

Oregon Patient Safety Commission

Report to the Governor and Legislative Assembly
(As required by 182.472 and ORS 192.245)

January 10, 2005

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Executive Summary

The Oregon Patient Safety Commission is a new semi-independent state agency. It was created by the Legislature in 2003 and charged with “improving patient safety by reducing the risk of serious adverse events occurring in Oregon’s healthcare system and by encouraging a culture of patient safety in Oregon.” As a semi-independent agency, the Commission is accountable to the public. It has a mission that is clearly in the best interests of both the public and the healthcare industry. The National Academy for State Health Policy has cited Oregon and five other states as innovators in the field of patient safety for having created ‘patient safety centers.’

Medical errors and adverse events affect many people. The Institute of Medicine found that as many as 44,000 to 98,000 people die in hospitals each year as the result of such events. The Federal VA system believes that about 180,000 deaths occur each year in the United States from “errors in medical care” across all healthcare settings. Other studies place the number of deaths even higher. In addition to deaths many adverse events lead to serious, but non-fatal injuries. A recent survey of physicians and the public offers a different perspective, but with similar intent—35 percent of practicing physicians and 42 percent of the public have experienced a preventable medical error either personally or within their families. In Oregon, even with a healthcare system continually working to improve quality, more people probably die as the result of adverse events than from diabetes, Alzheimer’s disease, or pneumonia.

The Patient Safety Commission has a critical role in reducing medical errors. Medical errors represent a problem that can be addressed. Research findings consistently indicate that 50 to 70 percent of errors are preventable—if systems issues are identified and corrected.

The Patient Safety Commission offers new solutions. It is the only organization in Oregon with the sole function of reducing the number of adverse events in the state. Until now healthcare providers and organizations have not had a legally safe place to report or to share information about medical errors. The Commission is addressing this problem by creating a voluntary reporting program and by actively using the information it collects to change the healthcare industry. Ultimately the reporting program will cover hospitals, long-term care facilities, pharmacies, ambulatory surgical centers, outpatient renal dialysis facilities, freestanding birthing centers, and independent professional healthcare societies or associations. The Commission’s innovative legal protections offer a safe haven where errors can be reported, shared, discussed and fixed. The Commission will also establish quality improvement techniques to reduce systems’ errors and will share evidence-based prevention practices to improve patient outcomes.

The Patient Safety Commission is making rapid progress. As a new start-up organization the Commission has been faced with the immediate challenges of getting organized, securing funding, and building a reporting program. It held its first public meeting in March 2004 and met seven times in 2004. Its leadership team is in place.

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The Commission has successfully raised money to support its own operations. The Commission receives no state general fund dollars. To date, 18 organizations have contributed \$262,150 to support its public mission.

The Commission has initiated a pilot demonstration of its reporting program. Five hospitals have agreed to partner with the Commission in the pilot phase—OHSU Hospital, Providence Hood River Memorial Hospital, Rogue Valley Medical Center, St. Anthony Hospital, and Salem Hospital. The Commission has developed a draft list of objective and definable serious adverse events and will use the pilot to build reporting infrastructure and to test the ability of hospitals to gather such data.

The Commission has defined what success will look like. It expects that 50% of Oregon hospitals will be participating in the reporting program by June 2005. The Commission will issue its first summary report regarding hospital-based adverse events in September 2005. It will also co-sponsor a statewide conference on adverse event reporting and analysis by September 2005.

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Report to the Governor and Legislative Assembly

1. Introduction and Overview

At almost every public meeting of the Patient Safety Commission a citizen of Oregon will stand up and talk about things they often want to forget – a surgery that inadvertently left the patient injured; a baby that should have been saved, but wasn't; an infection that couldn't be controlled. These members of the public tell their stories haltingly; they tell their stories eloquently. These speakers don't fit any obvious pattern. They vary in age and economic status. They come from all over. Invariably these mothers and fathers, these grandmothers and sisters look at the Commission and say 'Do something.'

In talking about medical errors it is customary to quote from the 1999 study, *To Err is Human*, written by the Institute of Medicine. 44,000 to 98,000 people die in hospitals each year as the result of adverse events, says this report. Unfortunately such statistics suffer from overuse, are too abstract; they lose their ability to move us. But the voices of Oregonians from all walks of life have the capacity to reinvigorate those numbers. They offer a reminder that Oregon is not immune to these problems. In fact, applying the IOM findings to Oregon suggest that Oregon hospitals might experience between 10,000 and 13,000 adverse events a year. Of these, between 700 and 1,800 probably result in death. Survey data confirm the scope of the problem. One recently published survey reported that 35 percent of practicing physicians in the United States and 42 percent of the public have experienced a preventable medical error either personally or within their families.

Oregon's Response

The IOM made it very clear that medical errors represent a problem that can be addressed. Research findings consistently indicate that 50 to 70 percent of adverse events are preventable with current knowledge. Therefore, in response to the growing recognition that too many people suffer preventable injuries when in Oregon facilities, the Office of the Public Health Officer and the Office of Health Systems Planning brought together a workgroup in September 2002. The work group represented a broad spectrum of healthcare providers, insurers, purchasers and consumers. Initially guided by IOM recommendations they agreed to create the framework for a patient safety reporting system in Oregon.

The workgroup met more than ten times between September 2002 and April 2003. Its participants came to strongly agree that Oregon needed an organization such as the Patient Safety Commission. They expressed their agreement in the form of draft legislation that became the initial version of House Bill 2349. As an indicator of the consensus gained, all ten stakeholders became official 'requesters' of HB 2349. The bill won widespread bipartisan support in the Legislature and was approved in July 2003 (ORS 442.820).

2. Mission and Objectives of the Patient Safety Commission

By statute, the Patient Safety Commission is charged with “improving patient safety by reducing the risk of serious adverse events occurring in Oregon’s healthcare system and by encouraging a culture of patient safety in Oregon.”

In order to fulfill its mission, the Patient Safety Commission was given three interlocking objectives:

- establish a confidential, voluntary serious adverse event reporting system in Oregon;
- establish quality improvement techniques to reduce systems’ errors;
- share evidence-based prevention practices to improve patient outcomes.

The mission and the objectives of the Patient Safety Commission hang together via a few basic ideas. One is the *culture of patient safety*; another is the idea of *system improvement*. The culture of patient safety attempts to address basic attitudes about why errors occur and how best to deal with them. In the past, errors typically have been blamed on individual practitioners. However, the scientific evidence clearly indicates that many medical errors are systems related and not attributable to individual negligence or misconduct. As a result, the healthcare community is attempting to create a climate of patient safety that emphasizes non-punitive actions, collaboration, and system fixes. While personal responsibility will always be a cornerstone of competent care, the Commission’s focus is on improving systems, not on blaming individuals.

The Patient Safety Commission is the only organization in Oregon with the sole function of reducing the number of adverse events in the state. It will accomplish this task by creating a voluntary reporting program and then actively using the information to change the healthcare industry. The Commission seeks to create an environment where errors can be reported, shared, discussed and fixed. Currently hospitals and other healthcare organizations do not have any legally safe means to accomplish these goals. If the Patient Safety Commission is successful healthcare organizations will be able to learn from one another. If a bad outcome occurs at one place, it will be less likely to happen at another. With regard to patient safety the Commission seeks to create and to sustain “a state of intelligent and respectful wariness.”

Six types of organizations are eligible to participate in the reporting program: hospitals, long-term care facilities, pharmacies, ambulatory surgical centers, outpatient renal dialysis facilities, and freestanding birthing centers. In addition, the statute covers independent professional healthcare societies or associations so they might have a legally protected ability to discuss serious adverse events.

As a new start-up organization, the Patient Safety Commission has set itself the challenge of accomplishing three initial tasks in its first year of operation. We will discuss each in turn:

- Get organized
- Secure funding
- Build a reporting program

3. Organizational Structure

The Patient Safety Commission is a semi-independent state agency with a 17-member board of directors appointed by the Governor and confirmed by the Senate. This board reflects the diversity of facilities, providers, insurers, purchasers and consumers involved in patient safety.

The Senate confirmed the first round of appointees to the Board in January 2004. Current board members are: Sandra D. Douma, R.N., Andreas Goldner, PhD (vice-chair), Mr. David Hartwig, Judith H. Hibbard, Dr.P.H., Grant Higginson, M.D., M.P.H., Bruce C. Johnson, M.D., Susan King, R.N., M.S., Gloria Larson, R.N., M.B.A., Lewis McCoy, M.A., A. Roy Magnusson, M.D., George Miller, M.D. (chair), Andrew Picken, M.D., Glenn Rodriguez, M.D., Ms. Deandra Vallier, David L. Widen, R.Ph., M.B.A., and Maureen Wright, M.D. One position (private purchaser) is vacant.

In February 2004, Commissioners attended a 2-day orientation workshop (organized by Health Systems Planning and the Agency for Healthcare Research and Quality). In March, they held their first public meeting. Grant Higginson, the state Public Health Officer, chaired the first two Commission meetings. By the second meeting the Commission had established ground rules, approved bylaws, and elected a chair (George Miller, MD) and a vice chair (Andreas Goldner, PhD).

Because the Commission is a new organization with much work to do, it decided that it would hold public meetings every six weeks for the first year or longer. In 2004 the Commission held seven public meetings. In 2005 it has scheduled nine public meetings:

Patient Safety Commission–Public Meeting Schedule	
2004*	2005
March 30	January 18
May 11	March 1
June 22	April 12
August 3	May 24
September 14	July 12
October 26	August 23
December 7	October 4
	November 15
	December 20

* Minutes for all 2004 public meetings are available on the Commission’s website at:

<http://www.dhs.state.or.us/publichealth/hsp/patientsafety/commission.cfm>

In order to create a clear operational framework the Commission drafted a set of start-up principles. These principles speak to the Commission’s philosophy and to its desire for positive and consistent action over time.

The Patient Safety Commission's principles are:

- 1) The Commission has a sense of urgency about reducing harm to patients and improving quality of care in Oregon. The status quo is not acceptable.
- 2) The Commission represents an independent voice for patient safety. It will create a safe, non-punitive, and confidential haven for the collection and use of patient safety information where all representatives and users of the healthcare system can come together to work on shared goals.
- 3) The Commission aims to change the climate of patient safety in Oregon. Such change will require a long-term, sustained effort.
- 4) The Commission believes the patient and the patient's experience represent "true north" in healthcare. It believes that consumers should have an important role in reducing errors. As such, the Commission will engage consumers fully in patient safety efforts.
- 5) The Commission believes in the ideas of a 'just culture.' As such it will attempt to balance individual accountability with the need for non-punitive approaches and system improvements. A primary focus of the Commission will be to reduce errors by addressing systems-related issues. To the extent that individual negligence or misconduct occurs, such activity will be handled independently by existing regulatory agencies.
- 6) The Commission will maintain a high level of accountability—to the public, to the Legislature, to participating reporting entities, to the healthcare community.
- 7) The Commission will work in close collaboration with consumers, policy makers and leaders of the healthcare delivery system in Oregon in order to gain their active support for the goals of the Commission and to identify, share, and implement best practices.
- 8) The Commission acknowledges its current status as a small, semi-independent, and newly created organization. It needs to build credibility and forge a strong and enduring identity. Therefore it resolves to:
 - Find its appropriate and unique niche among all the other organizations involved in patient safety efforts.
 - Keep a narrow initial focus in its patient safety efforts.
 - Create, nurture and sustain powerful public-private partnerships and coalitions.
 - Have a clear, compelling and sensible vision that it communicates to all Oregonians: simply, consistently, repeatedly, and effectively.
 - Balance long-term goals with short-term visible results (wins).

- 9) The Commission will strive to minimize the burden on reporting entities and to complement data systems that already exist.
- 10) The Commission recognizes that securing startup and over-time funding is of critical importance to its work. To the extent possible such costs will be defrayed over a large base of funders. The Commission expects both public (at a minimum via in-kind contributions) and private financial participation (donations, in-kind, participant fees).
- 11) The creation of a patient safety reporting program represents the key initial aspect of the Commission's work. However, it does not represent the only aspect. Over time, the Commission will explore other patient safety projects, including the dissemination of best practices and the support of quality improvement initiatives.

4. Funding the Commission – Operating Budget

The Patient Safety Commission receives no state general fund dollars. As defined by statute, it has four options for funding its operations:

- Participant fees: Eligible entities may chose not to participate in the Commission's voluntary reporting program, but all entities would be required to contribute their share of funding, if asked to do so.
- In-kind services: The Commission could accept contributions in the form of staff time, office space, computer services, etc.
- Grants: The Commission may apply for and accept grants and federal matching funds.
- Donations: The Commission may accept cash donations.

At its May 11, 2004 meeting the Commission agreed that it was important to distinguish between start-up budgets and longer term operating budgets. For its first year of operation it decided to concentrate on seeking donations and in-kind services. As a new organization it wants to create a 'product' before it considers the use of participant fees. However, as soon as the Commission has established a reporting program it will then consider the use of participant fees to cover its operating expenses. Over time, those fees are likely to provide a large portion of the Commission's budget.

Because the Commission started its existence without funding and because it has been operating with borrowed staff (in the form of an in-kind contribution from the State) it has not yet adopted an official operating budget. It did agree to a general business plan however. This plan calls for a very lean administrative structure and maximum use of subcommittees with active participation from Commissioners. The Commission also agreed that it wanted to hire its own administrator as soon as it had raised sufficient funds.

Toward that end the Commission created a fund raising plan. Staff developed fund raising materials and Commissioners were cast in the role of 'ambassadors.' Specific commissioners were matched with potential donor organization and assigned the responsibility of making initial

contacts. In addition, to provide realistic targets for their fund raising efforts, the Commission created *unofficial* budget projections for its first three years of existence:

Estimated Costs (see Appendix for details)

Year	FTEs	Estimated Costs
First Year	3.0	\$430,000
Second Year	3.8	\$487,000
Third Year	4.7	\$588,000

To date, the Commission has raised \$262,150 from 18 contributors (see Appendix for a list of financial contributors). As a next step, the Commission will discuss a revised budget at its January 18, 2005 public meeting. That discussion will include the possible use of participant fees. The Commission will then take steps to adopt an official operating budget in accordance with ORS 182.462 by Spring 2005.

The Commission believes it now has sufficient funds to begin a search for an administrator to run day-to-day activities. The job description has been written and will be posted shortly. Initial screening of applicants is scheduled for late January 2005.

5. Audit

As a new organization that is still raising start-up capital, that lacks its own staff, and does not yet have an official operating budget, the Patient Safety Commission has not had an official audit. As soon as it has adopted its official operating budget it will take immediate steps to comply with ORS 182.464. In the meantime the Commission has developed a series of “Accounting and Internal Control Procedures” that established basic accounting procedures and protocols for signing authority and for expenditure approval.

6. Building a Reporting Program

A principal task of the Commission is to create a voluntary reporting program for serious adverse events. As previously mentioned, the reporting program is meant to gather and to use data from six types of reporting entities: hospitals, long term care facilities, pharmacies, ambulatory surgical centers, outpatient renal dialysis facilities, and freestanding birthing centers. The Commission has decided that effective implementation requires the setting of time-specific goals. As a broad framework the Commission agreed to the following concepts (which the Commission defined as “Beginning with the End in Mind”):

1. Within one year, Commission Members and Hospital Administrators will agree that the Commission is collecting valid and useful information regarding adverse events in Oregon Hospitals.

2. Within two years, Commission Members and Hospital Administrator will be able to point to specific instances in which patient safety has been enhanced as a direct result of this reporting program and the activities of the Commission.
3. Within three years, Commission Members and Representatives from the six specified types of healthcare providers and other key stakeholders will agree that the activities of the Oregon Patient Safety Commission are enhancing the safety of patients in Oregon.

Having settled on these concepts, the Commission then adopted the following short-range goals:

1. Begin the collection of data regarding adverse events, the root causes, and collective action plans in January 2005. Initial reports may come from only small groups of hospitals on a trial or test basis.
2. By June 2005 receive reports of adverse events, the root causes, and corrective action plans from at least 50% of Oregon hospitals (which means that half of all institutions must participate and that half of all hospital discharges must be represented).
3. Issue a summary report regarding adverse events to Oregon hospitals in September 2005. This initial summary report will be based on very limited data because the reporting program will still be in start-up mode.
4. Participate in or sponsor a statewide conference regarding adverse event reporting and analysis prior to September 2005.
5. Receive reports of adverse events, their root causes, and corrective action plans from at least 75% of Oregon hospitals by January 2006.

As a first step toward establishing a reporting program the Commission was charged with “developing a list of objective and definable serious adverse events to be reported by participants.” To accomplish this task, a definitions subcommittee met six times in 2004. Their work included:

- Review of approaches used by other states;
- Review of approaches adopted by the Joint Commission on Accreditation of Healthcare Organizations and by the National Quality Forum;
- Understanding the epidemiology of errors;
 - o Close analysis of research used by IOM;
 - o Consultation with hospital-based epidemiologists;
- Analysis of alternative strategies (explicit and implicit models).

As a product, the subcommittee produced a definition-matrix of serious adverse events. See Appendix for a copy of the matrix and for a description of the process the subcommittee used to create it.

With a draft definition in hand, the Commission has launched a two-phase pilot test of the reporting program. Phase One began in December 2004. Five hospitals have agreed to participate: OHSU Hospital, Providence Hood River Memorial Hospital, Rogue Valley Medical Center, St. Anthony Hospital, and Salem Hospital. Overall, these hospitals represent a purposeful mix of hospital types – large and small, urban and rural, Portland and not-Portland. Phase One includes a retrospective look at sentinel event data already collected by pilot hospitals. The

Commission is using the information to compare reporting variations and to design a collection system that provides needed information but that also meshes (if possible) with current hospital practices. The Commission believes that a voluntary system will work only if the reporting process is made efficient. Phase Two will begin the actual collection of reportable data and is scheduled to start in late January or February 2005.

7. Administrative Rules

By statute the Patient Safety Commission must adopt rules “necessary for the implementation of the Oregon Patient Safety Reporting Program.” Such rules must include a list of objective and definable serious adverse events, a budget, a process for seeking grants and other funding, a method for determining participant fees, a process for establishing auditing and oversight procedures, and criteria for terminating participants from the program.

As outlined in Section 6, the Commission launched a pilot project of its reporting program in December 2004. The pilot is being built upon some key assumptions about what success looks like:

- Strong collaboration
- Public input and support
- Consensus solutions
- Pilot participants become champions of industry-wide adoption of reporting program

Given these guidelines, the Commission decided that permanent rules would be established after the initial phase of the pilot project. In a sense, the pilot represents the first step in a very open and very transparent discussion about what the reporting program should look like. Permanent rules will be adopted in the Spring 2005.

Finally, as described in Section 4 the Commission has independently raised \$262,150 to fund its public mission. With sufficient revenues in hand it will now modify its draft budget and take steps to adopt an official operating budget in accordance with ORS 182.462 by Spring 2005.

8. Licenses, complaints, investigations

The Patient Safety Commission is not a regulatory body. It does not review licenses, permits, certifications or registrations. However, as it continues the development of its reporting program it will adopt standards for when it might terminate a participant in the reporting program. Even though the program is voluntary a hospital (or other entity) that agrees to participate must comply with all Commission guidelines. If they do not, they may be terminated. When the reporting system is operational the Commission will provide updates on which organizations are participating and which, if any, have been terminated.

9. Lawful procedures

The Board of Directors is adequately and effectively discharging its lawful responsibilities. To date it has not received any consumer complaints or requests from the Governor's office.

Consumer and professional education will become a major part of the Commission's activities. However, such education will be built upon the implementation of the Patient Safety Reporting Program. That work is on going.

Personnel policies and contracting and purchasing procedures comply with applicable state and federal law. Fund raising efforts have generated \$262,150 to support a new public health initiative that otherwise would go unfunded and unimplemented.

10. Consumer publications/outreach

The Commission's Principle's Statement speaks directly to the need to ensure that consumers are at the center of the patient safety movement. Specific on-going efforts include:

- Having two consumers sit on the Board of Directors.
- Development of a Patient Safety Web site:
<http://www.dhs.state.or.us/publichealth/hsp/patientsafety/commission.cfm>).
- Creation of a master communications plan (including identifying consumers as a 'key audience') ratified by full Commission
- Requirement that all reporting entities tell patients or their families—in writing—if an adverse event affected them.
- Requirement to publish annual reports designed specifically for consumer that will show aggregate trend data.
- Ongoing outreach to the media
- Presentations to organizations
- Ever-growing mailing list
- Plans for a consumer advisory board
- Encouragement of public testimony
- Joint planning effort with the Oregon Medical Association and others for an annual patient safety convocation (Scheduled for Fall 2005).

When the Commission has a full time administrator, such consumer activities will increase.

11. Challenges

The Patient Safety Commission has had a successful first year and is making good use of its status as a semi-independent state agency. However, significant challenges loom. These include:

- How to ensure stable funding? The Commission has done a good job of raising start up capital in a tight funding environment. Now it must decide if it wants to impose

participant fees on all eligible reporting entities. Such a decision will require a wise balancing act. First, the Commission must make sure that it truly has something to offer participants, so they can justify the outlay. Second, the Commission needs to decide how to apportion fees across the various types of organizations eligible to participate. Should fees be assessed only against hospitals in the first reporting year, or should costs be spread among other types of organizations?

- How to balance the different aspects of its mission? The Commission is charged with building a confidential voluntary reporting program. But it is also charged with establishing quality improvement techniques and disseminating evidence-based prevention practices to improve patient outcomes.
- How to brand its name? The Commission seeks to be known as the dominant patient safety organization in Oregon. It has made a good start in this effort: attendance at its meetings continues to grow; Commissioners have made presentations to many groups around Oregon; fund raising efforts have raised its profile; it was able to recruit participants for its pilot study. But name recognition and trust must come from sustained efforts and measurable improvements.
- How to better include consumers? While consumers are important to the Commission, it faces a natural tension with helping patients and families and with maintaining the confidentiality of data. The Commission is not in the business to create scorecards, nor is it going to make specific recommendations about which hospital might be safer. Instead, it will help consumers by making the entire industry safer, by providing aggregate reports and via consumer advice. The Commission needs to make these consumer activities concrete and enduring.
- How to ensure that the pilot project is successfully converted to a full-blown reporting program? The Commission's decision to create a pilot project to test the reporting program allows for a collaborative implementation strategy, but it must move quickly and it must maintain its independence.
- How to increase participation in the reporting program to all reporting entities? Of the six types of reporting organizations, the Commission has focused its initial efforts on creating a reporting program tailored to hospitals. It must now develop reporting programs for the others.
- How to put data to good use? The Commission is creating a two-way pipeline of information. It will succeed only if the information it gathers from participating organizations is compiled, understood and acted upon. The promise of the Commission is its potential ability to facilitate rapid sharing of patient safety problem areas and improvement strategies. The Commission must consider the role of computerized information technology to facilitate this rapid sharing.

12. Conclusions

The Patient Safety Commission represents a new voice in the movement to reduce the number of serious adverse events affecting patients in Oregon. It is an emotional experience, yet heartening to hear consumers speak before the Board, tell their stories, and to ask for help. And the Commission is in a position to offer help. For an organization that didn't exist until July 2003, didn't have a Board of Directors until January 2004, and didn't hold its first official meeting until March 2004, the Commission has made excellent progress:

- It is now well organized. It held seven public meetings in 2004 and plans nine meetings for 2005. Its Commissioners are active participants; its subgroups and committees are productive.
- It has successfully raised start-up funds. The \$262,150 represents funding that would not otherwise be available for public health programs.
- It has taken steps to build a reporting program. It has crafted a set of reporting standards. It has drafted an implementation plan and gained the cooperation of five hospitals to help test the system.

Appendices

**Oregon Patient Safety Commission
Preliminary Budget Estimates: Years 1 - 3**

Introduction/overview:

As defined by statute, the Patient Safety Commission can seek funds from four sources:

- Participant fees: Eligible entities may chose not to participate in the Commission’s voluntary reporting program, but all entities would be required to contribute their share of funding, if asked to do so.
- In-kind services: The Commission could accept contributions in the form of staff time, office space, computer services, etc.
- Grants: The Commission may apply for and accept grants and federal matching funds.
- Donations: The Commission may accept cash donations.

At its May 11, 2004 meeting the Commission decided to concentrate its fund raising efforts on seeking donations and in-kind services. As a new organization it wants to create a ‘product’ before for considers the use of participant fees. However, as soon as the Commission has established a reporting program it will then consider the use of participant fees to cover its operating expenses. Over time, those fees are likely to provide a large portion of the Commission’s budget.

The following budget estimates are meant as just that – estimates that will help in the work of seeking funds. These numbers represent the Commission’s current best answer to the question—*how much will it cost?*

Approach to forecasting an operating budget:

- Review of National Academy’s “Cost Implications of State Medical Error Reporting Programs: A briefing paper.”
- Review of cost data from NY, Florida, Utah
- Discussions with staff who run State Registries (injury, trauma, cancer)
- Made assumptions about staffing needs based on defining core functions and start-up sequence/timing. Made estimates of system needs and reasonable community level salaries, overheads, etc.

Functions of the Patient Safety Commission:

Core Function	Description
Commission Start-up	Build support, establish Board of Directors, education, outreach, facility by facility contact, letters of agreement, etc.
Information system design or acquisition	Hardware, software, establish networks, create websites, install database programs and security systems.
Data Collection and entry	Collection, filing, entry of reported information into database (Method of reporting has big impact on costs).

Core Function	Description
Desk Review/Follow-up	Review data received from participating facilities and providers. Determine appropriate course of action (Costs depend on process used and amount of follow-up).
Validation	Activities related to validating reports in order to determine whether facilities and providers are complying with reporting requirements.
Analysis	Compiling, interpreting, trending, etc.
Training, Information Sharing, Education	Educating facilities and providers about Commission, 1 to 1 training sessions, regional and state-wide forums, reporting, etc
Administration	Ongoing management, support to Board, problem solving, staff hiring/training, etc.

Staging:

Year	Activities
First year	Startup, outreach and training, publicizing, building capacity, systems planning and development, including data security. Agreements with participating entities. Some data received and processed.
Second year	Continued system development, outreach, increased participation of other reporting facilities and providers. Established data stream, beginning to use data for education.
Third year	Fully functioning

Staffing needs:

Anticipated costs are driven mostly by staffing needs and system development. Budget model assumes staff will include a full time administrator and one support staff. Also assumes part time analyst/trainer, grant writer/fund raiser (trainer position becomes full time as demand increases). Model includes clinical and legal consultation costs.

Estimated Costs

Year	FTEs	Estimated Costs*
First Year	3.0	\$430,000
Second Year	3.8	\$487,000
Third Year	4.7	\$588,000

*Costs include estimates for staffing, overhead, support services. Assumes no in-kind contributions. Year one assumes full year of activity (actual year one costs likely to be lower since it will be phased-in). The budgetary wild card is systems development. This model budgets \$50,000 in year 1, \$25,000 in years 2 and 3 for systems. Depending on approach taken, this could be woefully inadequate.

FINANCIAL CONTRIBUTORS

The Patient Safety Commission would like to thank the following donors for their generous support of the work of the Commission. Together we will make a difference:

Asante Health System	\$10,000
Blue Cross Blue Shield of Oregon	\$25,000
Kaiser Permanente	\$50,000
Legacy Health System	\$15,000
Lifewise Health Plan of Oregon	\$10,000
Mercy Medical Center	\$1,000
Mid-Valley IPA, Inc.	\$10,000
Northwest Physicians Mutual	\$5,000
ODS	\$5,000
Oregon Health Care Association	\$5,000
Oregon Health & Science University	\$15,000
Oregon Medical Association	\$25,000
Oregon Society for Healthcare Risk Managers	\$150
PeaceHealth	\$15,000
Providence Health System	\$50,000
Salem Hospital	\$15,000
Tuality Healthcare	\$5,000
Willamette Falls Hospital	\$1,000
<hr/>	
Total to date*	\$262,150

*Current as of January 7, 2004

Proposed List of Reportable Events – Oregon Patient Safety Commission		
Type of Events	Additional Specifications	Source(s)
1. GENERAL CATEGORY		
Any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.	Serious physical injury defined to be consistent with JCAHO guidelines. Examples of “serious physical injury include, but are not limited to: <ul style="list-style-type: none"> • Event that results in an unplanned return to the operating room or major procedural intervention. • Event that results in transfer to the ICU with ventilatory or pressor support. • Event that results in substantial extension of hospital stay greater than 5 days above expected. • Event that results in an unplanned transfer to a higher level hospital. • Healthcare acquired infections that result in patient death or serious physical injury. • Serious adverse events that occur in hospital-sponsored outpatient settings but result in hospitalization. 	Modeled on JCAHO’s general sentinel event policy and JCAHO Patient Safety Goal #7.
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.	NQF’s List of Serious Reportable Events
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.	NQF
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.	NQF
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.	NQF
E. Intraoperative or immediately post-operative death in an ASA Class I patient.	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.	NQF
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.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
B. Patient death or serious physical injury associated with the use or function of a device in patient care in which the device is poorly	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i> . Also, <i>poorly</i>

Proposed List of Reportable Events – Oregon Patient Safety Commission		
Type of Events	Additional Specifications	Source(s)
designed, or is used or functions other than as intended.		<i>designed</i> added to NQF definition.
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.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>

4. PATIENT PROTECTION EVENTS		
A. Infant discharged to the wrong person		NQF
B. Patient death or serious physical injury associated with patient elopement (disappearance) for more than four hours.	Excludes events involving competent adults.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
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.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
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.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
B. Patient death or serious physical injury associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products		Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
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	Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
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		Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
E. Death or serious physical injury (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.	NQF
G. Patient death or serious physical injury due to spinal manipulative therapy		Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
H. Any perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.		Modified JCAHO

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6. ENVIRONMENTAL EVENTS		
A. Patient death or serious physical injury associated with an electric shock while being cared for in a healthcare facility	Excludes events involving planned treatments such as electric countershock	Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.		NQF
C. Patient death or serious physical injury associated with a burn incurred from any source while being cared for in a healthcare facility.		Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>
D. Patient death or serious physical injury associated with a fall while being cared for in a healthcare facility.		Modified NQF – <i>serious physical injury</i> added to definition
E. Patient death or serious physical injury associated with the use of restraints or bedrails while being cared for in a healthcare facility.		Modified NQF - <i>serious physical injury</i> replaces <i>serious disability</i>

**Oregon Patient Safety Commission
Reporting/definitions Subcommittee**

August 3, 2004

Proposed approach for defining “serious adverse event”

Approaches reviewed to date:

- “General-definition” models, such as those used by JCAHO sentinel event reporting and VA’s Patient Safety Reporting Program.
- “Explicit-list” models such as NQF’s “serious reportable events.”
- Initial review of 11 state-specific approaches.

Draft Guidelines

- Oregon statutes call for “objective and definable” language. Make definitions as explicit as possible while allowing for some flexibility.
- Definitions should be comparable to national standards and to important state standards.
- Definitions should consider both severity and probability of events (severity could include extent of harm/injury, length of stay, level of care required, cost).
- A culture of patient safety includes a strong emphasis on creating a ‘reporting culture.’ A successful reporting program will therefore:
 - Improve trust;
 - Provide rapid, useful, accessible, and intelligible feedback to the reporting community;
 - Allow for easy, non-duplicative reporting.

Outline of proposed approach (also see “crosswalk”)

- Combine “general-definition” model with “explicit-list” model
- Explicit definitions would be modeled after NQF and would become the core data set.
- NQF definitions would be modified:
 - to make them consistent with Oregon statute
 - to include certain hospital-acquired infections
- Under the umbrella of a general definition, reporting entities would be “invited” to report additional events. Language would be similar to JCAHO, but based on Oregon statute.

Some additional things to think about:

- How do we create a reasonably-sized data set that balances need to know with level of effort?
- Are we needlessly excluding any important categories of errors?
- Will this ‘definition set’ work across all eligible reporting entities?
- It is likely that Congress will call for national voluntary reporting system. Implications?
- AHRQ patient safety indicators are getting attention (viz. HealthGrades study: July, 2004). Their indicators are based on hospital discharge data. How best to take this approach into account?

Next Steps?

- Review proposal with Commission
- Convene expert panel to create list of reportable healthcare-acquired infections
- Discuss with hospital association and hospital administrators
- Discuss with line staff (quality managers/risk managers)
- Organize and hold public hearings
- Discuss ‘pilot’ of volunteer hospitals as a way to begin reporting program.