

In a 1999 study entitled *To Err is Human: Building a Safer Health System*, The Institute of Medicine (IOM) reported that as many as 44,000 to 98,000 people die in hospitals each year as a result of injuries caused by medical interventions. The IOM called such injuries *adverse events*. While these events are unrelated to a patient's medical condition, they are not always preventable, nor do they necessarily signal poor quality care. For preventable adverse events that harm patients we typically use the term *medical error*.

The IOM's report was based on an *estimate* of deaths from adverse events. Other studies have calculated even higher numbers of deaths. For example, the Federal Veterans Health Administration believes that about 180,000 deaths occur each year in the United States from "errors in medical care" across all healthcare settings. A 2004 study by HealthGrades estimated that 195,000 die each year in US hospitals from preventable adverse events. In addition to deaths, many adverse events lead to serious, but non-fatal injuries.

Whatever the exact toll, the associated costs are huge. The IOM estimated that such errors cost at least \$17 billion a year. A recent study from a large community-based, tertiary-care facility found that errors added, on average, \$2,411 to the cost of treating each affected patient. Unlike previous studies that focused on medication errors and adverse drug

THE OREGON PATIENT SAFETY COMMISSION

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The Link between Patient Safety and Reporting of Medical Errors

events, this study included all types of adverse events—falls, medication events, infection control issues, surgical events, laboratory and test issues, treatments/procedures, and others.

►Of course, behind the statistics are stories of individual tragedies. At almost every public meeting of the Oregon Patient Safety Commission someone will stand up and talk about a surgery that inadvertently left a patient injured; a baby that should have been saved, but wasn't; a hospital-acquired infection that raged out of control. At the end of the day, these voices from all walks of life reinvigorate the numbers. They remind us that Oregon is not immune to the problem of adverse events and medical errors. In fact, applying the IOM findings to Oregon suggests 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. In Oregon, even with a healthcare sys-

tem continually working to improve quality, more people probably die as the result of adverse events than from diabetes, Alzheimer's disease, or pneumonia.

►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 errors are preventable with current knowledge. With this growing recognition that too many people suffer preventable injuries while in Oregon facilities, the Office of the Public Health Officer and the Office of Health Systems Planning convened a workgroup in 2002 to consider solutions. This group of healthcare providers, insurers, purchasers, and consumers crafted a series of agreements that led to the passage of bipartisan legislation creating the Oregon Patient Safety Commission in July, 2003 (ORS 442.820).

The Commission's Organization and Mission

►The Patient Safety Commission is a semi-independent state agency and is the only organization in Oregon with the sole function of reducing the number of adverse medical events in the state. Leading it is a seventeen-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.

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.

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.

A Progress Report

As a new organization, the Patient Safety Commission spent part of its first year creating a leadership structure, drafting bylaws, and defining strategic goals. It also spent significant energy raising money, since the Commission receives no state general-fund dollars. By statute, the Commission has four funding options: assess fees on eligible participants, seek in-kind services, apply for grants, and solicit contributions. Because the Commission didn't immediately have a 'product' to offer participants, it chose to fund its start-up activities with contributions from interested parties. To date, the Commission has

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IOM: Institute of Medicine

The Institute of Medicine of the National Academies (IOM) is a non-profit volunteer organization whose purpose is to provide evidence-based, scientific advice on nationally pertinent health matters. It was created as a branch of the National Academy of Sciences under a government charter in 1970, though the IOM and its affiliated organizations are privately run. Most of the reports published by the IOM are written by volunteers who are experts in their fields, and to assure that its reports are free from bias, a strict peer-review process is used. As with the National Academy of Sciences, most of the IOM's studies and reports are done at the request of government agencies.

One such report published in April focuses on the controversial issue of embryonic stem cell research, calling for an oversight committee of experts to regulate organizations that conduct privately funded research. Because of federal restrictions on embryonic stem cell research, there has been a lack of standardized regulations and guidelines to maintain the ethical and scientific integrity of this research, but the IOM suggestions could solve this problem.

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raised \$269,000 from 19 contributors. The Commission is now considering how and when it might charge fees to all eligible participants.

The Commission is also building its voluntary reporting program. The program will start with hospitals, and then expand to include other health care facilities and retail pharmacies. As a first step, the Commission was charged with "developing a list of objective and definable serious adverse events." It has completed a *draft* list for hospital reporting. With that in hand, the Commission has launched a two-phase pilot test of the reporting program. Five hospitals are participating: OHSU Hospital, Providence Hood River Memorial Hospital, Rogue Valley Medical Center, St. Anthony Hospital, and Salem Hospital. Phase One includes a retrospective look at sentinel-event data already collected by pilot hospitals. Phase Two will begin the actual collection of reportable data.

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The Commission aims to have the pilot demonstration completed by July of this year. It hopes to adopt administrative rules soon after. These rules will cover the details of the reporting program and establish the terms of participation. The Commission's stated goal is that 75 percent of Oregon's hospitals will be reporting data by year end, 2005.

In addition, the Commission has embraced the Institute for

Healthcare Improvement's "100,000 Lives Campaign." IHI's goal is to save 100,000 lives in the next 18 months by introducing six evidence-based practices into 2000 hospitals across the United States. The Commission is partnering with IHI in this effort. Our role will be to increase enrollment in Oregon and to act as a communications hub and technical consultant.

Essential Aspects of the Program:

a. The Commission's Philosophy:

As the only state-wide organization solely dedicated to patient safety, the Commission is creating a voluntary reporting program with the intention of using the information to change the healthcare industry. The Commission seeks to create a legally safe environment where errors can be reported, shared, discussed, and **fixed**. Healthcare organizations will learn from one another—adverse outcomes at one facility will be less likely to happen at another. With regard to patient safety, the Commission seeks to produce and sustain "a state of intelligent and respectful wariness."

b. Voluntary Reporting

The Patient Safety Commission is building a **voluntary** reporting program, which means that hospitals and other eligible organizations can choose **not** to participate. In its 1999 report, the IOM called for mandatory reporting for the most serious errors and voluntary approaches for less serious events. Oregon has chosen to combine the two systems into one program.

Critics of voluntary approaches worry that the reporting program will be under-utilized, and that important information will be lost. They often cite the fact that most other states with reporting programs have created mandatory systems. So, how does the Commission justify its voluntary approach? First, a voluntary system is consistent with the Commission's mission of encouraging industry change through adoption of best

practices. Our goal is to find the best programs and help replicate them at other facilities. Second, a voluntary approach is consistent with the Commission's belief that most errors are driven by failures of complex systems. We are not an organization dedicated to finding, then punishing bad doctors or bad organizations. Our approach is meant to complement the job already being done by the state's regulatory agencies.

That said, how does the Commission induce organizations to participate in its voluntary program? Why won't organizations simply say, "No thanks"? Here are a few answers:

- The legislation that created the Patient Safety Commission enjoyed bipartisan support. Industry, consumers, and health providers rallied behind the idea. Stakeholders want this approach to succeed.
- The Commission offers a new opportunity for healthcare organizations to share information and to learn from adverse events within a legally protected arena. Until now no such forum has existed.
- All eligible reporting organizations will have to pay fees, even if they choose not to report. This is a uniquely Oregon solution: *voluntary reporting, mandatory fee assessments*. While all organizations will pay fees, only those organizations that share data will have access to Commission findings and best-practice information.
- The Commission will publish the names of organizations that do and don't submit data.
- Health care purchasers will begin to demand that their networks participate in the Commission's reporting program. The Public Employee's Benefit Board (PEBB) is leading the way in this market-based response.
- If an organization chooses to participate, it then must provide

complete data, including summaries of root-cause analysis, action plans, and follow-up activities. Such completeness and thoroughness will be monitored by the state Public Health Officer. Failure to comply could mean termination from the reporting program (which the Commission will make public).

- In 2007, the Legislature must evaluate the usefulness of the Patient Safety Commission. If it finds the Commission lacking, it must consider whether a conversion to mandatory reporting would be an appropriate solution.

c. A Systems Approach

The Patient Safety Commission believes that most errors are systems-related and not attributable to individual negligence or misconduct. The Commission assumes that errors are often consequences, not causes. It sees such errors as gateways to the evaluation of complex and perhaps poorly designed systems.

Sharpe, "this new way of thinking takes it for granted that... errors will occur in complex, high-risk environments, and participants in that system are responsible for active, committed attention to that fact. Responsibility takes the form of preventive steps to design for safety, to improve on poor system design, to provide information about potential problems, to investigate causes, and to create an environment where it is safe to discuss and analyze error." Finding the right balance between personal accountability and systems accountability will be a significant challenge. However, that balance goes to the heart of creating the safer patient environment championed by the Commission.

d. Confidentiality

The Patient Safety Commission was designed as a legal safe haven. It will allow participating organizations to share information about adverse events in ways that were not possible before the Commission's existence.

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Changing how we think about errors also influences how we think about accountability. The traditional goal was to assign blame. Blame is personal and it is retrospective: You made a mistake. However, traditional remedies that focus on assigning blame to individual providers have failed to reduce the number of adverse events in our healthcare system. A systems approach, on the other hand, emphasizes responsibility in a forward-looking or prospective manner. In the words of ethicist Virginia

The Commission's structure and its legal protections reflect its overall goal of encouraging systems improvement.

►At least three kinds of legal protections come into play. First, information flowing to and from the Commission will be "confidential and privileged." The actual legal language is modeled after Oregon's peer-review statutes, which protect medical data and other personal information when it is conveyed to a healthcare peer review body. As a result of this protection, patient safety



data provided to the Commission will not be admissible as evidence in any civil action, including but not limited to a judicial, administrative, arbitration, or mediation proceeding. Such information will not be subject to civil or administrative subpoena, discovery in connection with a civil action, or disclosure under state public records law (and if permissible, federal public records laws). Second, patient safety data reported to the Commission or developed as part of the Commission's auditing and oversight role are legally off limits to any state regulatory agency (one exception: mandatory reporting obligations, if they arise, trump confidentiality protections). Third, for the purposes of the Health Insurance Portability and Accountability Act (HIPAA), which protects patient privacy, the Patient Safety Commission is a public health authority. Participating organizations may therefore disclose protected health information to the Commission.

e. Informing the Public

Even though the Commission is building a confidential reporting program, it intends to share summary data with the public. This information will include overall trends organized by type of adverse event. However, the Commission will not create scorecards that attempt to grade individual hospitals on safety. The Commission will also maintain a website so that consumers can obtain up-to-date patient safety information.

Perhaps of more immediate importance, organizations that participate in the reporting program must agree to tell patients and their families when a serious adverse event has occurred. This disclosure must be in writing. The Commission will soon begin deliberations on how best to structure this requirement. In doing so, it must wrestle with at least three questions: How do we ensure legal protections to providers making a disclosure; how do we strengthen, not weaken, the relationship between

patient and provider; and how do we offer accountability to consumers?

f. Medical Liability and Patient Safety

While the Patient Safety Commission does not have any direct role in addressing medical liability issues, its mission of reducing adverse events goes to the heart of the problem. This link between patient safety and medical liability was highlighted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in a recent policy report. In that April 2005 document, JCAHO outlined strategies for improving the medical liability system and preventing patient injury. JCAHO made three recommendations:

- Pursue patient safety initiatives that prevent medical injury. (JCAHO cited error reporting as an essential component of safety programs.)
- Promote open communication between patients and practitioners.
- Create an injury compensation system that is patient-centered and serves the common good.

The first two points are similar in spirit to the mission of the Patient Safety Commission: JCAHO declares that injury prevention is a fundamental goal; it places the patient at the center of the discussion. In addition, JCAHO speaks of a “fundamental dissonance” between the medical liability system and the patient safety movement. In doing so, it acknowledges that the effectiveness of the tort system “in deterring negligence, compensating patients, and exacting corrective justice is being called into question.”

Challenges for the Future

The Patient Safety Commission has had a successful first year. However, significant challenges loom. These include:

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- 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. Because building a reporting program is a slow process, the Commission must also challenge itself to make a more immediate contribution to patient safety efforts. Partnering with IHI is one such endeavor.
- How to better include consumers? This challenge is made more difficult because the public seems to view quality issues through a different frame than the Commission. Based on a recent Kaiser Family Foundation survey, a large majority of the public seems to prefer mandatory reporting to voluntary approaches. Also, the public tends to hold individual practitioners responsible for errors. System-based thinking can seem, at best confusing, at worst, an evasion. Finally, a majority of the public says that if quality information is

being reported it should be made available by facility. Given these differences, the Commission needs to find the right combination of listening and leading.

- How to put data to good use? The Commission is creating a two-way pipeline of information that will succeed only if the information it gathers from participants is compiled, understood, and acted upon. The Commission has the potential to facilitate rapid sharing of patient safety problem areas and improvement strategies.
- How to extend 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.

Conclusions

Medical errors and adverse events represent a widespread problem: A recent national survey suggests that 34 percent of the public has experienced a preventable medical error either personally or within their families. One of those families was mine. Two years ago my mother died of a medical error. She was having elective knee-replacement surgery, in another state, when things went wrong. From that experience, I learned what “failure to rescue” means, though the words do not begin to describe what such a loss feels like. I now understand the confusion and the anger that medical errors create. I appreciate the difficulty in trying to separate the desire to blame from the recognition that improvement often comes in fixing complex systems. I considered a lawsuit and found the process wanting. I came to know my mother’s surgeon and to have some recognition of one physician’s anguish—both professional and personal—at having lost a patient.

If there is any comfort in my mother’s death (and I resist such thinking), it comes from believing that the world is changing. The public is paying attention. Healthcare organizations are pushing patient safety to the top of their priorities.

The Patient Safety Commission represents another voice in this growing movement to reduce the number of serious adverse events affecting patients in Oregon. 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 steady progress. We have a lot of work to do, however. Please join us. Our website: <http://www.oregon.gov/DHS/ph/pscommission/index.shtml>



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