Oregon patient safety Commission

Disclosure Forum/October 11, 2006
Working Paper

Introduction

Every patient seeks high quality care. Every healthcare organization seeks to provide it. But sometimes patients are inadvertently harmed during the course of their treatment. In those situations, the Patient Safety Commission believes that healthcare organizations have a responsibility to communicate with patients—openly and directly—about what happened. It is in this spirit that the Commission requires reporting organizations to provide written notification to patients in a timely and consistent fashion .[1]

Because the guidelines are so general, the Commission hosted a workshop on October 11, 2006 to generate ideas on how best to implement the notification requirement. Our continuing goal is to put together a tool kit of good ideas and best practices. Sixty-two people participated in the workshop. Thirty five hospitals and health systems were represented, as well as two nursing home chains. Participants included physicians, nurses, risk managers, academics, quality managers, CEOs and administrators, lawyers, and healthcare and insurance consultants. They came from as far away as Lakeview, John Day, La Grande, Klamath Falls and Bellevue, Washington.

The report that follows is a distillation of eight hours of workshop discussion, leavened with some additional comments and observations. The last section focuses specifically on the issues related to written disclosure; we end with a summary of the Commission's plan of action.

A place to start – a few principles

During the workshop, conversation and debate seemed to revolve around a few critical themes. Some of these can be bundled into an emerging set of principles:

1. *Disclosure is an ethical obligation*. It is the right thing to do.
2. *Disclosure is difficult*. Perhaps because it is difficult, it tends to reveal the essential values and nature of an organization. Disclosure highlights fundamental ethical issues such as stewardship and truth telling. It speaks to an organization's ideas about the role of a patient in his or her own care. It calls for organizational unity and consistency over time.
3. *Disclosure is about trying to maintain a relationship with the patient*. It strives to restore a patient to wholeness and to find appropriate closure. It is a human endeavor requiring empathy and touch of tenderness.

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[1] As written in statute: "After a serious adverse event occurs, a participant must provide written notification in a timely manner to each patient served by the participant who is affected by the event. Notice provided under this subsection may not be construed as an admission of liability in a civil action. [2003 c.686 §4]"

4. *Disclosure is, or can be, an essential part of a quality improvement program.* An organization can only address issues that it identifies and discusses. The ability to face problems openly is a prerequisite for change.
5. *Disclosure is a process*. Written notification is only a small piece of that process. A letter can never substitute for a face-to-face meeting. It should never be given to a patient without warning or preparation.
6. *Done well, written notification can strengthen a disclosure process*. The Patient Safety Commission understands that written notification is new and feels risky to some. However, a properly prepared letter can demonstrate and reinforce a continuing commitment to the patient.

A bright light on a difficult subject

We began the workshop by asking participants *what kept them up at night* regarding the subject of written disclosure. Participants had a lot to say, though the tone of the conversation suggested that many of the fundamental issues are about disclosure in general. There was also a strong sense that organizations were no longer debating '*why should we disclose?*' but had moved to '*how can we do it better?'* Some of the issues that came up included:

- The difficulty in gaining the support of everyone in the organization; the challenge of aligning interests. Specifically mentioned – physicians, senior management, liability insurers.
- A fear that written disclosure, if handled poorly, could make the patient/family situation worse.
- Concern about the legal implications of a written notification. Could a letter be used against a healthcare organization?
- An interest in getting concrete suggestions on how to write a good letter. What should be included? What are the right words to use?
- How to handle the actual process? When is the best time to notify in writing?
- How to provide support to clinicians and staff involved in the adverse event and the actual disclosure.

Emerging consensus, continuing discussion

Much of the disclosure workshop was devoted to practical issues of how to think about and how to implement a written notification policy. But because notification must be part of a coherent disclosure framework, we also spent time discussing the more general subject of talking with patients in the wake of adverse events. Following is a summary of the highlights, organized around four areas: patient-centered care, managing the risk of disclosure, managing the process, and legal issues.

Patient-centered Care

Disclosure and written notification must start with the needs of the patient.

Build a relationship: More than a few participants described disclosure as an attempt to maintain a relationship with a patient during a difficult time. This impulse to focus on the relationship is both a

powerful emotional response and a reasonable risk management strategy. Good relationships are durable and allow for the possibility of forgiveness. Some basic framing questions:

- How would I want to be treated if I were a patient?
- What does the patient want to know? (a question that must be approached without a hint of paternalism or preconceived assumptions.)
- What actions enhance, maintain, or rebuild trust?

Workshop participants strongly urged all healthcare organizations to establish on-going connections to their patients from first contact. After an adverse event it is probably too late to establish a relationship where none previously existed. Besides, it is simply a good business practice to include patients in their own care.

<u>Acknowledge an adverse event quickly</u>: Generally patients don't want to be kept in the dark. They worry, they grow suspicious, they lose trust. General consensus – tell patients immediately, but no later than 24 hours.

<u>Tell the truth, in a way a patient can understand:</u>

- Strive to be honest and clear
- Emphasize face to face communication
- Understand that patients and their families will be emotionally on edge and may not hear or remember what you are telling them. Repeat your message using different approaches.

<u>Seek genuine empathy</u>: While most of us consider ourselves empathetic, it can be difficult to genuinely identify with someone else's situation when loyalties may be divided. This sort of empathy-under-pressure requires training and experience. Done poorly, an attempt at empathy might be felt by the patient as indifference or pity or defensiveness or even cunning. Some of the ideas mentioned during the forum:

- Just listen. Give the family a chance to be heard.
- Try hard to understand what the patient is really asking for.
- Don't run from anger or other strong emotions.
- Follow up.

<u>Apologize:</u> A sincere apology can be an act of empathy. At its best it acknowledges the humanness of the injured patient and the seriousness of the event. It can also signal the transition from fact-finding to resolution. But organizations must be clear about what they mean when they issue an apology. It is not the same as a factual disclosure. It may or may not come with an admission of responsibility. Apology must also be reviewed for its legal significance (see below).

<u>Know your audience</u>: Patients vary in their ability to understand clinical findings, principles of causation, and quality improvement activities. Some will be sophisticated, many will not (upwards of 40% of Americans are health-illiterate). As a result healthcare organizations need to be flexible and find a communication style that fits the particular situation. Some ideas:

- Consider individual patient/family in determining appropriate language to use; don't insult patients by talking down to them; don't use jargon. Use active voice in sentence structure (active voice clearly identifies who is saying and doing what); limit written comments to one page.
- Say "investigation," not "root cause analysis."

- Find out what patient and family want to know by asking them (keep them involved in the process); ask them to describe their ideas on what will help rectify the situation.

Dig deep, offer to share some results: Patients typically want to understand what happened. They also want some reassurance that it will not happen to someone else. Therefore, once an organization understands the facts, that organization should make an effort to explain them. Once an organization has a remedy, it should share information about what it intends to do.

Consider other ways to sustain relationships with patients after a harm event: While the workshop participants did not reach any firm agreements on this subject, many have begun exploring ways to include patients as part of the solution. At least consider how patients might become your partner. What role might they play? Perhaps as a member of an advisory group, for example. Some even suggested there might be a role for patients in the root cause process.

Consider negative consequences: It is only fair to mention some of the possible negative consequences of placing a strong emphasis on patient-centered care. Does a healthcare organization ever risk 'being held hostage' by the patient who makes unceasing demands? Also, managing these 'relationships' costs time and money (at least in the short run, though more and more evidence suggests that litigation costs can decline). A healthcare organization should be honest with itself about its level of commitment to the patient.

Managing the risk of disclosure

Adverse events are traumatic: a patient is harmed; clinicians struggle; organizations face uncertain legal actions. Even given a belief in the ethical responsibility to disclose, organizations must understand and manage the risks appropriately. Some ideas from the workshop included:

Assess the true risks on a case-by-case basis: Participants disagreed about how much information to share with a patient after an adverse event. In essence the risks must be assessed on a case-by-case basis. If an organization believes – after an internal investigation – that care did not meet its own standards, it might reach a different conclusion about what information to share. In addition, if a healthcare organization has an early settlement program (admit responsibility, offer a settlement, don't go to court), it might treat the case differently than an organization that does not have such a program.

Silence is not golden: Participants strongly agreed that silence is a bad strategy for managing the risk of legal action. Faced with a reticent physician or stonewalling administrator, a patient is likely to feel betrayed, to grow angry, and to sue simply to learn what happened. Silence is also bad for morale within an organization, since staff will share partial information, conjecture, pass along rumors.

Disclose early; reinforce relationship often: Initiating a conversation with patients as soon as possible is a good risk management strategy. Once the conversation begins, look for additional ways to update, inform, seek the advice of the patient and family.

Coordinate communication efforts: Learn to speak with a unified voice. Risk increases, for example, if the physician tells a patient one thing and the risk manager another.

Do not over-promise: Do not disclose more than you really know. For many providers it is tempting to rush to fill the silence, to offer an explanation before the investigation has been completed, even to take the blame (out of ignorance of the true cause, or guilt, or presumed authority). But seat-of-the-pants hunches are often wrong. It is okay to tell a patient that you don't know what happened, but that you are looking into it. In addition, don't promise to fix things you can't.

Managing the process

Implementing a timely and effective disclosure policy that includes written notification requires a coherent and well managed process. Some of the themes that emerged from the workshop included:

Stay patient-centered: See earlier section.

Establish a clear disclosure policy: Draft a coherent policy, follow it. Such a policy should mesh with and amplify overall organizational philosophy.

Build/align support: Make sure that administration and clinical staff, especially physicians are in agreement on best approach. Make sure that hospital and physician malpractice insurers are supportive. Work to create a non-punitive culture of safety that rewards error detection. Make sure that Board is integrated into process.

Know when to notify: Narrowly interpreted, reporting organizations have an obligation to notify patients harmed by any *serious reportable adverse event*. These events include JCAHO sentinel events and the National Quality Forum's List of Serious Adverse Events. Some organizations have told the Commission that its list is too vague and that it is therefore difficult to know when to notify a patient. Certainly the Commission will continue to clarify its definitions based on such input. But a bigger issue is at stake here. In the words of the American Society for Healthcare Risk Management:

> Discussion about disclosure is incomplete at best—and misguided at worst—if the focus is on when the patient must be told of an outcome in order to comply with [external] standards. The more important question is: How do we build a system that supports honest communication between patients and practitioners so that discussion of error and harm are part of the process, not separate concerns.

Establish clear responsibilities: Participants discussed two approaches…

> Team approach: Build a team from a variety of services. Consider using 'risk management professionals with heart,' manager, nurse, physician. A team approach can be labor intensive, but the sharing of responsibilities reinforces a spirit of learning and a culture of safety.
>
> Single contact approach: Designate one person, typically the risk manager, as go-to person for all disclosure communication. This is useful for small organizations with limited staff. However this model doesn't emphasize a culture of shared responsibility and open communication as part of everyone's job.

Establish a training program: Disclosure requires hard-to-master skills. It takes training and practice. Consider a formal training program to create a basic understanding and a just-in-time refresher/strategy in advance of an actual discussion with a patient.

Make sure physicians and staff have access to experts: Don't set up physicians and staff to fail by leaving them without support. Make sure that physicians have 24/7 access to disclosure experts. Meet with practitioners before they meet with patients. Coach physician in what to say (physicians may tend to extremes, either taking too much responsibility or not any).

Get the investigation going: Good disclosure needs an accurate understanding of what actually happened. Get physicians involved in root cause analysis (RCA) with risk management. The timing of the investigation is also important. If it occurs too soon after the event, staff may be too distraught to provide good input. Consider a structured supportive debriefing prior to the investigation.

Prepare for the initial meeting with patient and family: Hold a pre-conference discussion for staff and physicians prior to meeting with family. Decide who will participate, review roles, outline possible conversation path.

Meet with the patient and family: On their terms, when they are ready.

Follow up: Since disclosure is about building and maintaining relationships always consider the very real possibility that another meeting, another call, another interaction will be helpful. Timely contact by CEO or medical director can add a level of acknowledgement of respect for patient.

Work on consistency: Organizations often reach conceptual agreement on a strategy but don't effectively put the agreement into practice. Use pre-conferences. Make sure that what you say in the beginning matches what you say in the end. Make sure that written notification reflects what was actually said.

Decide on billing plan: Are fees waived? If so, make sure accounting is notified before a bill is sent. If fees are not waived, make sure to talk with patient/family before the bill is sent.

Establish documentation protocols: What goes in the medical chart? Where are notification letters kept? Generally workshop participants felt that Risk Management should retain copies for seven years. Participants did not reach a consensus on what notification information should be part of the chart. Whatever the policy, make sure that physicians understand, agree, and comply.

Provide on-going support to staff and to physicians: Never minimize the stress and difficulty on staff and clinicians. Adverse events can undermine sense-of-self and damage careers. Create a support network.

Legal Issues

[Note: This summary is not meant to offer advice on legal issues faced by a healthcare organization when deciding what to disclose. Organizations must look to their legal counsel. In addition, the

Oregon Association of Hospitals and Health Systems (OAHHS) has drafted a report, available on their website, that should be required reading: The OAHHS GUIDELINES FOR PARTICIPATION: OREGON PATIENT SAFETY REPORTING PROGRAM.]

Protected information, confidential information: By statute, information shared with the Patient Safety Commission is confidential and privileged and not admissible in evidence in any civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding. Patient safety data, patient safety activities and reports are not subject to:

- Civil or administrative subpoena;
- Discovery in connection with a civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding; or
- Disclosure under state public records law

And, as mentioned earlier, written notification to a patient may not be construed as an admission of liability in a civil action.

In addition, the OAHHS suggests this (see above report): "Train all staff, including physician staff, that any oral communications regarding a disclosure or report to the Oregon Patient Safety Reporting Program must be made discreetly, so as not to be overheard by others who may not understand its context."

Another suggestion from the OAHHS: "Train all staff to understand that any oral communication regarding a disclosure or report to the Oregon Patient Safety Reporting Program is not subject to disclosure at deposition or other legal setting."

Apology: *I am sorry this happened* is a benevolent expression of sympathy and is protected, whether it is made in writing, orally or by conduct. *I'm sorry I did this to you* suggests liability and is not protected.

Root Cause Analysis: If a healthcare organization mentions **specific** peer-protected information in its notification letter (detailed results of a RCA for example) that information might then become discoverable. Release of such information might well be in the best interest of an organization, but it should be an explicit choice, not an inadvertent lapse.

Admissible/admission: A notification letter is admissible in the sense that it can be brought into a court room. Its contents are not an admission of liability.

HIPAA: A notification letter can be shared with a patient or a patient's personal representative. Other family members do not have such legal status. For the purposes of HIPAA, the Patient Safety Commission is a Public Health Authority.

Issues specific to Written Notification

Contrasting ways to conceive of written notification

The letter you write depends on the model you use. Here are a few possibilities:

- Bureaucratic requirement – Even if you believe this to be true, it will not serve your cause to act on this premise. A letter that begins, "Some regulation requires me to say this" will not be well received (see example from Pennsylvania in packet distributed at workshop).
- Act of closure – Such a letter might include a summary of findings. It would be delivered to a patient later in the process.
- Process map – A letter could be used to orient patients and family to what the hospital intends to do. It would discuss the process of investigation, and indicate when the hospital would be ready to share more information.
- Evidence of ongoing relationship – Such a letter would indicate the healthcare organization's strong interest in future contact and open communication. It would provide specific ideas and contact information.
- Mediation-like contract – This option was not much discussed in the workshop, but such a letter would summarize agreements. Imagine a letter jointly written by the organization and the patient. Might work well with 'early settlement' approaches.

Some general rules on written notification (from the workshop):

- Be truthful and honest. Don't lie. Tell what you know and don't know.
- No surprises - don't put any new information in notification (except perhaps for specific contact information). Disclose orally first.
- Have physicians work with hospital on letter; team approach limits blaming.
- Don't inadvertently undermine a good overall disclosure process by making the written notice sound too distant or formal.
- Short is OK but no cover-ups by omission.
- Don't speculate before you know what happened. Don't get ahead of the investigation.
- Unless you have a good reason to the contrary, always hand-deliver a letter.

Possible content elements to include in a written notification:

- Display of empathy
- Apology
- Recap of what was said orally
- Description of the process that will be taken to investigate and improve
- Summary of actual process improvements that will be made
- Name, phone number, email of contact person
- Statement of commitment from organization leaders.
- A nod to the future – organization will be there for them in the future.

Standardized or individualized letter: Some organizations have argued for creating a standardized notification letter. Such an approach is easier to produce, and might—some have argued—lower legal risk. Others believe that a 'cookie cutter approach' would undermine the point of open and honest disclosure since each situation and each family is unique.

When best to give written notification to patient? Timing depends on the kind of notification used. In all cases, written notification should never substitute for face-to-face communication. Written notification early in the process would be useful to reinforce the organization's action plan for investigating and making sense of the event. Patients strongly interested in seeing something done might appreciate this sort of written communication. Alternately, notification might come later in the process, and act as a summary or even closure document. Organizations might even consider combining approaches and providing more than one written communication to a patient.

Who should sign the notification? In order to show a united front, letters should be signed by the physician and a senior representative of the organization. In all cases, the 'we' used in a letter should match the signatures on the page. Signers must agree with the content of the letter or risk sparking an internal trust war.

Next Steps

The Patient Safety Commission will continue to build a notification toolkit with the help of participating organizations. Some specific next steps:

- Identify and share good examples of hospital disclosure policies. Make them available on the Commission's website.
- Continue to identify and share best practices – from within the state and across the country.
- Coordinate an on-going discussion about disclosure and notification.
- Consider another gathering in six months to a year to see how far we have come.
- Coordinate an informal network of "ask-the-experts" to provide consultation on difficult issues.
- Work with other organizations interested in patient safety to develop a centralized posting of related events.
- Work with professional associations, insurers and others to develop consistent and mutually supporting policy statements on disclosure and notification.

About the Oregon Patient Safety Commission…

The Patient Safety Commission is a semi-independent state agency with the mission of reducing the risk of adverse events in Oregon and encouraging a culture of patient safety with the healthcare system. We are working to:

- *Establish a voluntary and confidential reporting program for serious adverse events*
- *Encourage quality improvement activities*
- *Disseminate evidence-based best practices*

www.oregonpatientsafety.org