Recommendations: Consistent use of the review tool to determine the acceptability of each report and regular sharing of the results with hospitals*
- *Anticipated Progress: Commission staff will continue review the report quality and facilitate improvement where necessary The annual action plan follow up will provide staff with an opportunity to revisit proposed improvements*

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. The level of diffusion of tools and ideas is a measure of overall program integrity.

In 2006 the Commission implemented a number of communication tools to explore and share best practices and assist hospitals with reducing harm from adverse events. There were two safety alerts sent out electronically which were rated highly by hospitals for quality and relevance. Patient Safety Tips and answering individual email inquiries were also used to get the word out. Furthermore, the Commission hosted teleconferences for small and rural hospitals about Rapid Response Teams and Medication Reconciliation. In October 2006 thirty-five hospitals gathered for a day-long discussion about strategies to implement the statutory requirement of written notification to patients and families following a serious adverse event. This conference is an example of attempting to develop best practices and share ideas. In late 2006, the Commission was approached by a member hospital about guidance on use of colored wristbands to quickly identify patients' conditions and other pre-determined orders. Staff swiftly produced a report and the Commission made recommendations for a single statewide standard in January 2007. Demonstrating their partnership, the Oregon Association of Hospitals and Health Systems has taken the challenge of implementing of these recommendations. Finally, the Commission website is a well-maintained information source.

It is the assessment of the PHO that the Commission has made a excellent start with limited resources in communicating with participants and the broader health care community. With the passage of stable funding legislation in 2007, there will be more possibilities for staff to build on progress.

- *Assessment: Very good work with limited resources in a start-up year*
- *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: The Commission will 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 is 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 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).

There were 25 events that required written disclosure in 2006. In 17 (68%) of the cases hospitals sent letters to patients and family as part of the disclosure process. Of the eight (32%) that did not complete written notification, two were pending at the time of this report, three were not sent due to long period between event and investigation, one was unable to locate an appropriate recipient and two gave no explanation.

The concept of disclosure regarding adverse events in writing is a relatively new and unfamiliar one for health care providers and patients alike. There is also 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 PHO Certification will continue to expect 100% written notification for each serious adverse event, while accepting that there may be rare exceptions. We recommend that the Commission

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.

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 is acceptable for the first year considering the stage of development of the program*
- *Recommendations: Continue to help hospitals address the barriers and provide a clear vision of the patient-centered foundation of the written notification*
- *Anticipated Progress: 100% written notification for each serious adverse event*

Conclusions

The Patient Safety Commission has achieved an important milestone toward fulfilling their mission by establishing the Patient Safety Reporting Program for hospitals in 2006. The program plays a key role in reducing the harm from serious adverse events in Oregon. The program is demonstrating good overall integrity as seen in the strong design and implementation of the reporting program. The Public Health Officer finds that quality of hospital reporting at this early stage is good while the absolute quantity of reports is too low. Success of the Patient Safety Reporting Program will be the result of collaborative efforts of the Commission and hospitals as well as all future reporting health care facilities. The Public Health Officer looks forward to following the progress of the Commission's Reporting Programs in the coming years.

We recognize that the Commission is in an early phase of operation and will need time and resources to fully develop all aspects of the reporting program. In addition, the hospitals are also in a learning phase as they build up their internal patient safety programs and systems for identifying adverse events. The Public Health Officer understands that a strong reporting program able to use the collected patient safety data effectively to support real measurable change will require the continued collaboration of the Commission and hospitals.

The future success of the Patient Safety Reporting Program for hospitals will be built on the strong partnership between the Commission and hospitals. They have shown that they are willing to voluntarily enroll in the program, which indicates an impressive commitment to improving patient safety for Oregonians. However, the reduction of adverse events will require more than enrollment. It will likely involve the continual review of patient safety systems to identify adverse events and to efficiently and effectively share the data, both internally across departments and externally to the Commission reporting program. Hospitals can learn about strategies for safer systems for the benefit of all patients in Oregon. The program needs more than the good work of the Commission, it will also involve hospitals' commitment to participate and engage in collective quality improvement.

We believe that 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 have assessed the status, offered recommendations and anticipated progress for the coming year. In the second year we will note the progress and adopt some standards for the third year. After the third year, the Public Health Officer will officially certify the reporting program using objective standards.

Public Health Officer Certification Results – Summary

The assessment of the Patient Safety Reporting Program takes into account the developmental stages of both the program and the reporting hospitals. The first year of the certification is mainly intended to determine the current status although we do make initial statements about acceptability of the broad areas of hospital reporting and overall integrity of the program.

Recommendations are made with consideration of the current status and early phase of implementation. We begin by setting reasonable expectations of progress for the next year. They represent our best estimate of possible improvement. The advancement will be revisited after the second year in order to set some minimum standards for the third year.

I. Hospital Reporting Assessment

Quality:

- Assessment: The PHO Certification finds that the total report quality is good. The certification rated the total quality as high in about two-thirds (67.3%) of the submitted reports, as medium in 21.2% of reports and low for 10.9% of the reports. The quality for adverse event investigation was generally higher than for event description and action plan development.
- Recommendations:
 - Provide training or guidelines to complete Commission report form
 - Share feedback to hospitals about their report quality as determined by Commission report review tool
 - Consider clarification of reporting form questions where applicable
 - Set clear expectations for hospitals regarding acceptability of adverse event reports
 - Revise event description question in the Commission report form
 - Continue to provide support to hospital participants for completing the adverse event reports
- Anticipated Progress:
 - Increase the percentage of total report quality to 80% in the high quality category
 - Maintain level of completeness
 - Increase the proportion of event descriptions in the “met” category for all harm levels to above 50%
 - Increase the proportion of reports with high quality adverse event analysis to above 90%
 - Increase proportion of action plans in high quality category to 75%

Quantity:

- Assessment: The Public Health Officer Certification finds that the total number of submitted reports in Oregon to be within the wide range observed in similar although

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 states with comparable reportable adverse event definitions. Although reporting levels in Oregon are within the range of that seen in similar state programs, this should not be regarded as the 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^{30,31,32}. The broad consideration of other estimates from the Institute of Medicine report, Institute for Healthcare Improvement trigger tools and the Pennsylvania data leads us to believe that there are more reportable serious adverse events to be identified and reported by Oregon hospitals. As the program matures and participants gain confidence, we anticipate a higher volume of reporting.

- Recommendations:
 - 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
 - Pursue electronic web-based reporting option
 - Support hospitals in efforts to improve identification of reportable adverse events
 - Set clear expectations 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 20%
 - All hospitals submitting some reports, even in lower harm level optional category if appropriate

II. Overall Integrity of the Patient Safety Reporting Program

The PHO Certification looked beyond reporting quality and quantity to other activities that contribute to the integrity of the reporting program as a whole. The certification elements included hospital participation rates, reporting tool design and implementation, report review process, action plan follow-up, learning and best practice dissemination and rates of written notification. We found that the Oregon Patient Safety Commission is demonstrating good overall

³⁰ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

³¹ 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.

³² Commonwealth of Pennsylvania, Patient Safety Authority. *2006 Annual Report*. Available at http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2006.pdf. accessed on March 31, 2007.

integrity in their endeavors to create and put into practice a statewide adverse event reporting system.

- **Assessment:**
 - Excellent hospital enrollment rates for the first year of a voluntary program
 - The adverse event reporting tool is generally clear and collects relevant information about contributing factors and action plan strategies
 - Commission has made good progress in implementation of the reporting program. The staff has communicated with hospitals and requested and acted upon their feedback regarding the report form. They have assisted personnel from hospitals in filling out the forms and done so in a timely manner
 - The internal review process for submitted reports was improved and formalized the end of 2006 and has been implemented for the 2007 reports. This will allow Commission to provide feedback to hospitals about the quality of their reports relative to a clear standard
 - Good dissemination of learning with limited resources in a start-up year
 - The rate of completed written notification to the patients and families is less than 100% for the first year, which may be expected considering the stage of development of the program and complexity of fulfilling this aspect of the program

- **Recommendations:**
 - Maintain enrollment for the second year by continuing to show value added for hospitals and work to convert the non-reporting enrolled hospitals to true reporting participants
 - Clarify the definition of reportable and serious adverse events and serious physical injury, provide written guidelines or an annotated report form with set expectations of detail required in answering questions, provide sample reports for participants and consider including additional questions if deemed appropriate
 - Consider designing a more formal orientation for first time reporters, which could be written guidelines or in-person brief seminar style training. Some facilities may benefit from reviewing root cause analysis training
 - Consistent use of the review tool to determine the acceptability of each report and regular sharing of the results with hospitals
 - 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)
 - Continue to help hospitals address the barriers and provide a clear vision of the patient-centered foundation of the written notification

- **Anticipated Progress:**
 - Enrollment maintenance – hold the gains
 - A reporting template that enables hospitals to understand the Commission's expectations and fulfill them with reasonably low administrative burden
 - The Commission will continue to assess the needs of hospital participants and find ways to assist facilities

- Commission staff will review the report quality and request improvements where necessary. We also anticipate the annual action plan follow up to take place and be used as an opportunity to revisit proposed improvements
 - The Commission will maintain the close connections to participants to best understand how to provide value-added information and activities
 - 100% compliance with the written notification to patients
-
-

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 actions³³.

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 failure³⁴.

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)³⁵.

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 non-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.

Non-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.

³³ 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.

³⁴ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

³⁵ 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 occur³⁶.

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 objective 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).

³⁶ Kohn LT, Corrigan JM, Donaldson, MS, eds. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.

- 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 recurrence³⁷.

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)

³⁷ 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.

Appendix A

Oregon Patient Safety Reporting Program for Hospitals Public Health Officer Certification Tool 2006

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
 - 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 (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/individual-level action plans
 - Are action plans specific and concrete?
 - Percentage of reports met/partially met/not met (met: all action plans have implementation plans and timelines, partially met: some action plans with implementation details and timelines, not met: no mention of implementation plans or timelines)

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)
 - Are action plans specific and concrete?
 - Percentage of reports met/partially met/not met (met: all action plans have implementation plans and timelines, partially met: some action plans with implementation details and timelines, not met: no mention of implementation plans or timelines)
- 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

Appendix B Hospital Adverse Event Reporting Form 2006



Serious Adverse Events

Please report all **Serious Adverse Events** and the results of your investigation into the event to the Oregon Patient Safety Commission within 45 days of discovery. If you believe the situation requires an immediate alert to Oregon hospitals, please provide an initial report within 3 business days of discovery. The full report would follow within 45 days.

A definition of Serious Adverse Event is found in administrative rule OAR 325-325-010-0001 (8). Briefly, a Serious Adverse Event is an unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury. Such events are typically unrelated to the natural course of the patient's illness or underlying condition. Please be sure to include

- Events that result in either temporary or permanent harm, if that harm is serious or
- Healthcare-acquired infections that result in patient death or serious harm

We invite participating organizations to report ***Other Adverse Events***, including close calls. Please do so if you believe other organizations can benefit from your experience. For these less serious events you only need to complete the first section of the reporting form. Please report the events within 45 days of discovery.

Directions for completing the form: The reporting form is a MS Word document that we have formatted to allow for easy input of data. You may click on shaded fields or move through the fields using the tab key or up and down arrow keys. For questions regarding reporting or use of the form, please call Leslie N. Ray at the Oregon Patient Safety Commission. Telephone: 503/224-9227.



Hospital _____

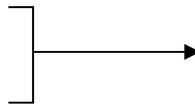
Serious Adverse Event Reporting Form

PART 1

Level of Patient Harm

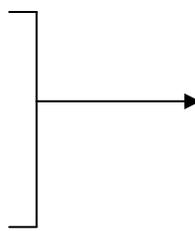
(Check one box only)

- 9. Death
- 8. Serious-Permanent Harm
- 7. Serious-Temporary Harm



**Serious Adverse
Event: Please complete
PARTS 1-2.**

- 6. Moderate-Permanent Harm
- 5. Moderate-Temporary Harm
- 4. Minimal-Permanent Harm
- 3. Minimal-Temporary Harm
- 2. No Detectable Harm
- 1. Did not reach the patient



Other Adverse Event:
Please complete **PART**
1 only

Event Descriptors

Please provide a complete description of the event:

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

Medication	<input type="checkbox"/>	Equipment/Product/Device	<input type="checkbox"/>	Fall	<input type="checkbox"/>
Surgical procedure	<input type="checkbox"/>	Maternal/Neonatal	<input type="checkbox"/>	Spinal Manipulation	<input type="checkbox"/>
Nosocomial infection	<input type="checkbox"/>	Environmental	<input type="checkbox"/>	Hypoglycemia	<input type="checkbox"/>
Patient Protection	<input type="checkbox"/>	Skin integrity	<input type="checkbox"/>	Hemolytic reaction	<input type="checkbox"/>
Restraint	<input type="checkbox"/>	Other (please describe)			

Where did the event occur?

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

Patient Demographic Descriptors:

Sex		Admission Date	YYYY	MM	DD
Age		Date of event	YYYY	MM	DD
Ethnicity		Time of Event	Hour	[24hr clock]	Min
Race (Check all that apply)	American Indian or Alaska Native	<input type="checkbox"/>	Native Hawaiian or Other Pacific Islander		<input type="checkbox"/>
	Asian	<input type="checkbox"/>	White		<input type="checkbox"/>
	Black or African American	<input type="checkbox"/>	Other		<input type="checkbox"/>

Date reported to Quality Management:

YYYY	MM	DD
------	----	----

Role/position of person who discovered the event?

Other Adverse Event: (If reporting a Serious Adverse Event, skip to PART 2.)

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

What corrective actions did your organization take?

PART 2

Serious Adverse Event Notification & Review

Was senior management notified of this event?

Yes No Unsure

Was the Board of Directors made aware of this event?

Yes No Unsure

Has your organization given written notification of the event to the patient or personal representative?

Yes No Unsure

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

Physician(s)	<input type="checkbox"/>	Nursing Management	<input type="checkbox"/>
Nursing staff	<input type="checkbox"/>	Pharmacist(s)	<input type="checkbox"/>
Quality Management	<input type="checkbox"/>	Engineering staff	<input type="checkbox"/>
Risk Management	<input type="checkbox"/>	Other (please describe)	

Date review and analysis completed:

YYYY MM DD

What difficulties or barriers, if any, did you encounter in conducting the review?

Did the Review Team have a post-analysis briefing with senior management?

Yes No Unsure

Approximately how many person-hours* were directly spent on this Review and Analysis?

(*for example, 2 people working 30 minutes each would be 1 person hour, 2 people working 2 hours each would be 4 person hours)

Serious Adverse Event Analysis

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

Please list any major co-morbidities:	Please list any relevant procedures:
---------------------------------------	--------------------------------------

Patient's discharge status:

Please help us understand the causes or contributing factors for the event you are reporting:

A. Did communications play a role in this event? Yes No Unsure

If yes, was this event related to...(check all that apply):

Sharing patient information in timely manner	<input type="checkbox"/>	Having appropriate information available when needed (e.g. lab results, medical chart)	<input type="checkbox"/>
Policies and procedures	<input type="checkbox"/>	Communication between patient/family and healthcare personnel	<input type="checkbox"/>
Communication between staff	<input type="checkbox"/>	Communication during hand-offs or shift reports	<input type="checkbox"/>
Other (please describe)			

B. Did patient management factors play a role in this event? Yes No Unsure

If yes, was this event related to...(check all that apply):

Identifying a patient	<input type="checkbox"/>	Delegation of clinical care	<input type="checkbox"/>
Patient consent process	<input type="checkbox"/>	Response to changing condition	<input type="checkbox"/>
Initial diagnosis	<input type="checkbox"/>	Tracking or follow-up	<input type="checkbox"/>
Care plan	<input type="checkbox"/>	Referral or consultation	<input type="checkbox"/>
Other (please describe)			

C. Did training or supervision play a role in this event? Yes No Unsure

If yes, was this event related to...(check all that apply):

Job Orientation	<input type="checkbox"/>	Special training	<input type="checkbox"/>
Competency demonstration	<input type="checkbox"/>	Continuing Education	<input type="checkbox"/>
In-service education	<input type="checkbox"/>	Supervision	<input type="checkbox"/>
Availability of training programs	<input type="checkbox"/>	Other (please describe)	

D. Did the physical work area play a role in this event? Yes No Unsure

If yes, was this event related to...(check all that apply):

Work area design and specifications	<input type="checkbox"/>	Work environment distractions (please list)
Other (please list)		

E. Did organizational factors play a role in this event? Yes No Unsure

If yes, was this event related to... (check all that apply):

Adequacy of budget	<input type="checkbox"/>	Staff selection	<input type="checkbox"/>
Systems to identify risks	<input type="checkbox"/>	Staffing levels	<input type="checkbox"/>
Internal reporting	<input type="checkbox"/>	Leadership	<input type="checkbox"/>
Overall culture of safety	<input type="checkbox"/>	Management skill level	<input type="checkbox"/>
Work Allocation/assignment	<input type="checkbox"/>	Other (please describe)	

F. Did problems with policies, procedures or rules play a role in this event? Yes No Unsure

If yes, was this event related to... (Check all that apply):

Too complicated	<input type="checkbox"/>	Absent	<input type="checkbox"/>
Inaccurate	<input type="checkbox"/>	Poorly presented	<input type="checkbox"/>
Unrealistic	<input type="checkbox"/>	Other (please list)	

G. Did any patient factors play a role in this event? Yes No Unsure

If yes, check all that apply...

Language	<input type="checkbox"/>	Mental Status	<input type="checkbox"/>
Culture	<input type="checkbox"/>	Family Dynamics/Relationships	<input type="checkbox"/>
Behavioral Problems	<input type="checkbox"/>	Other (please describe)	

H. Did equipment, software, products, or material defects play a role in this event? Yes No Unsure

(If yes) Please describe

I. Were there any additional factors that played a role in this event? Yes No Unsure

(If yes) Please describe

J. Were there any factors that helped reduce the seriousness or consequences of the event?

Yes No Unsure

(If yes) Please describe

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.
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.	