New Standards, New Dilemmas — Reflections on Managing Medical Mistakes

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This article describes one hospital's development of a proactive, patient centered program, which emphasizes total honesty in dealing with all aspects of patient care. This process includes the full and timely disclosure of errors which affect the patient's health and well being. The article describes the process by which the medical facility identifies error and works with healthcare providers to arrive at a consensus on the management of these errors. Included is a step by step analysis of how disclosure can be successfully accomplished.

Since 1987, the management of the Lexington Kentucky Veterans Administration Medical Center has addressed risk management issues in a different manner from other government or private facilities. Their policy and experience have been previously described and favorably reviewed (Kramen and Hamm 1999).

Briefly, when a patient is harmed by an act of negligence or error at Lexington, management, with the hospital attorney, attempts to avoid the use of litigation by fully disclosing the facts to the injured party; that is, by apologizing, accepting and stating full responsibility (including legal liability), and offering fair compensation. When patients or surviving relatives are unaware of the incident, the hospital proactively contacts them and makes the disclosure. This policy is rigid and does not allow for discretion once it is clear that an error or act of negligence occurred and a patient was adversely affected.

Although this policy design would seem to be extremely expensive, the results have been otherwise. For the seven-year period previously reported, Lexington paid an average of $200,000 per year in total liability payments and had an average of eleven claims per year. These figures compare favorably to those reported by thirty-five similar VA medical facilities.

Lexington's annual liability experience for the twelve years since it began keeping adequate records is similar: the organization reports an average of fourteen settlements per year totaling $215,000 per year, or about $15,000 per settlement. The mean malpractice settlement within the VA system in 2000 was $98,000.

Even more remarkable, during these twelve years, the Lexington facility went to trial only three times and lost only one case on the merits. In one case, the facility contested damages only (having previously acknowledged responsibility but without being able to reach settlement). The facility won the remaining case.

Much has been written about how poor communication and denial of responsibility for errors generate outrage and the desire for revenge among patients. It stands to reason that avoiding these incendiary behaviors would have the opposite effect, and in Lexington's case, at least, this assumption is true.

JCAHO Patient Safety Standards

On July 1, 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) put into place its new Patient Safety standards, among them standard RI.1.2.2: "Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes." It is too early to tell how strictly this standard will be interpreted and what proof the JCAHO surveyors will accept as evidence of compliance. Judging from the number of contacts Lexington has received from hospitals and healthcare systems preparing to comply with this standard, many in the industry are taking it seriously. Disclosure, however, is only one part of Lexington's practice.

The JCAHO standards do not address accepting legal responsibility or offering compensation although a disclosure would lead naturally to such actions. An unanswered question is whether legal representatives of hospitals and their malpractice insurers will allow disclosures that may inflate claims or support proactive offers and settlements. If a disclosure of information about a medical error is followed by refusal to accept legal responsibility or to discuss settlement (thus leading to more lawsuits), a disclosure policy could result in increased monetary losses.

> ***Disclosure describes the healthcare provider's ethical duty to fully inform the patient about the patient's care and treatment.***

The Lexington experience suggests that such losses will not happen if the door to fair compensation is left open and the patient is treated in a way that he or she perceives as open and fair. In reality, however, many healthcare defense attorneys remain skeptical. We believe that practices will vary and some hospitals will embrace the entire program, including settlement offers. Within two or three years, we hope to have sufficient data to answer these questions to the skeptics' satisfaction. The recent JCAHO standards will greatly accelerate this process.

New Dilemmas for Healthcare

In the traditional sense, disclosure describes the healthcare provider's ethical duty to fully inform the patient about the patient's care and treatment. This duty includes information about the patient's diagnosis, treatment options, and prognosis; and obligates the provider to obtain full informed consent for all treatments.

What does "disclosure" mean to the provider?

Truth telling has been the standard for many years. Most providers will declare that they are always truthful with their patients. Depending on the provider and his or her style of practice, errors may or may not be included in the telling. In many cases, patients place full trust in the provider and may not expect to be told of errors in their care.

Following the early publication of the Lexington experience, the ethical responsibilities for disclosing medical errors came under national scrutiny. "Full disclosure" as viewed by Lexington goes beyond the clinical facts and requires that medical mistakes and their consequences be disclosed to affected patients or their families.

This disclosure presents an entirely new set of problems for a profession that has often lived in a world of silence about medical mistakes. Too often providers feel that they will be unsupported by hospital administrators, peers, patients, and even their own families. Most medical malpractice insurance policies require that the carrier be informed of any potential claims and allowed to direct management of the claim and information surrounding it. In the past, disclosure has meant exposure and provoked fear and uncertainty for providers.

Who decides what and when to disclose?

In an ideal world, a healthcare provider would manage errors by revealing the problem to the patient in his or her best "bedside manner." After making an apology, of offering an explanation or some form of remuneration, such as writing off bills, or providing corrective treatment, the provider would carry on secure in the knowledge of having done the right thing. Sadly, the world of medical practice is far more complicated. Providers have partners, hospital administrators, insurance carriers, peers, the public, and their families, all of whom affect the way a provider acts in a given situation.

The "Lexington Model" may be the best approach for complying with the ethical obligation to full disclosure. This model brings all who impact the provider to the table for a thorough analysis of the case. It also brings in outside peer reviewers to aid the process. In this way consensus can be reached before the disclosure is made. This model is surely the ideal solution.

> ***"Full disclosure" should be made as soon as consensus is reached that an error has occurred which harmed a patient.***

The patient or family should be told the clinical facts as soon as they are known, advised that the care of the patient is under review, and that they will be fully advised regarding the outcome of the review. It is often tempting to make immediate admissions based on the earliest information, but a hasty decision before adequate review is concluded can be devastating to the patient and the provider. An admission in most states constitutes an expert opinion for the injured patient. It is often impossible to reverse an erroneous opinion once it is offered.

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Full Disclosure Handbook

Situation: Disclosure of a wrongful death due to staff oversight abetted by minimal staffing and absence of computer reminders. The cause of death by medical error was not established with certainty until two weeks after the incident. Family not yet aware of the facts. The patient's wife has been advised to come to the hospital to talk about new facts relating to her husband's death. Advised that she may bring anyone she likes to the meeting including an attorney. (The meeting may be arranged at a place near the next-of-kin's home if more convenient.)

Patient: 76-year-old man with COPD. Retired, receiving $625.00/month disability pension. Wife with whom he lives and two grown self-sufficient children.

Hospital staff present: High-ranking clinical representative of the facility, attorney, and a member of the quality management staff familiar with the circumstances.

Disclosure: Begin with an expression of sympathy, then make the disclosure. For example "We have recently discovered some facts relating to your husband's death. As you know, he was in the hospital because of a lung infection and difficulty breathing. At the time of his death, he was supposed to be receiving X amount of Y drug. However, because of an error by a staff member, he never received the medicine and we believe that this error contributed to his death. We had been investigating this error for some time after he died but did not come to this conclusion until a few days ago. I know that this is painful for you to hear but we feel that we owe you this information and an explanation."

Allow people time for processing of this information, for questions, reaction, crying, or anger.

Describe the details of the incident including any system failures and what is being done to avoid similar events in the future. (Only information protected by law is not disclosed. This may

include specific personnel actions directed at hospital employees.)

"I want to tell you, on behalf of the hospital, how sorry we are that this happened. As this occurred here, we are responsible for it. The (insert name of hospital or federal or state agency) owes you a full explanation and fair compensation. I can answer any questions you have about this incident and our attorney is here to explain compensation in more detail and to assist in the process."

If the wife has an attorney, explain that it is appropriate for the legal discussions to proceed between legal counsel. If she does not have an attorney, then explain,

"I want to make sure that you understand that although we want and intend to help you receive fair compensation, we cannot act as your legal advocate and therefore advise you to hire a lawyer."

It is better for the facility if the plaintiff has an attorney as it precludes having to explain the concept of legal damages to a grieving widow. Nevertheless, it can be done either way if handled sensitively.

Potential reactions and response: *This part of the process should ALWAYS include counsel for the hospital.*

Wife: "You have been awfully good to my husband and honest with me. No one is perfect, he hadn't long to live anyway. I don't want any money."

Response: She is appreciative and honest. She would feel guilty profiting from her husband's death. A year or two later, she may feel the absence of the lost disability income and suspect that she was taken advantage of. Explain the actual loss and the fact that you are only trying to replace what is fairly hers. It is not punishment for the hospital and will not create bad feelings against her. Suggest that she discuss this with her family or other trusted friends before making a final decision.

Wife: "No amount of money can replace my husband!" "I want no less that $5 million." (This response is uncommon, but it can happen in a wrongful death case or with surrogates).

Response: She is really angry or being opportunistic depending on her personality and what the family dynamics were like previously. If she has an attorney, this is the time to make an appointment to discuss damages. Don't overreact. If there is no attorney, then strongly recommend that she get one experienced in malpractice claims. In any event, let some time pass before presenting an offer substantially less than $5 million. If she refuses to accept any reasonable offer (rare in our experience), then decline settlement and let her sue. Don't try to defend what you have already disclosed. The fact that you are not being defensive will help assure a fair judgment.

Wife: Has an attorney and relies on him or her for negotiation and advice. She accepts a fair negotiated settlement within a few months. (This is the most common response).

Response: Negotiate in good faith. Provide all records promptly, stay friendly, and hide nothing.

Wife: "You killed my husband! I'm going to the press!" (Very Rare)

Response: The fact that you disclosed, apologized and offered compensation makes it very unlikely that any coverage will be negative for the facility. However, if contacted, always provide a knowledgeable, sympathetic, and articulate spokesperson to speak for the facility. Don't issue bureaucratic-sounding written statements. Write a letter to the wife, stating the disclosure again and offering to speak with her or her legal representative at her convenience. Then wait ■

All providers who were involved in the error must be full partners in the process. As part of the decision-making process, they choose responsibility, but do not have it imposed upon them.

"Full disclosure" should be made as soon as consensus is reached that an error has occurred which harmed a patient. The determination should be based on reasonable medical probability or certainty. Errors that do no actual harm should be disclosed if reviewers deem that the disclosure is appropriate. This action should be decided on a case-by-case basis when the disclosure would benefit the patient.

Who is "at the table" for this process?

Those who sit at the decision-making table for this process can and will vary depending on the situation. It is important to follow the needs of the case and not simply a formula or algorithm. Certainly the providers involved in the alleged error or omission are involved from the beginning. The group should also include a neutral moderator or facilitator. Often a member of the quality assurance or risk management team can fulfill this function (in Lexington, risk management facilitates the team). Other participants include the hospital attorney, someone with authority to make decisions for top management, the head of clinical activities, insurers, their attorneys, and others who may help facilitate resolution.

The "Lexington Model" may be the best approach for complying with the ethical obligation to full disclosure.

Peer reviewers are a valuable asset in guiding the decision. They can be involved in person or in written reviews depending on the case. The critical piece is that everyone be prepared to look at the situation and make professional judgments based on the applicable standard of practice. Personal agendas and punitive notions have no place in this process. The decisions made at this table will affect many people, have financial impact, and may be subject to public comment through the media. The process requires a quality decision.

When are therapeutic exceptions appropriate?

When making a disclosure would do more harm than benefit to the recipient of the information, a therapeutic exception is appropriate. This exception to disclosure should be based on the impact to the patient or family and not to relieve the obligation of those who already have the information. It is most often used when the injured party has a psychiatric illness that could be exacerbated by the information or where disclosure would cause unnecessary grief to the family of a deceased patient. It should not be used if there is a duty to compensate an injured patient as a result of a medical error.

If there is risk of causing further harm through direct disclosure, a surrogate could be appointed to act in the patient or family member's stead. Deciding when therapeutic exceptions apply requires a heightened scrutiny of the case and the individuals to be affected. The hospital ethics committee is an appropriate tool for advising decision makers in the clinical setting.

Who discloses?

Lexington Veteran Affairs Medical Center takes the position that the ethical obligation is institutional partly because it is a teaching medical center where residents deliver much of the patient care. But it is rare even outside teaching institutions that one individual causes a medical mistake. Systems fail and errors occur.

At Lexington, the chief of staff assumes the institutional responsibility. Usually medical center counsel is involved. The conversation begins with the acknowledgment of an error accompanied

by a formal apology and a full explanation of the error and the harm caused. Next, the chief of staff shares with the patient or family the steps the hospital has taken to correct the problem and prevent future harm.

The patient or family then has the opportunity to ask questions and have an open dialogue, after which discussion turns to resolution of the harm. The options are reviewed with counsel. If appropriate, settlement is initiated.

Patients and families are also advised to seek counsel to aid them in the process. The patient and his or her family are invited to return for further information or if they have questions. The attorney then continues the legal process to conclusion. The attorney, with the input of the chief of staff, the risk group, and additional experts, assesses the damages based on the law of damages for the state in which the error occurred.

Wu (1999) suggests that the provider who made the error should make the disclosure and apology. This tactic may be advisable with seasoned providers who have a relationship with the patient, but only if they have the comfort level and skills in communication to do so. The emotional climate in a disclosure is delicate and a break in communications or perceived defensiveness can destroy the entire effort. In Lexington, the providers are always welcome to be a part of the disclosure or meetings to follow, but never forced to take this responsibility.

Should "near misses" be disclosed?

The disclosure of near misses is an area of uncertainty. Explaining how close the providers came to an error might become an area of wide speculation and serve no legitimate purpose for the patient. Near misses should only be disclosed when the circumstances warrant. An exception should be made when a near miss occurs in the presence of the patient or members of the patient's family and the situation causes questions or concerns. Certainly an explanation of what occurred would be in keeping with the philosophy of total honesty in patient care. To attempt to reveal all near misses would be overwhelming and confusing to the patient.

What is at stake for the provider?

All conscientious healthcare providers are concerned with professional image. Reports to Medical Licensure Boards and the National Practitioner Data Bank are often construed as evidence of incompetence and viewed with fear. The reality is that if an error occurs and compensation is paid for damages, reports will be generated. The manner in which the decision is made to pay for harms caused by error and the contents of any report are important. As noted earlier, a practitioner who "self-reports" and becomes a partner in the decision that a compensable error has occurred will accept the reporting process more readily than one who feels railroaded or blindsided in the medical and legal process.

Other barriers to disclosure are fear of media interest, loss of patients, and peer and family pressures. But the simple truth is that it is tough to criticize someone for being honest. It doesn't make good headlines. We all want to be told the truth, and it is human nature to forgive the errors of those who are open and honest with us. So it is with patients, newspaper reporters, peers, and family members. An honest apology, explanation, and doing something to "make things right" have served Lexington well and should be the model for medical risk management practice. Error scenarios and sample methods of managing disclosure issues using this model can be found in the excerpt from the full Disclosure Handbook that accompanies this article.

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